

Federal Register





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Rules and Regulations

Federal Register

Vol. 52, No. 76

Tuesday, April 21, 1987

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 946

Irish Potatoes Grown in Washington; Suspension of Provision on Mandatory Committee Membership for Certified Seed Producers in District No. 5, and Conforming Change

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule will suspend a provision in § 946.25(c) of the marketing order that requires one producer member and that member's alternate on the State of Washington Potato Committee from District No. 5 to be a certified seed producer. Suspension of the provision will allow any producer in District No. 5 to serve on the committee. Over the years, the number of tablestock market producers relative to seed producers has increased. The rule also will make conforming changes in § 946.104 of the rules and regulations issued under the order to reflect the suspension of the order provision. This action was recommended unanimously by the committee.

EFFECTIVE DATE: This final rule becomes effective April 21, 1987.

FOR FURTHER INFORMATION CONTACT: James M. Scanlon, Acting Chief, Marketing Order Administration Branch, F&V, AMS, USDA, Washington, DC 20250-1400, telephone (202) 475-3914.

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

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the

Administrator of the Agricultural Marketing Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (The Act, 7 U.S.C. 601-674), and rules promulgated thereunder, are unique in that they are brought about through the group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

This rule will suspend an order provision in § 946.25(c) requiring one producer member of the State of Washington Potato Committee from District No. 5, and that member's alternate, to be a certified seed producer. It will also remove the requirement in § 946.104(a)(5) of the rules and regulations that makes only potato seed producers eligible for committee membership from District No. 5. These actions are designed to make the producer membership from District No. 5 more representative of the producer makeup in that district. District No. 5 includes 17 counties west of the Cascade mountain range slope in Washington. It is bounded on the south by the Oregon border, on the north by the Canadian border, and on the west by the Pacific Ocean.

There are approximately 60 handlers of Washington potatoes subject to regulation under the marketing order for potatoes grown in Washington. In addition, there are approximately 350 producers of Washington potatoes. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having average annual gross revenues for the last three years of less than \$100,000, and agricultural service firms are defined as those whose gross annual receipts are less than \$3,500,000. The majority of these handlers and producers may be classified as small entities. This action is primarily of an administrative nature and, as such, does not impose any additional costs on handlers or producers.

A proposed rule inviting comments on this action was published in the February 26, 1987, *Federal Register* (52 FR 5778). Interested persons were given until March 9, 1987, to file written comments. None were received.

The rule is issued under the Marketing agreement and Order No. 946, both as amended (7 CFR Part 946), regulating the handling of Irish potatoes grown in the State of Washington. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The actions are based on the recommendation of the State of Washington Potato Committee established under the order, and upon other available information.

The rule will suspend the proviso in § 946.25(c) of the marketing order regarding District No. 5 producer representation. The proviso being suspended reads as follows: "Provided, That one producer member of the committee from District No. 5, with his respective alternate, shall be a certified seed producer". Section 946.104(a)(5) of Subpart—Rules and Regulations (7 CFR 946.100 through 946.142) allocates one producer member and alternate member to District No. 5 and requires each to be a certified seed producer. A conforming change in § 946.104(a)(5) is necessary because of the suspension.

The suspension of the proviso in § 946.25(c) and the conforming change in § 946.104(a)(5) removing the certified seed producer requirements are necessary to reflect changes in the producer makeup in that district in recent years. District No. 5 had originally been composed mostly of certified seed producers. However, the number of tablestock growers has increased over the years, and currently they substantially exceed seed growers. Allowing both certified seed and tablestock growers to serve on the committee in District No. 5, will foster more equitable producer representation on the committee reflective of the current producer makeup and recognize that it is inequitable to allot the one position for District No. 5 only to certified seed producers.

Therefore, after consideration of all relevant matter presented, including that in the notice, the information and recommendation submitted by the committee, and other information, it is

hereby found and determined that the proviso in § 946.25(c) obstructs the establishment of equitable producer representation of District No. 5 and thus does not tend to effectuate the declared policy of the Act and is suspended pursuant to § 946.63(b).

It is further found that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* (5 U.S.C. 553). Procedures for obtaining names of eligible candidates for the member and alternate member for District No. 5 are in progress and are expected to be completed soon. The vote for nominees to fill these positions is scheduled to begin in April. Hence, postponing the effective date of this action would not allow the nominations to be conducted as scheduled. Moreover, this action is not controversial and is fully supported by the producers in District No. 5.

List of Subjects in 7 CFR Part 946

Marketing agreements and orders, Potatoes, Washington.

For the reasons set forth in the preamble, 7 CFR Part 946 is amended as follows:

PART 946—IRISH POTATOES GROWN IN WASHINGTON

1. The authority citation for 7 CFR Part 946 continues to read as follows:

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

2. Section 946.25(c) is revised by changing the colon to a period and by indefinitely suspending the proviso in paragraph (c) which reads as follows: "Provided, That one producer member of the committee from District No. 5, with his respective alternate, shall be a certified seed producer."

3. Section 946.104 is amended by removing the last sentence in paragraph (a)(5). As revised § 946.104(a)(5) reads as follows:

§ 946.104 Reapportionment of committee membership.

(a) * * *

(5) District No. 5—One producer member and one handler member.

Dated: April 14, 1987.

Karen K. Darling,

Deputy Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 87-8861 Filed 4-20-87; 8:45 am]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Part 151

[Docket No. 86-086]

Recognized Breeds and Books of Record; Aberdeen-Angus Cattle

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the "Recognition of Breeds and Books of Record of Purebred Animals" regulations by adding the Irish Angus Herd Book to the list of recognized books of record for Aberdeen-Angus cattle. This action is necessary because Veterinary Services has determined that the book qualifies for this listing, thereby providing for duty-free entry into the United States of cattle that are registered in the book.

EFFECTIVE DATE: May 21, 1987.

FOR FURTHER INFORMATION CONTACT: Dr. William E. Ketter, Regulatory Communications and Compliance Policy Staff, VS, APHIS, USDA, Room 827, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8565.

SUPPLEMENTARY INFORMATION: In a document published in the *Federal Register* on June 3, 1986 (51 FR 19846-19848), we proposed to amend the regulations in 9 CFR Part 151 (referred to below as the regulations) by adding to the list of recognized books of record for Aberdeen-Angus cattle the Irish Angus Herd Book, maintained by the Irish Angus Cattle Association, Ltd. Comments on this proposal were solicited for a period of 60 days; however, no comments were received.

Veterinary Services has examined and approved the Irish Angus Herd Book, thereby making it eligible to be added to the list contained in the regulations. In accordance with the regulations and 19 U.S.C. 1202, Schedule 1, Part 1, Item 100.01, cattle that are registered in a recognized book of record may enter the United States free of duty if imported for breeding purposes.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule". The Department has determined that this action will not have a significant effect on the economy; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local

government agencies, or geographic regions; and will have no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

Under this final rule, Aberdeen-Angus cattle listed in the Irish Angus Herd Book may be imported duty-free into the United States for breeding purposes. We anticipate that the number of these Aberdeen-Angus cattle imported into the United States annually will be less than one percent of the total number of cattle imported into the United States annually. For most cases of importation of Aberdeen-Angus, cattle small entities are not involved and will not be affected. In a few cases, small entities will benefit by being allowed to import these cattle, but no adverse effects on small entities are expected.

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

Executive Order 12372

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

List of Subjects in 9 CFR Part 151

Animals, Animal pedigree, Imports, Purebred animals.

PART 151—RECOGNITION OF BREEDS AND BOOKS OF RECORD OF PUREBRED ANIMALS

Accordingly, 9 CFR Part 151 is amended as follows:

1. The authority citation for Part 151 is revised to read as set forth below and the authority citations following all the sections in Part 151 are removed.

Authority: 19 U.S.C. 1202; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 151.9, the chart in paragraph (a) is amended by adding the following after Code 1112 under the heading "Cattle":

§ 151.9 Recognized breeds and books of record.

(a) * * *

CATTLE

Code	Name of breed	Book of record	By whom published
116	Aberdeen-Angus	Irish Angus Herd Book	Irish Angus Cattle Society Ltd., John L. Murphy, Secretary, Agriculture House, Kildare Street, Dublin 2, Ireland.

Done in Washington, DC, this 16th day of April, 1987.

J.K. Atwell,

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

[FR Doc. 87-8862 Filed 4-20-87; 8:45 am]

BILLING CODE 3410-34-M

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

22 CFR Part 224

Implementation of the Program Fraud Civil Remedies Act; Request for Comments

AGENCY: Agency for International Development, IDCA.

ACTION: Interim regulations with request for comments.

SUMMARY: The Agency for International Development is issuing interim regulations to implement the Program Fraud Civil Remedies Act of 1986. The regulations will establish administrative procedures for imposing the statutorily authorized civil penalties and assessments against any person who makes, submits, or presents a false, fictitious, or fraudulent claim or written statement to the Agency for International Development.

DATES: Effective date is April 21, 1987. Comments must be received on or before May 21, 1987.

ADDRESS: Written comments should be mailed to the Assistant General Counsel of Litigation and Enforcement, Agency for International Development, Department of State, Room 6947, Washington, DC 20523.

FOR FURTHER INFORMATION CONTACT: Gary Winter, (202) 647-8874.

SUPPLEMENTARY INFORMATION: The Program Fraud Civil Remedies Act, Pub. L. 99-509, enacted on October 21, 1986, codified at 31 U.S.C. 3801 through 3812 generally provides that any person who knowingly submits a false claim or statement to the Federal Government in

an amount less than \$150,000 may be liable for an administrative civil penalty of not more than \$5,000 for each false claim or statement and in certain cases, in which the Government has paid the false claim, to an assessment equal to double the amount falsely claimed.

This action will not have a significant economic impact on a substantial number of small entities; does not constitute a "major rule" under Executive Order No. 12291; and is not a major Federal action significantly affecting the quality of the human environment.

List of Subjects in 22 CFR Part 224

Claims, Penalties.

For the reasons set forth in the preamble, Title 22, Chapter II of the Code of Federal Regulations is amended to add a new Part 224 to read as follows:

PART 224—PROGRAM FRAUD CIVIL REMEDIES

- Sec.
- 224.1 Basis and purpose.
- 224.2 Definitions.
- 224.3 Basis for civil penalties and assessments.
- 224.4 Investigation.
- 224.5 Review by the reviewing official.
- 224.6 Prerequisites for issuing a complaint.
- 224.7 Complaint.
- 224.8 Service of complaint.
- 224.9 Answer.
- 224.10 Default upon failure to file an answer.
- 224.11 Referral of complaint and answer to the ALJ.
- 224.12 Notice of hearing.
- 224.13 Parties to the hearing.
- 224.14 Separation of functions.
- 224.15 Ex parte contacts.
- 224.16 Disqualification of reviewing official or ALJ.
- 224.17 Rights of parties.
- 224.18 Authority of the ALJ.
- 224.19 Prehearing conferences.
- 224.20 Disclosure of documents.
- 224.21 Discovery.
- 224.22 Exchange of witness lists, statements, and exhibits.
- 224.23 Subpoenas for attendance at hearing.
- 224.24 Protective order.
- 224.25 Fees.

- Sec.
- 224.26 Form, filing and service of papers.
- 224.27 Computation of time.
- 224.28 Motions.
- 224.29 Sanctions.
- 224.30 The hearing and burden of proof.
- 224.31 Determining the amount of penalties and assessments.
- 224.32 Location of hearing.
- 224.33 Witnesses.
- 224.34 Evidence.
- 224.35 The record.
- 224.36 Post-hearing briefs.
- 224.37 Initial decision.
- 224.38 Reconsideration of initial decision.
- 224.39 Appeal to A.I.D. Administrator.
- 224.40 Stays ordered by the Department of Justice.
- 224.41 Stay pending appeal.
- 224.42 Judicial review.
- 224.43 Collection of civil penalties and assessments.
- 224.44 Right to administrative offset.
- 224.45 Deposit in Treasury of the United States.
- 224.46 Compromise or settlement.
- 224.47 Limitations.

Authority: 22 U.S.C. 2381; 31 U.S.C. 3801-3812.

§ 224.1 Basis and Purpose.

(a) *Basis.* This part implements the Program Fraud Civil Remedies Act of 1986, Pub. L. No. 99-509, sections 6101-6104, 100 Stat. 1874 (October 21, 1986), to be codified at 31 U.S.C. 3801-3812. 31 U.S.C. 3809 of the Statute requires each authority head to promulgate regulations necessary to implement the provisions of the statute.

(b) *Purpose.* This part (1) establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims for written statements to the Agency for International Development or to its agents, and (2) specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

§ 224.2 Definitions.

A.I.D. means the Agency for International Development.

ALJ means an Administrative Law Judge in the authority appointed pursuant to 5 U.S.C. 3105 or detailed to the authority pursuant to 5 U.S.C. 3344.

Benefits means, except as the context otherwise requires, anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee.

Claim means any request, demand, or submission—

(a) Made to A.I.D. for property, services, or money (including money

representing grants, loans, insurance, or benefits);

(b) Made to a recipient of property, services, or money from A.I.D. or to a party to a contract with A.I.D.—

(1) For property or services if the United States—

(i) Provided such property or services;

(ii) Provided any portion of the funds for the purchase of such property or services; or

(iii) Will reimburse such recipient or party for the purchase of such property or services; or

(2) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

(i) Provided any portion of the money requested or demanded; or

(ii) Will reimburse such recipient or party for any portion of the money paid on such request or demand; or

(c) Made to A.I.D. which has the effect of decreasing an obligation to pay or account for property, services, or money.

Complaint means the administrative complaint served by the reviewing official on the defendant under § 224.7.

Defendant means any person alleged in a complaint under § 224.7 to be liable for a civil penalty or assessment under § 224.3.

Government means the United States Government.

Individual means a natural person.

Initial decision means the written decision of the ALJ required by § 224.10 or § 224.37, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Investigating official means the Inspector General for A.I.D. or an officer or employee of the Office of Inspector General designated by the Inspector General and serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

Knows or has reason to know, means that a person, with respect to a claim or statement—

(a) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent;

(b) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or

(c) Acts in reckless disregard of the truth or falsity of the claim or statement.

Makes, wherever it appears, shall include the terms presents, submits, and causes to be made, presented, or submitted. As the context requires, *making* or *made*, shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association, or

private organization, State, political subdivision of a State, municipality, county, district, and Indian tribe, and includes the plural of that term.

Representative means an attorney.

Reviewing official means the General Counsel of A.I.D. or his designee who is:

(a) Not subject to supervision by, or required to report to, the investigating official;

(b) Not employed in the organizational unit of A.I.D. in which the investigating official is employed; and

(c) Is serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made—

(a) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or

(b) With respect to (including relating to eligibility for)—

(1) A contract with, or a bid or proposal for a contract with; or

(2) A grant, loan, or benefit from, A.I.D., or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit.

§ 224.3 Basis for civil penalties and assessments.

(a) *Claims*. (1) Any person who makes a claim that the person knows or has reason to know—

(i) Is false, fictitious, or fraudulent;

(ii) Includes or is supported by any written statement which asserts a material fact which is false, fictitious, or fraudulent;

(iii) Includes or is supported by any written statement that—

(A) Omits a material fact;

(B) Is false, fictitious, or fraudulent as a result of such omission; and

(C) Is a statement in which the person making such statement has a duty to include such material fact; or

(iv) Is for payment for the provision of property or services which the person has not provided as claimed;

shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such claim.

(2) Each voucher, invoice, claim form, or other individual request or demand

for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to A.I.D., a recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of A.I.D. or such recipient or party.

(4) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(5) If the Government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section shall also be subject to an assessment of not more than twice the amount of such claim or that portion thereof that is determined to be in violation of paragraph (a)(1) of this section. Such assessment shall be in lieu of damages sustained by the Government because of such claim.

(b) *Statements*. (1) Any person who makes a written statement that—

(i) The person knows or has reason to know—

(A) Asserts a material fact which is false, fictitious, or fraudulent; or

(B) Is false, fictitious, or fraudulent because it omits a material fact that the person making the statement had a duty to include in such statement; and

(ii) Contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject to in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such statement, shall be subject to in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such statement.

(2) Each written representation, certification, or affirmation constitutes a separate statement.

(3) A statement shall be considered made to an authority when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of such authority.

(c) No proof of specific intent to defraud is required to establish liability under this section.

(d) In any case in which it is determined that more than one person is liable for making a claim or statement under this section, each such person may be held liable for a civil penalty under this section.

(e) In any case in which it is determined that more than one person is liable for making a claim under this section on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severely against any combination of such persons.

§ 224.4 Investigation.

(a) If an investigating official concludes that a subpoena pursuant to the authority conferred by 31 U.S.C. 3804(a) is warranted—

(1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued, and shall identify the records or documents sought;

(2) He or she may designate a person to act on his behalf to receive the documents sought; and

(3) The person receiving such subpoena shall be required to tender to the investigating official or the person designated to receive the documents a certification that the documents sought have been produced, or that such documents are not available and the reasons therefore, or that such documents, suitably identified, have been withheld based upon the assertion of an identified privilege.

(b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall submit a report containing the findings and conclusions of such investigation to the reviewing official.

(c) Nothing in this section shall preclude or limit an investigating official's discretion to refer allegations directly to the Department of Justice for suit under the False Claims Act or other civil relief, or to preclude or limit such official's discretion to defer or postpone a report or referral to avoid interference with a criminal investigation or prosecution.

(d) Nothing in this section modifies any responsibility of an investigating official to report violations of criminal law to the Attorney General.

§ 224.5 Review by the reviewing official.

(a) If, based on the report of the investigating official under § 224.4(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under § 224.3 of this part, the reviewing official shall, transmit to the Attorney General a written notice of the reviewing official's intention to issue a complaint under § 224.7.

(b) Such notice shall include—

(1) A statement of the reviewing official's reasons for issuing a complaint;

(2) A statement specifying the evidence that supports the allegations of liability;

(3) A description of the claims or statements upon which the allegations of liability are based;

(4) An estimate of the amount of money or the value of property, services, or other benefits requested or demanded in violation of § 224.3 of this part;

(5) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and

(6) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments. Such a statement may be based upon information then known or an absence of any information indicating that the person may be unable to pay such an amount.

§ 224.6 Prerequisites for issuing a complaint.

(a) The reviewing official may issue a complaint under § 224.7 only if:

(1) The Department of Justice approves the issuance of a complaint in a written statement described in 31 U.S.C. 3803(b)(1); and

(2) In the case of allegations of liability under § 224.3(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in (b)), the amount of money or the value of property or services demanded or requested in violation of § 224.3(a) does not exceed \$150,000.

(b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official's authority to join in a single complaint against a person claims that are unrelated or were not submitted simultaneously, regardless of the amount of money or the value of property or services demanded or requested.

§ 224.7 Complaint.

(a) On or after the date the Department of Justice approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1), the reviewing

official may serve a complaint on the defendant, as provided in § 224.8.

(b) The complaint shall state:

(1) Allegations of liability against the defendant, including the statutory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;

(2) The maximum amount of penalties and assessments for which the defendant may be held liable;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the defendant's right to request a hearing by filing an answer and to be represented by a representative; and

(4) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the maximum amount of penalties and assessments without right to appeal.

(c) At the same time the reviewing official serves the complaint, he or she shall serve the defendant with a copy of these regulations.

§ 224.8 Service of complaint.

(a) Service of a complaint must be made by certified or registered mail or by delivery in any manner authorized by Rule 4(d) of the Federal Rules of Civil Procedure.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:

(1) Affidavit of the individual making service;

(2) An acknowledged United States Postal Service return receipt card; or

(3) Written acknowledgment of the defendant or his representative.

§ 224.9 Answer.

(a) The defendant may request a hearing by filing an answer with the reviewing official within 30 days of service of the complaint. An answer shall be deemed to be a request for hearing.

(b) In the answer, the defendant:

(1) Shall admit or deny each of the allegations of liability made in the complaint;

(2) Shall state any defense on which the defendant intends to rely;

(3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and

(4) Shall state the name, address, and telephone number of the person authorized by the defendant to act as defendant's representative, if any.

§ 224.10 Default upon failure to file an answer.

(a) If the defendant does not file an answer within the time prescribed in § 224.9(a), the reviewing official may refer the complaint to the ALJ.

(b) Upon the referral of the complaint, the ALJ shall promptly serve on defendant in the manner prescribed in § 224.8, a notice that an initial decision will be issued under this section.

(c) If the defendant fails to answer, the ALJ shall assume the facts alleged in the complaint to be true and, if such facts establish liability under § 224.3, the ALJ shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.

(d) Except as otherwise provided in this section, by failing to file a timely answer, the defendant waives any right to further review of the penalties and assessments imposed under paragraph (c) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(e) If, before such an initial decision becomes final, the defendant files a motion with the ALJ seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing an answer, the initial decision shall be stayed pending the ALJ's decision on the motion.

(f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file a timely answer the ALJ shall withdraw the initial decision in paragraph (c) of this section, if such a decision has been issued, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the ALJ denying defendant's motion under paragraph (d) is not subject to reconsideration under § 224.38.

§ 224.11 Referral of complaint and answer to the ALJ.

Upon receipt of an answer, the reviewing official shall file the complaint and answer with the ALJ.

§ 224.12 Notice of hearing.

(a) When the ALJ receives the complaint and answer, the ALJ shall promptly serve a notice of hearing upon the defendant in the manner prescribed by § 224.8. At the same time, the ALJ shall send a copy of such notice to the representative for the Government.

(b) Such notice shall include:

- (1) The tentative time and place, and the nature of the hearing;
- (2) The legal authority and jurisdiction under which the hearing is to be held;

(3) The matters of fact and law to be asserted;

(4) A description of the procedures for the conduct of the hearing;

(5) The name, address, and telephone number of the defendant, if any; and

(6) Such other matters as the ALJ deems appropriate.

§ 224.13 Parties to the hearing.

(a) The parties to the hearing shall be the defendant and A.I.D.

(b) Pursuant to 31 U.S.C. 3730(c)(5), a private plaintiff under the False Claims Act may participate in these proceedings to the extent authorized by the provisions of that Act.

§ 224.14 Separation of functions.

(a) The investigating official, the reviewing official, and any employee or agent of A.I.D. who takes part in investigating, preparing, or presenting a particular case may not, in such case or a factually related case:

(1) Participate in the hearing as the ALJ;

(2) Participate or advise in the initial decision or the review of the initial decision by the A.I.D. Administrator, except as a witness or representative in public proceedings; or

(3) Make the collection of penalties and assessments under 31 U.S.C. 3806.

(b) The ALJ shall not be responsible to, or subject to, the supervision or direction of the investigating official or the reviewing official.

(c) Except as provided in paragraph (a) of this section, the representative for the Government may be employed anywhere in A.I.D., including in the offices of either the investigating official or the reviewing official.

§ 224.15 Ex parte contacts.

No party or person (except employees of the ALJ's office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiry about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 224.16 Disqualification of reviewing official or ALJ.

(a) A reviewing official or ALJ in a particular case may disqualify himself or herself at any time.

(b) A party may file with the ALJ a motion for disqualification of a reviewing official or ALJ. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.

(c) Such motion and affidavit shall be filed promptly upon the party's

discovery of reasons requiring disqualification, or such objections shall be deemed waived.

(d) Such affidavit shall state specific facts that support the party's belief that personal bias or other reason for disqualification exists and the time and circumstances of the party's discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.

(e) Upon the filing of such a motion and affidavit, the ALJ shall proceed no further in the case until he or she resolves the matter of disqualification in accordance with paragraph (f) of this section.

(f)(1) If the ALJ determines that the reviewing official is disqualified, the ALJ shall dismiss the complaint without prejudice.

(2) If the ALJ disqualifies himself or herself, the case shall be reassigned promptly to another ALJ.

(3) If the ALJ denies a motion to disqualify, the A.I.D. Administrator may determine the matter only as part of his or her review of the initial decision upon appeal, if any.

§ 224.17 Rights of parties.

Except as otherwise limited by this part, all parties may:

(a) Be accompanied, represented, and advised by a representative;

(b) Participate in any conference held by the ALJ;

(c) Conduct discovery;

(d) Agree to stipulations of fact or law, which shall be made part of the record;

(e) Present evidence relevant to the issues at the hearing;

(f) Present and cross-examine witnesses;

(g) Present oral arguments at the hearing as permitted by the ALJ; and

(h) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

§ 224.18 Authority of the ALJ.

(a) The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The ALJ may:

(1) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery;

(8) Regulate the course of the hearing and the conduct of representatives and parties;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and

(14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.

(c) The ALJ does not have the authority to decide upon the validity of Federal statutes or regulations.

§ 224.19 Prehearing conferences.

(a) The ALJ may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The ALJ may use prehearing conferences to discuss the following:

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations, admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery;

(9) The time and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The ALJ shall issue an order containing all matters agreed upon by

the parties or ordered by the ALJ at a prehearing conference.

§ 224.20 Disclosure of documents.

(a) Upon written request to the reviewing official, the defendant may review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under § 224.4(b) are based unless such documents are subject to a privilege under Federal law. Upon payment of fees for duplication, the defendant may obtain copies of such documents.

(b) Upon written request to the reviewing official, the defendant also may obtain a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.

(c) The notice sent to the Attorney General from the reviewing official as described in § 224.5 is not discoverable under any circumstances.

(d) The defendant may file a motion to compel disclosure of the documents subject to the provisions of this section. Such a motion may only be filed with the ALJ following the filing of an answer pursuant to § 224.9.

§ 224.21 Discovery.

(a) The following types of discovery are authorized:

(1) Requests for production of documents for inspection and copying;

(2) Requests for admissions of the authenticity of any relevant document or the truth of any relevant fact;

(3) Written interrogatories; and

(4) Depositions.

(b) For the purpose of this section and §§ 224.22 and 224.23, the term "documents" includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless mutually agreed to by the parties, discovery is available only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.

(d) *Motions for discovery.* (1) A party seeking discovery may file a motion with the ALJ. Such a motion shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.

(2) Within ten days of service a party may file an opposition to the motion and/or a motion for protective order as provided in § 224.24.

(3) The ALJ may grant a motion for discovery only if he finds that the discovery sought:

(i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;

(ii) Is not unduly costly or burdensome;

(iii) Will not unduly delay the proceeding; and

(iv) Does not seek privileged information.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

(5) The ALJ may grant discovery subject to a protective order under § 224.24.

(e) *Deposition.* (1) If a motion for deposition is granted, the ALJ shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and place at which the deposition will be held.

(2) The party seeking to depose shall serve the subpoena in the answer prescribed in § 224.8.

(3) The deponent may file with the ALJ a motion to quash the subpoena or a motion for a protective order within ten days of service.

(4) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition which it shall make available to all other parties for inspection and copying.

§ 224.22 Exchange of witness lists, statements and exhibits.

(a) At least 15 days before the hearing or at such other time as may be ordered by the ALJ, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 224.33(b). At the time the above documents are exchanged, any party that intends to rely on the transcript of deposition testimony in lieu of live testimony at the hearing, if permitted by the ALJ, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects, the ALJ shall not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the ALJ finds

good cause for the failure or that there is no prejudice to the objecting party.

(c) Unless another party objects within the time set by the ALJ, documents exchanged in accordance with paragraph (a) shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 224.23 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the ALJ issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefore not less than 15 days before the date fixed for the hearing unless otherwise allowed by the ALJ for good cause shown. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed in § 224.8. A subpoena on a party or upon an individual under the control of a party may be served by first class mail.

(f) A party or individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within ten days after service or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§ 224.24 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or, with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery other than that requested;

(4) That certain matters not inquired into, or that the scope of discovery be limited to certain matters;

(5) That discovery be conducted with no one present except persons designated by the ALJ;

(6) That the contents of discovery or evidence be sealed;

(7) That a deposition after being sealed be opened only by order of the ALJ;

(8) That a trade secret or other confidential research, development, commercial information, or facts pertaining to any criminal investigation, proceeding or other administrative investigation not be disclosed or be disclosed only in a designated way; or

(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the ALJ.

§ 224.25 Fees.

The party requesting a subpoena shall pay the cost of the fee and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in the United States District Court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of A.I.D., a check for witness fees and mileage need not accompany the subpoena.

§ 224.26 Form, filing and service of papers.

(a) *Form.* (1) Documents filed with the ALJ shall include an original and two copies.

(2) Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the ALJ, and a designation of the paper (e.g., motion to quash subpoena).

(3) Every pleading and paper shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the paper was filed or his or her representative.

(4) Papers are considered filed when they are mailed. Date of mailing may be established by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.

(b) *Service.* A party filing a document with the ALJ shall at the time of filing, serve a copy of such document on every other party. Service upon any party of any document other than the complaint or notice of hearing shall be made by delivering or mailing a copy to the party's last known address. When a

party is represented by a representative, service shall be made upon such representative in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, shall be proof of service.

§ 224.27 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day.

(b) When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government shall be excluded from the computation.

(c) Where a document has been served or issued by mail, an additional five days will be added to the time permitted for any response.

§ 224.28 Motions.

(a) Any application to the ALJ for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ shall make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 224.29 Sanctions.

(a) The ALJ may sanction a person, including any party or representative for:

(1) Failing to comply with an order, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition or for the production of evidence within the party's control, or a request for admission, the ALJ may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.

(e) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

§ 224.30 The hearing and burden of proof.

(a) The ALJ shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under § 224.3, and if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.

(b) A.I.D. shall prove defendant's liability and any aggravating factors by a preponderance of the evidence.

(c) The defendant shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the ALJ for good cause shown.

§ 224.31 Determining the amount of penalties and assessments.

(a) In determining an appropriate amount of civil penalties and assessments, the ALJ and the A.I.D. Administrator, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the

intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, ordinarily double damages and a significant civil penalty should be imposed.

(b) Although not exhaustive, the following factors are among those that may influence the ALJ and the A.I.D. Administrator in determining the amount of penalties and assessments to impose with respect to the misconduct (i.e., the false, fictitious, or fraudulent claims or statements) charged in the complaint:

(1) The number of false, fictitious, or fraudulent claims or statements;

(2) The time period over which such claims or statements were made;

(3) The degree of the defendant's culpability with respect to the misconduct;

(4) The amount of money or the value of the property, services, or benefit falsely claimed;

(5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the costs of investigation;

(6) The relationship of the amount imposed as civil penalties to the amount of the Government's loss;

(7) The potential or actual impact of the misconduct upon national defense, public health or safety, or public confidence in the management of Government programs and operations, including particularly the impact on the intended beneficiaries of such programs;

(8) Whether the defendant has engaged in a pattern of the same or similar misconduct;

(9) Whether the defendant attempted to conceal the misconduct;

(10) The degree to which the defendant has involved others in the misconduct or in concealing it;

(11) Where the misconduct of employees or agents is imputed to the defendant, the extent to which the defendant's practices fostered or attempted to preclude such misconduct;

(12) Whether the defendant cooperated in or obstructed an investigation of the misconduct;

(13) Whether the defendant assisted in identifying and prosecuting other wrongdoers;

(14) The complexity of the program or transaction, and the degree of the defendant's sophistication with respect to it, including the extent of defendant's prior participation in the program or in similar transactions;

(15) Whether the defendant has been found, in any criminal, civil, or administrative proceeding, to have engaged in similar misconduct or to have dealt dishonestly with the

Government of the United States or of a State, directly or indirectly; and

(16) The need to deter the defendant and others from engaging in the same or similar misconduct.

(c) Nothing in this section shall be construed to limit the ALJ or the A.I.D. Administrator from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 224.32 Location of hearing.

(a) The hearing may be held:

(1) In any judicial district of the United States in which the defendant resides or transacts business;

(2) In any judicial district of the United States in which the claim or statement in issue was made; or

(3) In such other place as may be agreed upon by the defendant and the ALJ.

(b) Each party shall have the opportunity to present argument with respect to the location of the hearing.

(c) The hearing shall be held at the place and at the time ordered by the ALJ.

§ 224.33 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which allows sufficient time for such other parties to subpoena such witness for cross-examination at the hearing of the witness who made the statement. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in § 224.22(a).

(c) The ALJ shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ shall permit the parties to conduct such cross-examination as may be required for a full and true disclosure of the facts.

(e) At the discretion of the ALJ, a witness may be cross-examined on matters relevant to the proceeding

without regard to the scope of his or her direct examination. To the extent permitted by the ALJ cross-examination on matters outside the scope of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the ALJ shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This rule does not authorize exclusion of:

- (1) A party who is an individual;
- (2) In the case of a party that is not an individual, an officer or employee of the party designated by the party's representative; or
- (3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by the Government engaged in assisting the representative for the Government.

§ 224.34 Evidence.

(a) The ALJ shall determine the admissibility of evidence.

(b) Except as provided herein, the ALJ shall not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence.

(c) The ALJ shall exclude irrelevant and immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ pursuant to § 224.24.

§ 224.35 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from ALJ at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, all papers and requests filed in the proceeding constitute the record

for the decision by the ALJ and the authority head.

(c) The record of the hearing may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ pursuant to § 224.24.

§ 224.36 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ shall fix the time for filing briefs, at a time not exceeding 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 224.37 Initial decision.

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

- (1) Whether the claim or statements identified in the complaint, or any portion thereof, violate § 224.3;
- (2) If the person is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering any mitigating or aggravating factors that he or she finds in the case, such as those described in § 224.31.

(c) The ALJ shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired. The ALJ shall at the same time serve all defendants with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration with the ALJ or a notice of appeal with the A.I.D. Administrator. If the ALJ fails to meet the deadline contained in this paragraph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.

(d) Unless the initial decision of the ALJ is timely appealed to the A.I.D. Administrator, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the A.I.D. Administrator and shall be final and binding on the parties 30 days after it is issued by the ALJ.

§ 224.38 Reconsideration of initial decision.

(a) Except as provided in paragraph (d), any party may file a motion for

reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be five days from the date of mailing in the absence of contrary proof.

(b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.

(c) Responses to such motions shall be allowed only upon request of ALJ.

(d) No party may file a motion for reconsideration of an initial decision that has been revised in response to a previous motion for reconsideration.

(e) The ALJ may dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.

(f) When a motion for reconsideration is made, the time periods for appeal to the A.I.D. Administrator contained in § 224.38, and for finality of the initial decision in § 224.36(d), shall begin on the date the ALJ issues the denial of the motion for reconsideration or a revised initial decision, as appropriate.

§ 224.39 Appeal to A.I.D. Administrator.

(a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a civil penalty or assessment may appeal such decision to the A.I.D. Administrator by filing a notice of appeal with the A.I.D. Administrator in accordance with this section.

(b)(1) No notice of appeal may be filed until the time period for filing a motion for reconsideration under § 224.38 has expired.

(2) If a motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ denies the motion or issues a revised initial decision, whichever applies.

(3) If no motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ issues the initial decision.

(4) The A.I.D. Administrator may extend the initial 30 day period for an additional 30 days if the defendant files with the A.I.D. Administrator a request for an extension within the initial 30 day period and shows good cause.

(c) If the defendant files a timely notice of appeal with the A.I.D. Administrator, the ALJ shall forward the record of the proceeding to the A.I.D. Administrator.

(d) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.

(e) The representative for the Government may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.

(f) There is no right to appear personally before the A.I.D. Administrator.

(g) There is no right to appeal any interlocutory ruling by the ALJ.

(h) In reviewing the initial decision, the A.I.D. Administrator shall not consider any objection that was not raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(i) If any party demonstrates to the satisfaction of the A.I.D. Administrator that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure to present such evidence at such hearing, the A.I.D. Administrator shall remand the matter to the ALJ for consideration of such additional evidence.

(j) The A.I.D. Administrator may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment determined by the ALJ in an initial decision.

(k) The A.I.D. Administrator shall promptly serve each party to the appeal with a copy of his/her decision. At the same time, the authority head shall serve the defendant with a statement describing the defendant's right to seek judicial review.

(l) Unless a petition for review is filed as provided in 31 U.S.C. 3805 after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the authority head serves the defendant with a copy of his/her decision, a determination that a defendant is liable under § 224.3 is final and is not subject to judicial review.

§ 224.40 Stays ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the A.I.D. Administrator a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the authority head shall stay the process immediately. The authority head may order the process resumed only upon receipt of the written authorization of the Attorney General.

§ 224.41 Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the authority head.

(b) No administrative stay is available following a final decision of the authority head.

§ 224.42 Judicial review.

Section 3805 of Title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the authority head imposing penalties or assessments under this part and specifies the procedures for such review.

§ 224.43 Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of Title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 224.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under § 224.42 or § 224.43, or any amount agreed upon in a compromise or settlement under § 224.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under the subsection against a refund of an over payment of Federal taxes, then or later owing by the United States to the defendant.

§ 224.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 224.46 Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The A.I.D. Administrator has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during pendency of any review under § 224.42 or during the pendency of any action to collect penalties and assessments under § 224.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 224.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the A.I.D. Administrator, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the A.I.D. Administrator, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

§ 224.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 224.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 224.10(b) shall be deemed notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

Ain H. Kivimae,

Deputy Assistant to the Administrator for Management.

April 13, 1987.

[FR Doc. 87-8840 Filed 4-20-87; 8:45 am]

BILLING CODE 6116-01-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF-250 Re: Notice No. 570]

Establishment of the Northern Neck George Washington Birthplace Viticultural Area.

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

ACTION: Final Rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area located in the tidewater area of Virginia to be known as the Northern Neck George Washington Birthplace. Because the viticultural area named has five words, it may appear on wine labels or in advertisement on one line or two (in the same size and style of print type). This viticultural area is a five-county peninsula or neck located to the east of Fredericksburg, Virginia. ATF feels that the establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling

and advertising will help consumers identify the wines they may purchase. It will also allow wineries to better designate the specific grape-growing area where their wines come from.

EFFECTIVE DATE: May 21, 1987.

FOR FURTHER INFORMATION CONTACT: Edward A. Reisman, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue NW., Washington, DC 20226 (202-566-7626).

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37672, 54624) revising regulations in 27 CFR, Part 4. These regulations allow the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements.

On October 2, 1979, ATF published Treasury Decision ATF-60 (44 FR 56692) which added a new Part 9 to 27 CFR, providing for the listing of approved American viticultural areas, the names of which may be used as appellations of origin. Section 4.25a(e)(1), Title 27, CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been delineated in Subpart C of Part 9.

Section 4.25a(e)(2), outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area.

The petition should include:

(a) Evidence that the name of the viticultural area is locally and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence relating to the geographical characteristics (climate, soil, elevation, physical features, etc.) which distinguish the viticultural area from the surrounding areas;

(d) A description of the specific boundaries of the viticultural area based on features which can be found on United States Geological Survey (U.S.G.S.) maps of the largest applicable scale; and

(e) A copy of the appropriate U.S.G.S. maps with the boundaries prominently marked.

Petition

ATF received a petition proposing an American viticultural area to be known as George Washington Birthplace. The

petitioner, Carl F. Flemer, Jr. is the owner of Ingleside Plantation Vineyards, a bonded winery located in Oak Grove, Westmoreland County, Virginia. The 590,080 acre (922 square mile) viticultural area includes all the land in the five counties (Westmoreland, King George, Richmond, Northumberland and Lancaster) of the Northern Neck. There are 16 established vineyards and one winery with a total of 92.5 acres planted in vitis Vinifera and French-American hybrid grapes located within the boundary of the viticultural area. The petitioner owns a bonded winery located within a few miles of the historic National Park Service landmark (known as George Washington Birthplace National Monument). The monument, which consists of a park facility and memorial home (the original home of George Washington was destroyed by fire), is located on 538 acres of land.

Notice of Proposed Rulemaking

In response to the petition, ATF published a notice of proposed rulemaking, Notice No. 570, in the *Federal Register* on Tuesday, September 17, 1985 (FR 37692). That notice proposed establishment of the Northern Neck viticultural area and solicited public comment concerning the proposal.

ATF had determined that the name Northern Neck satisfied informational requirements that the name of the proposed viticultural area is locally and/or nationally known as referring to the area specified in the petition. ATF felt that the evidence for the use of the name George Washington Birthplace to describe the entire five-county petitioned area was not conclusive.

Name of the Area

ATF initially had reservations about the use of the petitioned name George Washington Birthplace for the entire five-county peninsula because of insufficient evidence to substantiate its use in describing this area. Furthermore, the name Northern Neck appeared to be more appropriate than that of George Washington Birthplace because of the content of the name evidence provided by the petitioner.

The petitioner acknowledged that the petitioned area is locally known as the Northern Neck. However, he claimed that the name Northern Neck is not very well known throughout the rest of Virginia and is almost unknown regionally and nationally. The petitioner stated that George Washington's name and close relationship to the five-county area was the most important and readily recognizable name associated with the

area. On this basis, the petitioner still maintained that the name George Washington Birthplace was the most appropriate name for the viticultural area.

The evidence of name submitted by the petitioner did not establish that the name George Washington Birthplace was predominantly associated with the petitioned five-county area of land. On the hand, the evidence showed that the name Northern Neck has been well documented for over three centuries and is still used today in maps and other commonly used reference sources to describe the five-county peninsula.

Discussion of Comments

In Notice No. 570, ATF invited comments from interested parties regarding the proposal of the establishment of the Northern Neck viticultural area. ATF was particularly interested in receiving comments regarding evidence of name and boundary of the viticultural area.

ATF received 81 comments during the 45-day comment period. None of those comments disputed the geographical evidence (climate, soil, etc.) or boundaries presented in the notice of proposed rulemaking. However, all of the comments addressed whether the name of the viticultural area should be Northern Neck or George Washington Birthplace. Seventy-four of the comments favored the name George Washington Birthplace, 6 of the comments favored the name Northern Neck and 1 comment favored either name.

Approved Name

Although the petitioner and commenters provided some evidence supporting use of the name George Washington Birthplace, the evidence that the entire peninsula is locally or nationally known as referring to the area specified in the petition, more strongly supports the name Northern Neck. The land area proposed by the petitioner encompasses the entire neck or peninsula separated by the Rappahannock and Potomac Rivers and the Chesapeake Bay.

The notice of proposed rulemaking referred to many sources that identified the five-county area as the Northern Neck.

The notice also documented that George Washington's name was associated with entire Northern Neck because he was born there and frequented the area throughout his life. Today, both names are found on landmarks and businesses located

within the boundaries of the five-county area.

In addition, evidence gathered during the rulemaking process from sources such as the University of Virginia, The College of William and Mary, George Mason University, Rappahannock Community College, and the Commonwealth of Virginia, shows that both names have been used to identify the area. Furthermore, the names George Washington Birthplace and Northern Neck are often used together to identify and describe the area because of the unique history of the five-county area and the important link our first president had to it.

Therefore, a viticultural area name combining the names Northern Neck and George Washington Birthplace has been approved by ATF. The use of these two names on wine labels and advertisements would insure consumer recognition as to the identity and origin of the wine. This combined name is appropriate since the Northern Neck is, in fact, the birthplace of America's first president, George Washington.

Evidence of Boundaries

The Northern Neck George Washington Birthplace viticultural area is a peninsula bounded on the north by the Potomac River and Potomac Creek, on the east by the Chesapeake Bay, on the south by the Rappahannock River and on the west by the King George County/Stafford County line. The boundaries of the viticultural area were prominently marked by the petitioner on two U.S.G.S. maps.

The map names and complete boundary descriptions can be found in the new § 9.109, as added by this Treasury Decision. Having verified the boundaries, ATF agrees that they meet the requirements for approval of the Northern Neck George Washington Birthplace as an American viticultural area.

Evidence of Geographical Characteristics

Climate and Rainfall

The Northern Neck George Washington Birthplace viticultural area extends approximately 100 miles from the Chesapeake Bay westward to within a few miles of the City of Fredericksburg, Virginia. The distance on land from north to south between the Potomac and Rappahannock Rivers varies from 10 to 20 miles, making the area a long narrow neck or peninsula between the two tidal rivers. The climate begins to change throughout the proposed viticultural area, from the gentle influence of the Chesapeake Bay

and the Potomac and Rappahannock Rivers to the more harsh influences of Piedmont Virginia in the interior land areas.

Historical evidence of favorable grape-growing conditions within the viticultural area was documented in Notice No. 570. The climate of the Northern Neck George Washington Birthplace viticultural area is greatly influenced by the Chesapeake Bay, the Potomac and Rappahannock Rivers. The viticultural area is almost surrounded by these bodies of water. The fanning effect from these waters tend to moderate the climate, and this is the chief reason native stands of longleaf pine (*pinus taeda*), southern bayberry (*myrica cerifera*) and other plants are found growing from King George County eastward to the Chesapeake Bay. These varieties of native stands are not found in any substantial degree to the west of King George County in Stafford County. By contrast there are native stands of hemlock (*tsuga canadensis*) in Stafford County which are not found anywhere on the Northern Neck.

These climate features are the main characteristics which distinguish the Northern Neck George Washington Birthplace from the surrounding areas, and support its designation as a distinguishable viticultural area.

Soils

The Northern Neck George Washington Birthplace viticultural area is entirely within the Northern Coastal Plain with topography running into two general agricultural types called neckland and upland. Neckland, located along the river flats, is nearly level with a gently sloping plateau along the center of the Northern Neck with elevations beginning at 50 feet above sea level and reaching 190 feet above sea level in the western areas of Westmoreland and King George Counties.

The soils of the Northern Neck have been formed from material that has been transported by marine and steam action. The soils are also varied in age; the upland ridges are older and well drained while soils of the necklands are considered younger soils.

Sandy clay and other well-drained soil types are found on the ridge which extends generally through the center of King George County and eastward through Westmoreland County. Other agricultural soils are found along each of the rivers, in what is generally called the river flats, with excellent air drainage and a moderating climate influenced by the huge bodies of surrounding water.

Conclusion

The climate of the Northern Neck George Washington Birthplace viticultural area is milder, its native plants are of more southern variety, its snowfall less severe, its frost free days greater, and its temperatures more even and moderate than the adjoining Piedmont Plateau Region located to the west. This climate produces favorable grape-growing conditions. The U.S. Department of Agriculture classifies the soils of the Northern Neck as prime farmland. These factors, combined with a short but freezing winter season, abundant yearly rainfall, and a generally dry, sunny, grape ripening and harvest time, provide favorable grape-growing conditions for wine production.

After careful analysis of the evidence gathered pursuant to the petition, ATF finds the Northern Neck George Washington Birthplace viticultural area to be a delimited grape-growing region distinguishable by geographical features.

Miscellaneous

ATF does not wish to give the impression by approving Northern Neck George Washington Birthplace as an American viticultural area that it is approving or endorsing the quality of the wine that comes from this area. ATF is approving this area as being distinct and not better than other areas. By approving this area, wine producers are allowed to claim a distinction on labels and advertisements as to the origin of the grapes. Any commercial advantage gained can only come from consumer acceptance of Northern Neck George Washington Birthplace wines.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this final rule because it will not have a significant economic impact on a substantial number of small entities. This final rule will not impose or otherwise cause a significant increase in reporting, recordkeeping, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

Accordingly, it is hereby certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that this final rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12291

It has been determined that this final rule is not classified as a "major rule" within the meaning of Executive Order 12291, 46 FR 13193 (1981), because it will not have an annual effect on the economy of \$100 million or more; it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this final rule because no requirement to collect information is proposed.

Disclosure

A copy of the petition and supporting evidence are available for inspection during normal business hours at the following location: ATF Reading Room, Room 4406, Office of Public Affairs and Disclosure, 12th and Pennsylvania Avenue NW., Washington, DC 20226.

Drafting Information

The principal author of this document is Edward A. Reisman, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 9

Administrative practice and procedure, Consumer protection, Viticultural areas, Wine.

Issuance**PART 9—[AMENDED]**

Accordingly, 27 CFR Part 9, American Viticultural Areas, is amended as follows:

Paragraph A. The authority citation for Part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. B. The table of sections in 27 CFR Part 9, Subpart C, is amended to add the title of § 9.109, to read as follows:

Subpart C—Approved American Viticultural Areas

Sec.

* * * * *

9.109 Northern Neck George Washington Birthplace.

* * * * *

Par. C. Subpart C of 27 CFR Part 9 is amended by adding § 9.109, which reads as follows:

§ 9.109 Northern Neck George Washington Birthplace.

(a) *Name.* The name of the viticultural area described in this section is "Northern Neck George Washington Birthplace."

(b) *Approved maps.* The appropriate maps for determining the boundaries of the Northern Neck George Washington Birthplace viticultural area are 2 U.S.G.S. 1:250,000 scale maps. They are entitled:

- (1) Washington, DC; Maryland; Virginia, 1957 (Revised 1979); and
- (2) Richmond, VA; MD., 1973.

(c) *Boundaries.* The Northern Neck George Washington Birthplace viticultural area consists of all of the lands in the Counties of Westmoreland, King George, Northumberland, Lancaster and Richmond, in the Commonwealth of Virginia. The boundaries of the Northern Neck George Washington Birthplace viticultural area, using landmarks and points of reference found on the appropriate U.S.G.S. maps, are as follows:

- (1) Beginning on the Washington, DC; Maryland; Virginia U.S.G.S. map at a point on Potomac Creek where the King George County western boundary line at its northernmost point intersects Potomac Creek the boundary proceeds easterly and southeasterly on the Richmond, VA; MD. U.S.G.S. map, along the Virginia shoreline of the Potomac River for approximately 66 miles to Smith Point on the Chesapeake Bay;

(2) Thence southerly along the shoreline of the Chesapeake Bay for approximately 20 miles to Windmill Point at the mouth of the Rappahannock River;

(3) Thence northwesterly along the banks of the Rappahannock River for approximately 72 air miles to Muddy Creek at the point where the western boundary line of King George County at its southernmost point begins;

(4) Thence northward along the King George County/Stafford County line

approximately 7 miles to the point of the beginning.

March 30, 1987.

Stephen E. Higgins,
Director.

Approved: April 3, 1987.

John P. Simpson,
Deputy Assistant Secretary, Regulatory,
Trade and Tariff Enforcement.
[FR Doc. 87-8860 Filed 4-20-87; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 3**

[CGD 87-008]

Changes to Coast Guard District Boundaries and Reassignment of Units

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This rule redescribes the boundaries of Coast Guard Districts and reassigns various Marine Inspection and Captain of the Port Zones to reflect organizational changes in the Coast Guard. The Coast Guard, in conjunction with an internal realignment of support functions, is reducing the number of Coast Guard districts from 12 to 10. The Third and Twelfth Coast Guard Districts are being disestablished. The geographic area previously under the jurisdiction of the Twelfth Coast Guard District is being absorbed into the Eleventh Coast Guard District. The geographic area previously under the jurisdiction of the Third Coast Guard District is being divided; the northern portion becomes part of the First Coast Guard District and the southern portion becomes part of the Fifth Coast Guard District. This rule also assigns the Marine Inspection and Captain of the Port Zones previously in the Twelfth District to the Eleventh District, and those previously in the Third District to the First and Fifth Coast Guard Districts. These organizational changes will not affect any Coast Guard services to the public.

FOR FURTHER INFORMATION CONTACT: LCDR E.A. CALHOUN, Commandant U.S. Coast Guard (G-CPA), Washington, DC (202-267-2405).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was not prepared for this regulation. These amendments are matters relating to agency organization and are exempt from the notice and comment requirements of 5 USC 553(b). Since this rule reflects current organizational

changes being placed in effect and has no substantive effect, good cause exists to make it effective in less than 30 days after publication, under 5 U.S.C 533(d). The rulemaking merely changes District boundaries and reassigns Marine Inspection and Captain of the Port Zones to conform with changes in the Coast Guard's internal organization. There will be no effect on the public, since the First and Fifth Coast Guard Districts and Eleventh Coast Guard District will continue to perform all functions affecting the public that were previously performed by the Third and Twelfth Coast Guard Districts, respectively.

Drafting information: LCDR E.A. Calhoun, project manager; and LT. S. Sylvester, project counsel, Office of the Chief Counsel.

Discussion

In order to free up manpower for vital operational missions the Coast Guard is undertaking a realignment of functions within the organization. This realignment will result in the consolidation of many administrative and support activities, previously performed by the Coast Guard district offices, at two new commands: the regional Maintenance and Logistics Commands. The district offices will be primarily involved in the operational control of Coast Guard units in their areas. The Maintenance and Logistic Commands will begin operation on July 1, 1987.

One result of this ongoing realignment is the disestablishment of the Third and Twelfth Coast Guard Districts. Responsibility for the Coast Guard units and the administration of Coast Guard programs within the former Third Coast Guard District is being divided between the First Coast Guard District in Boston, Massachusetts and the Fifth Coast Guard District in Portsmouth, Virginia. Responsibility for the Coast Guard units and the administration of Coast Guard programs within the former Twelfth Coast Guard District is being assumed by the Eleventh Coast Guard District.

These changes are being implemented in phases. Some functions have already been transferred and others will be transferred during the next two months. All transfers will be completed by June 30, 1987 and the offices of the Commander, Third Coast Guard District and Commander, Twelfth Coast Guard District will be disestablished on that date. Rather than publishing a series of notices as each function is transferred, April 30, 1987 has been chosen as an appropriate date for amending the geographic description of the Coast

Guard Districts and reassigning the affected Marine Inspection Zones and Captain of the Port Zones. The actual date of transfer of administrative functions or operational control of affected units may precede or follow this date and, in many cases, the offices of Commander, Third Coast Guard District and Commander, Twelfth Coast Guard District will complete action on pending matters after transferring responsibility for new cases to the successor districts. Therefore, during the transition period Coast Guard officials may be exercising authority in locations that do not conform to the revised geographic areas of responsibility. This could include, but is not limited to, actions involving claims and litigation, civil penalty assessment, bridge permits and regulations, security and safety zones, regulated navigation areas, and pollution prevention and response.

No search and rescue stations or other types of Coast Guard units will be closed or moved. This notification serves to inform the public of the new district boundaries so that in those instances where the public desires to contact the cognizant district commander, the public can determine the proper district commander and his location.

This action is being taken as part of an ongoing realignment of Coast Guard functions and organization. This realignment is necessary to increase overall efficiency and effectiveness of the Coast Guard. This change will also tend to make the remaining ten districts more equal in terms of geographic area and responsibilities.

Elsewhere in Title 33, regulations may refer to or be arranged under headings for the Third Coast Guard District and the Twelfth Coast Guard District, for example: Part 80, *Colregs Demarcation Lines*; Subchapter G, *Regattas and Marine Parades*, Part 100; and Part 165, *Regulated Navigation Areas and Limited Access Areas*.

Affected sections in these parts will be redesignated and references to the Third Coast Guard District and Twelfth Coast Guard District will be deleted in future rulemaking documents. Since these changes are editorial in nature, and require extensive redrafting, they will be handled in later rulemakings. It is anticipated that these changes will be published prior to July 1, 1987.

Regulatory Evaluation

This final rule is exempt from the provisions of Executive Order 12291 since it pertains to matters of agency organization as provided for in section 1(a)(3) of the Order. It is considered to be non-significant under DOT regulatory

policies and procedures (44 FR 11034; February 26, 1979). The economic impact of this final rule has been found to be so minimal that further evaluation is unnecessary. This final rule places no requirements on any sector of the public. It will not affect Coast Guard services delivered to the public. The rule reflects a change in internal Coast Guard organization, streamlining the logistics and support functions. In accomplishing this, some functions, and personnel, will be transferred from one location to another. Since the impact of the final rule is expected to be minimal, the Coast Guard certifies that it will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 3

Coast Guard areas, Districts, Marine inspection zones, Captain of the port zones.

Final Regulation

In consideration of the foregoing, Part 3 of Title 33 of the Code of Federal Regulations is amended as set forth below.

PART 3—COAST GUARD AREAS, DISTRICTS, MARINE INSPECTION ZONES AND CAPTAIN OF THE PORT ZONES

1. The authority citation for Part 3 continues to read as follows:

Authority: 14 U.S.C. 633; 49 CFR 1.45, 1.46.

2. In § 3.01-1, paragraph (b) is revised and paragraph (h) is added, to read as follows:

§ 3.01-1 General description.

(b) The two Coast Guard Areas are the Atlantic Area (see § 3.04-1 of this part) and the Pacific Area (see § 3.04-3). The Coast Guard Area Commander is in command of a Coast Guard Area; the offices are referred to as a Coast Guard Area Office. Area Commanders have the responsibility of determining when operational matters require the coordination of forces and facilities of more than one district.

(h) Descriptions in this part are based on North American Datum 1927 unless otherwise indicated.

3. In § 3.04-1, paragraph (b) is revised to read as follows:

§ 3.04-1 Atlantic area.

(b) The Atlantic Area is comprised of the land areas and U.S. navigable waters of the First, Second, Fifth, Seventh, Eighth and Ninth Coast Guard

Districts and the ocean areas lying east of a line extending from the North Pole south along 95° W. longitude to the North American land mass; thence along the east coast of the North, Central, and South American land mass to the intersection with 70° W. longitude; thence due south to the South Pole. These waters extend east to the Eastern Hemisphere dividing line between the Atlantic and Pacific Areas which lies along a line extending from the North Pole south along 100° E. longitude to the Asian land mass and along a line extending from the South Pole north along 17° E. longitude to the African land mass.

4. In § 3.04-3, paragraph (b) is revised to read as follows:

§ 3.04-3 Pacific area.

(b) The Pacific Area is comprised of the land areas and the U.S. navigable waters of the Eleventh, Thirteenth, Fourteenth, and Seventeenth Coast Guard Districts and the ocean areas lying west of a line extending from the North Pole south along 95° W. longitude to the North American land mass; thence along the west coast of the North, Central, and South American land mass to the intersection with 70° W. longitude; thence due south to the South Pole. These waters extend west to the Eastern Hemisphere dividing line between the Atlantic and Pacific Areas which lies along a line extending from the North Pole south along 100° E. longitude to the Asian land mass and along a line extending from the South Pole north along 17° E. longitude to the African land mass.

5. In § 3.05-1, paragraph (b) is revised to read as follows:

§ 3.05-1 First district.

(b) The First Coast Guard District is comprised of: Maine; New Hampshire; Vermont; Massachusetts; Rhode Island; Connecticut; New York except that part north of latitude 42°N. and west of longitude 74°39' W.; that part of New Jersey north of 39°57' N. latitude, east of 74°27' W. longitude, and northeast of a line from 39°57' N. 74°27' W. north west to the New York, New Jersey, & Pennsylvania boundaries at Tristate; all U.S. naval reservations on shore at Newfoundland; the ocean area encompassed by the Search and Rescue boundary between Canada and the United States easterly to longitude 63° W; thence due south to latitude 41°N; thence southwesterly along a line bearing 219° T to the point of intersection at 36°43' N. latitude, 67°30' W. longitude with a line bearing 122° T

from the New Jersey shoreline at 39°57' N latitude (in the vicinity of Tom's River, New Jersey); thence northwesterly along this line to the coast.

§ 3.15-1 [Removed]

6. In Subpart 3.15, the subpart heading and § 3.15-1 are removed.

§ 3.15-10 [Redesignated as § 3.05-25]

7. Section 3.15-10 is redesignated § 3.05-25.

§ 3.15-25 [Redesignated as § 3.25-05]

8. Section 3.15-25 is redesignated § 3.25-05.

§ 3.15-55 [Redesignated as § 3.05-35]

9. Section 3.15-55 is redesignated as § 3.05-35.

§ 3.15-60 [Redesignated as § 3.05-30]

10. Section 3.15-60 is redesignated as § 3.05-30.

11. In § 3.25-1, paragraph (b) is revised to read as follows:

§ 3.25-1 Fifth district.

(b) The Fifth Coast Guard District is comprised of: Delaware; Maryland; Virginia; District of Columbia; North Carolina; that portion of New Jersey south of 39°57' N. latitude, west of 74°27' W. longitude, and southwest of a line extending northwesterly from 39°57' N., 74°27' W. to the New York, New Jersey, and Pennsylvania boundaries at Tristate; that portion of Pennsylvania east of a line drawn along 78°55' W. longitude south to 41°00' N. latitude, thence west to 70°00' W. longitude, and thence south to the Pennsylvania-Maryland boundary; the ocean area encompassed by a line bearing 122° T from the New Jersey shoreline at 39°57' N. latitude (in the vicinity of Tom's River, New Jersey) to 36°43' N. latitude, 67°30' W. longitude; thence along a line bearing 219° T to the point of intersection with a line bearing 122° T from the shoreline at the North Carolina—South Carolina border; thence northwesterly along this line to the coast.

12. In § 3.55-1, paragraph (b) is revised to read as follows:

§ 3.55-1 Eleventh district.

(b) The Eleventh Coast Guard District is comprised of: Arizona; Utah; Nevada; California; and the ocean area bounded by a line from the California-Oregon state line westerly to 40° N. latitude, 150° W. longitude; thence southeasterly to 5° S. latitude, 100° W. longitude; thence northeasterly to the border between Guatemala and Mexico on the

Pacific Coast (14°38' N. latitude, 92°19' W. longitude).

§§ 3.60-1 and 3.60-10 [Removed]

13. In Subpart 3.60, the subpart heading and §§ 3.60-1 and 3.60-10 are removed.

§ 3.60-55 [Redesignated as § 3.55-20]

14. Section 3.60-55 is redesignated as § 3.55-20.

Dated: April 16, 1987.

J.C. Irwin,

Vice Admiral, U.S. Coast Guard, Acting Commandant.

[FR Doc. 87-8892 Filed 4-20-87; 8:45 am]

BILLING CODE 4910-14-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 2090

[AA-320-07-4211-02; Circular No. 2594]

Special Laws and Rules; Final Rulemaking Removing Obsolete Provisions Concerning Homestead Requirements for Veterans

AGENCY: Bureau of Land Management, Interior.

ACTION: Final Rulemaking Removing Obsolete Regulatory Provisions Concerning Homestead Requirements for Veterans.

SUMMARY: This final rulemaking will delete from the existing regulations in 43 CFR Part 2090 obsolete provisions under which veterans could become eligible for a homestead entry on the public lands. These provisions have become obsolete because all laws governing homestead entries on public lands in the fourteen Western States and Alaska were repealed by section 702 of the Federal Land Policy and Management Act of 1976. The Subpart was retained after the enactment of the Federal Land Policy and Management Act to facilitate the processing of veteran homestead entries pending at that time.

EFFECTIVE DATE: April 21, 1987.

ADDRESS: Any inquiries or suggestions should be sent to: Director (320), Bureau of Land Management, Room 3643, Main Interior Bldg., 1800 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Gary L. Rowe, (202) 343-8693.

SUPPLEMENTARY INFORMATION: This final rulemaking reflects the administrative action of removing from the existing regulations provisions whose statutory authority has been

repealed. Therefore, this document is published as a final rulemaking with an effective date as of the date of publication. The provisions being removed are those covering entries for veterans homesteads authorized by the Act of October 17, 1940, as amended (50 U.S.C. App. 561-572) and the Act of September 27, 1944, as amended (43 U.S.C. 279-283). The regulatory provisions have been retained to facilitate the processing of applications that were pending at the time the statutes were repealed. All pending actions have been completed, and, therefore, the regulations are no longer needed. This administrative action removes the regulations in Subpart 2096 from the Code of Federal Regulations. To the extent that any question may exist or arise concerning rights associated with the regulations being removed, earlier editions of the Code of Federal Regulations will remain available to assist in interpretation.

The principal author of this final rulemaking is Gary L. Rowe, Division of Lands, Bureau of Land Management, assisted by the staff of the Division of Legislation and Regulatory

Management, Bureau of Land Management.

It is hereby determined that this rulemaking does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)) is required.

The Department of the Interior has determined that this document is not a major rule under Executive Order 12291 and that it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

There are no information collection requirements contained in this final rulemaking requiring the approval of the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 43 CFR Part 2090

Airports, Alaska, Coal, Grazing lands, Indian lands, Public lands—classification, Public lands—mineral resources, Public lands—withdrawal, Seashores, Veterans.

Under the authority of Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.), Part 2090, Group 2000, Subchapter B, Chapter II of the Code of Federal Regulations is amended as set forth below.

Dated: April 13, 1987.

J. Steven Griles,

Assistant Secretary of the Interior.

PART 2090—[AMENDED]

1. An authority citation for Part 2090 is added to read:

Authority: R.S. 2478 (43 U.S.C. 1201); R.S. 2275, 2276 (43 U.S.C. 851, 852); 43 U.S.C. 869 et seq.; 43 U.S.C. 641 et seq.; 43 U.S.C. 321-323; 43 U.S.C. 231, 321, 323, 327-329; 25 U.S.C. 334; 25 U.S.C. 336; 16 U.S.C. 485; 72 Stat. 339-340; 43 U.S.C. 852 note; 16 U.S.C. 818; 43 U.S.C. 315f; 43 U.S.C. 1601 et seq.; 16 U.S.C. 3101 et seq.; 43 U.S.C. 1701 et seq.; 30 U.S.C. 189; 48 U.S.C. 462 note.

Subpart 2096—[Removed]

2. Part 2090 is amended by removing Subpart 2096 in its entirety.

[FR Doc. 87-8886 Filed 4-20-87; 8:45 am]

BILLING CODE 4310-84-M

Proposed Rules

Federal Register

Vol. 52, No. 76

Tuesday, April 21, 1987

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1210

Extension of Time for Receipt of Post-Hearing Briefs; Proposed Watermelon Research and Promotion Plan

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Post-hearing briefs; extension of filing period.

SUMMARY: Notice is hereby given that the time period for filing written briefs on testimony presented at the public hearing on the proposed Watermelon Research and Promotion Plan is extended from April 20, 1987 to April 30, 1987. The extension will give interested persons additional time to file with the hearing clerk proposed findings and conclusions, and written arguments or briefs based upon evidence received at the hearing.

DATE: *Comments Due:* April 30, 1987.

ADDRESS: Comments should be sent to: Hearing Clerk, Room 1079, U.S. Department of Agriculture, Washington, DC 20250. Four copies of all written material shall be submitted. This material will be made available for public inspection at the office of the Hearing Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: James M. Scanlon, Acting Chief, Marketing Order Administration Branch, F&V, AMS, USDA, Washington, DC 20250, telephone (202) 475-3914.

SUPPLEMENTARY INFORMATION: Pursuant to the Watermelon Research and Promotion Act of 1985 (Title XVI, Subtitle C of Pub. L. 99-198, 99th Congress, approved December 23, 1985, 99 Stat. 1622) a continuous public hearing was held in Las Vegas, Nevada, on February 18 and 19 and in Atlanta, Georgia, on February 24 and 25, 1987 regarding the proposed Watermelon Research and Promotion Plan (52 FR 3588, Feb. 4, 1987). At the hearing, April

20, 1987 was established as the deadline for filing briefs based on evidence received at the hearing.

The Department has received a request for an extension of the deadline from the proponent group who provided the significant portion of the testimony. An extension of the deadline is justified to ensure that the intent of the proponents' proposal is made as clear as possible for further consideration by the USDA. Accordingly, the deadline for filing briefs is being extended by ten days to April 30, 1987.

Dated: April 17, 1987.

J. Patrick Boyle,
Administrator.

[FR Doc. 87-9082 Filed 4-17-87; 4:52 pm]

BILLING CODE 3410-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182, 184, and 186

[Docket No. 79N-0269]

Iron and Iron Salts; Proposed Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that elemental iron (iron) and ferrous ascorbate, ferrous carbonate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric ammonium citrate, ferric chloride, ferric citrate, ferric phosphate, ferric pyrophosphate, and ferric sulfate (iron salts) are generally recognized as safe (GRAS) as direct human food ingredients. However, the agency is not proposing to take any action on the listing of iron and several iron salts as GRAS substances in dietary supplements. FDA is also proposing to affirm that ferric oxide and oxides of iron are GRAS for use as indirect food ingredients. FDA is not proposing to take any action on the listing in Part 181 (21 CFR Part 181) of iron caprylate, iron tallate, iron linoleate, and iron naphthenate as prior-sanctioned driers that may migrate from food packaging material. In addition, FDA is proposing not to affirm that ferric sodium

pyrophosphate, iron peptonate, iron polyvinylpyrrolidone, sodium ferric ethylenediamine tetraacetate (EDTA), and sodium ferricitropyrophosphate are GRAS as direct human food ingredients (although ferric sodium pyrophosphate will continue to be listed in Part 182 as GRAS for use in dietary supplements). The safety of iron and of these iron salts has been evaluated under the comprehensive safety review conducted by the agency.

DATE: Comments by June 22, 1987.

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

FOR FURTHER INFORMATION CONTACT: Robert Leo Martin, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposals (see the Federal Register of July 26, 1973 (38 FR 20040)) initiating this review, under which the safety of elemental iron (reduced, electrolytic, or carbonyl), ferrous ascorbate, ferrous carbonate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric ammonium citrate, ferric chloride, ferric citrate, ferric phosphate, ferric pyrophosphate, ferric sodium pyrophosphate, ferric sulfate, iron caprylate, iron linoleate, iron tallate, iron peptonate, iron polyvinylpyrrolidone, sodium ferric EDTA, sodium ferricitropyrophosphate, oxides of iron, ferric oxide, and iron naphthenate has been evaluated. (These substances will be referred to collectively as "iron and iron salts" in this proposal unless specifically delineated.)

In accordance with the provisions of § 170.35 (21 CFR 170.35), the agency is proposing to affirm that elemental iron, ferrous ascorbate, ferrous carbonate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferric ammonium citrate, ferric citrate, ferric phosphate, and ferric pyrophosphate are GRAS for use as nutrient supplements in

conventional foods¹ and in infant formulas. The agency is proposing to affirm that ferrous sulfate is GRAS for these uses and as a processing aid. The agency is proposing to affirm as GRAS the use of ferric chloride and ferric sulfate as flavoring agents. The agency also is proposing to affirm that ferric oxide and oxides of iron are GRAS for use as indirect human food ingredients.

However, FDA has tentatively decided not to take any action with regard to the prior sanctions for the use of iron caprylate, iron linoleate, iron naphthenate, and iron tallate in food. Finally, in the absence of adequate biological studies and food use information, FDA is proposing to find that it cannot affirm that the use of ferric sodium pyrophosphate, iron peptonate, iron polyvinylpyrrolidone, sodium ferric EDTA, and sodium ferricitropyrophosphate in food is GRAS.

The GRAS status of the use of iron reduced and of certain iron salts in dietary supplements (i.e., over-the-counter vitamin preparations in forms such as capsules, tablets, liquids, and wafers) is not affected by this proposal. The agency did not request consumer exposure data on dietary supplement uses when it initiated this review. Without exposure data, the agency cannot evaluate the safety of using these ingredients in dietary supplements. The use of these ingredients in dietary supplements will continue to be listed in Subpart F of Part 182 (21 CFR Part 182). The uses of iron and iron salts prescribed by food additive regulations in 21 CFR Parts 172 through 178 also are not affected by this proposed regulation.

I. Background Information

Iron is the fourth most abundant element in the earth's crust, exceeded only by oxygen, silicon, and aluminum. Iron is essential for a number of biological processes and is present in all living matter. In water and soil, it is usually in the form of ferrous and ferric oxides and hydroxides, but in biological materials, the forms are considerably more numerous and varied. Thus, the iron in food may be ingested in its elemental form, as relatively simple inorganic and organic compounds, and as iron complexes, such as heme, in which iron is bound to porphyrin.

Iron is widely distributed in the animal body, where it exists in both ionic (loosely bound; "inorganic") and nonionic (tightly bound; "organic") forms. Iron is easily oxidized or reduced

and thus is found as a minute but vital part of certain enzymes that are involved in electron transfer (e.g., cytochrome, cytochrome oxidase, succinic dehydrogenase, and xanthine oxidase). Normally, approximately 70 percent of human body iron is functional or "essential" iron (i.e., in hemoglobin, myoglobin, and intracellular iron-containing enzymes), and 30 percent is storage or "nonessential" iron (i.e., in hemosiderin and ferritin). In women the storage reserve tends to be less than half that in men.

Iron deficiency is widely viewed as a prime example of nutritional inadequacy. In 1968, the World Health Organization characterized nutritional anemia as the most frequent type of malnutrition in the world. However, it has proven difficult to define "iron deficiency" with sufficient precision to obtain a reliable measure of its prevalence. Estimates are usually based on the incidence of hypochromic anemia and on the assumption that iron deficiency is the principal cause of that condition. Even if this assumption is correct, the estimates would denote only overt, and not latent, iron deficiencies. Furthermore, no unanimity exists concerning what constitutes normal hematological values. Use of different standards would alter the apparent incidence of anemia.

Because iron deficiency occurs in some individuals, and the content, form, and availability of iron in foods vary greatly, it has become customary to fortify certain foods with forms of iron to help ensure nutritional adequacy. Three factors must be considered whenever the decision is made to fortify foods with iron: (1) The level of iron to be added, (2) the vehicle to be used, and (3) the form of iron to be added.

The level of iron added to food is affected by an FDA regulation that imposes certain labeling requirements on foods that are fortified to provide 50 percent or more of the U.S. Recommended Daily Allowance of a vitamin or mineral in a single serving (21 CFR 101.9). Iron fortification of foods is usually kept below this level to avoid these labeling requirements.

The selection of a suitable vehicle for the addition of iron is important and depends largely on the eating habits of a given culture or country. Whatever food is selected should be one that is already widely consumed by the population and that will remain stable and palatable after enrichment.

In selecting the form of iron that is to be used as a fortifying agent in a food, one must consider, the chemical and physical properties of both the iron

compound and the food to be fortified. Solubility, stability, availability, organoleptic qualities, and cost are also factors in making this selection. Consequently, the food industry has used several different iron compounds, and no one iron compound has been clearly preeminent as an enrichment agent.

Of the compounds used by the food industry, ferric phosphate, ferric pyrophosphate, ferric sodium pyrophosphate, ferrous gluconate, ferrous lactate, ferrous sulfate, and iron reduced have been considered GRAS for use as nutrients and dietary supplements. Ferric sulfate and oxides of iron have been considered GRAS for use in paper and paperboard products used in food packaging.

In addition to the iron forms listed above, ferrous carbonate, ferrous citrate, ferrous fumarate, ferric ammonium citrate, ferric chloride, ferric citrate, ferric oxide, and iron peptonate have been authorized by FDA as unpublished GRAS substances for use as nutrients and dietary supplements or as ingredients of paper and paperboard products used in food and food packaging.

Additionally, in response to inquiries from the food industry, FDA has included sodium ferric EDTA, ferrous ascorbate, iron polyvinylpyrrolidone, and sodium ferricitropyrophosphate in this review to determine if these substances are GRAS.

FDA has also reviewed the safety of iron caprylate, iron linoleate, iron naphthenate, and iron tallate, which are prior-sanctioned for use in the manufacture of food-packaging materials.

The compounds described below are those iron compounds that have been evaluated by FDA.

Elemental Iron

The term "elemental iron" is the synonym for the three forms of metallic iron used in food fortification: reduced iron, electrolytic iron, and carbonyl iron. The processes employed in preparing elemental iron determine the particle size, surface area, density, amount of impurities, and other factors that in turn profoundly influence the bioavailability of the product.

"Reduced iron" or "ferrum reductum" is widely used as a term for all food-grade powdered iron. However, confusion exists about the meaning of this term because in metallurgy it refers to a specific form of powdered iron. Reduced iron is prepared by reacting ground ferric oxide with hydrogen or carbon monoxide at an elevated

¹ FDA is using the term "conventional food" to refer to food that would fall within any of the 43 categories listed in § 170.3(n) (21 CFR 170.3(n)).

temperature. The purity of the product reflects the purity of the ferric oxide used. The reduced product is pulverized, and those particles that pass through a 100 mesh sieve (149 microns and less) are used for food fortification.

Electrolytic iron is produced by plating chemically pure iron onto stainless steel electrodes. The iron deposit is removed from the electrodes, ground, and sieved to food-grade specifications. The resulting iron particles have irregular, dendritic, or fernlike shapes that provide greater surface areas than the more symmetrical reduced iron powder.

Elemental iron is obtained in the carbonyl iron process by decomposing iron pentacarbonyl [$\text{Fe}(\text{Co})_5$] under controlled conditions. The iron pentacarbonyl is produced by treating scrap or reduced iron with carbon monoxide under heat and pressure. This process yields iron particles of high purity and small size (0.5 to 10 microns in diameter).

Food-grade specifications for elemental iron are listed in the Food Chemicals Codex under "iron, reduced," "iron, electrolytic," and "iron, carbonyl."

Ferrous Gluconate

Ferrous gluconate is prepared by reacting barium or calcium gluconate with ferrous sulfate. It usually occurs as the dihydrate and is a pale, yellow-green powder with an odor of caramel. Ferrous gluconate is very soluble in water but nearly insoluble in alcohol. Its solutions are acid to litmus.

Ferrous Citrate

Ferrous citrate is prepared from the reaction of sodium citrate with ferrous sulfate or by direct action of citric acid on iron filings. The resulting product is insoluble in water, alcohol, and acetone. It is soluble in dilute acid.

Ferrous Fumarate

Ferrous fumarate occurs as a red-orange to red-brown powder. It is prepared by mixing hot aqueous solutions of sodium fumarate and ferrous sulfate. The product is slightly soluble in water but insoluble in alcohol.

Ferrous Lactate

Ferrous lactate, as prepared commercially, contains three molecules of water and is a greenish-white powder or crystalline mass. It is prepared by reacting calcium lactate with ferrous lactate or by direct reaction of lactic acid with iron filings. On exposure to air, it becomes darker and incompletely soluble in water.

Ferrous Sulfate

Ferrous sulfate usually occurs in hydrated forms. The heptahydrate forms blue-green monoclinic crystals that are soluble in water and absolute methanol but only slightly soluble in ethanol. It is prepared by reacting sulfuric acid with iron. In dry air, the compound is efflorescent, and in moist air, the compound is oxidized to brown ferric sulfate. Most ferrous sulfate is a byproduct of the steel industry.

Ferric Phosphate

Ferric phosphate is usually prepared by reacting sodium phosphate with ferric citrate or ferric chloride. The product is an odorless, yellowish-white to buff powder. The product occurs as the dihydrate. It is insoluble in water and acetic acid but is soluble in mineral acids.

Ferric Pyrophosphate

Ferric pyrophosphate is prepared by reacting sodium pyrophosphate with ferric citrate. As it is prepared commercially, it contains nine molecules of water and is a yellowish-white powder. It is insoluble in water and acetic acid but is soluble in mineral acids.

Ferric Sulfate

Ferric sulfate is prepared by reacting sulfuric acid and nitric acid with ferrous salts. The resulting product contains approximately 20 percent water and is yellowish in color. It is slightly soluble in water but nearly insoluble in alcohol.

Oxides of Iron

The term "oxides of iron" refers to ferrous oxide (FeO) and ferric oxide (Fe_2O_3) or to mixtures of ferrous oxide and ferric oxide.

Ferrous oxide is a black powder that oxidizes in the air. It can be made by heating ferrous oxalate in the absence of air. Ferric oxide is a red powder and is found in nature both as hematite and in hydrated forms (as rust and limonite). It can be prepared by calcining ferrous sulfate or hydrated ferric oxide. Ferric oxide is insoluble in water but soluble in acid.

Iron Caprylate

Iron caprylate is also known as "iron octanoate." The pure compound is prepared by reacting salts of octanoic acid with iron salts. However, because iron octanoate is relatively insoluble in oil, the octanoates used commercially are the more soluble salts of a branched-chain isomer, 2-ethyl hexanoic acid. This product is also referred to as iron caprylate.

Iron Linoleate

Iron linoleate is usually prepared by reacting iron salts with linseed oil or with the fatty acids of linseed oil. The final product contains not only iron linoleate but also iron salts of the other fatty acids present.

Iron Naphthenate

Iron naphthenate is obtained when iron salts are reacted with the various mixed acids occurring in naphthalene-base crude petroleum.

Iron Tallate

Iron tallate is prepared from the reaction of various iron salts with tall oil. Commercially tall oil is a byproduct derived from the waste liquors of pine wood pulp mills. It consists of a mixture of fatty and cyclic acids. Oleic and linoleic acids comprise the bulk of the fatty acids, although some linolenic and stearic acids are also present. The product resulting from the reactions of various iron salts with this mixture is referred to as iron tallate.

Ferrous Carbonate

Ferrous carbonate is an odorless, white solid prepared by treating solutions of ferrous salts with alkali carbonate salts. Ferrous carbonate is insoluble in water but soluble in dilute acids.

Ferric Ammonium Citrate

Ferric ammonium citrate is prepared by the reaction of citric acid with ferric hydroxide, followed by the addition of ammonium hydroxide. Ferric ammonium citrate is a complex salt of ammonia, iron, and citric acid. It can exist in two forms, depending on the concentrations of the initial reactants: (1) Ferric ammonium citrate, brown, and (2) ferric ammonium citrate, green. Both forms are soluble in water but insoluble in alcohol. According to industry representatives, ferric ammonium citrate is one of the few soluble iron compounds that can be added to dairy products without inducing an off-flavor.

Ferric Chloride

Ferric chloride is usually prepared from the reaction of chlorine with ferrous sulfate or ferrous chloride. It can also be prepared by reacting ferric oxide with hydrogen chloride. It is very hygroscopic and water soluble. It readily forms a hexahydrate.

Ferric Citrate

Ferric citrate is prepared from reaction of citric acid with ferric hydroxide. The product is soluble in hot

water and practically insoluble in alcohol.

Iron Peptonate

Iron peptonate is prepared by adding ferric oxide to peptones. The resulting product is a compound of undetermined structure. It contains 16 to 18 percent iron in nonionic form. It is made water-soluble by the addition of sodium citrate.

Sodium Ferric Ethylenediamine Tetraacetate (EDTA)

Sodium ferric EDTA (synonyms: Sodium iron EDTA, ferric versenate, sodium iron edetate, ferric sodium edetate) is prepared from disodium EDTA and ferric nitrate. It is readily soluble in water and in alkaline media but is insoluble in acid. Disodium EDTA is listed in 21 CFR 172.135 for use as a preservative in various foods and multivitamin preparations at concentrations of 36 to 500 parts per million. It chelates some of the iron present in these preparations to form the ferric EDTA complex.

Ferrous Ascorbate

Ferrous ascorbate can be prepared by treating ferrous hydroxide with ascorbic acid to yield a blue-violet product containing 16 percent iron.

Iron Polyvinylpyrrolidone

Iron polyvinylpyrrolidone is a mixture of reduced iron or an iron salt with polyvinylpyrrolidone in unspecified proportions. Although polyvinylpyrrolidone forms stable water-soluble complexes with various ions, complex formation of iron with polyvinylpyrrolidone presumably does not occur. The resulting product is nothing more than a mixture of reduced iron or an iron salt dispersed throughout the polyvinylpyrrolidone.

Sodium Ferricitropyrophosphate

Sodium ferricitropyrophosphate is a mixture of salts of uncertain composition produced by combining sodium pyrophosphate with ferric citrate.

Ferric Sodium Pyrophosphate

Ferric sodium pyrophosphate (sodium ferric pyrophosphate) usually occurs as a hydrate. The commercial product contains 15.5 to 16.5 percent iron and 50.5 to 52.5 percent phosphorus pentoxide.

II. Regulatory Status of Iron and Iron Salts

FDA listed iron reduced, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric phosphate, ferric

pyrophosphate, and ferric sodium pyrophosphate as GRAS nutrients in a regulation published in the *Federal Register* of November 20, 1959 (24 FR 9368). Subsequently, FDA listed them as GRAS nutrients/dietary supplements in a regulation published in the *Federal Register* of January 31, 1961 (26 FR 938).

However, in a regulation published in the *Federal Register* of September 5, 1980 (45 FR 58837), the agency divided the nutrient/dietary supplement category into separate listings for GRAS dietary supplements (21 CFR Part 182, Subpart F) and for GRAS nutrients (21 CFR Part 182, Subpart I). For example, iron reduced is listed as GRAS in § 182.5375 for use in dietary supplements and in § 182.8375 for use in food as a nutrient. Similarly, ferric phosphate (§ 182.5301), ferric pyrophosphate (§ 182.5304), ferric sodium pyrophosphate (§ 182.5306), ferrous gluconate (§ 182.5308), ferrous lactate (§ 182.5311), and ferrous sulfate (§ 182.5315) are listed for use as dietary supplements and under §§ 182.8301, 182.8304, 182.8306, 182.8308, 182.8311, and 182.8315, respectively, for use in food as nutrients.

After the published GRAS lists discussed above were established, FDA issued advisory opinion letters that stated that ferric ammonium citrate, ferrous carbonate, ferrous citrate, ferric citrate, and iron peptonate are GRAS for use as nutritional supplements. Also, FDA stated in an opinion letter dated October 27, 1960, that ferric chloride is GRAS when used as a direct food additive.

In addition to direct food use, iron and iron salts are used in food-packaging materials. Iron reduced, ferrous sulfate, ferric sulfate, and the oxides of iron are listed as GRAS in regulations published in the *Federal Register* of June 17, 1961 (26 FR 5421) (currently codified at 21 CFR 182.90) as substances migrating to food from paper and paperboard food-packaging materials. Iron caprylate, iron linoleate, iron naphthenate, and iron tallate are prior-sanctioned food ingredients listed in 21 CFR 181.25 for use as driers in food-packaging materials. Moreover, in a letter dated December 15, 1959, FDA stated that ferric oxide is GRAS for use in food packaging.

In an advisory opinion letter, FDA stated that the use of iron oxide to color food-packaging materials was acceptable.

In the following regulations, FDA has approved iron and iron salts for the following uses: (1) In 21 CFR 172.350, ferrous fumarate for use as a source of iron in foods for special dietary use; (2) in 21 CFR 172.430, iron ammonium

citrate for use as an anticaking agent in salt; (3) in 21 CFR 175.105, ferric chloride for use in adhesives; (4) in 21 CFR 175.300, iron and iron oxides for use in resinous and polymeric coatings; (5) in 21 CFR 175.390, iron oxide for use in zinc-silicon matrix coatings; (6) in 21 CFR 176.170, ferric chloride and ferrous ammonium sulfate for use as components of paper and paperboard in contact with aqueous and fatty foods; (7) in 21 CFR 176.180, ferric chloride for use as a component of paper and paperboard in contact with dry food; (8) in 21 CFR 177.1200, ferrous ammonium sulfate for use in cellophane; and (9) in 21 CFR 177.2600, iron oxide for use in rubber articles intended for repeated use. In addition, in 21 CFR 73.160, FDA approved the use of ferrous gluconate as a color additive for the coloring of ripe olives. These regulations are not affected by this proposal.

The use of iron and iron compounds for enrichment is required by the following food standards: Bakery products (21 CFR Part 136), cereal flours and related products (21 CFR Part 137), and macaroni and noodle products (21 CFR Part 139). FDA in the past has defined the types of iron compounds that may be used in these regulations as "forms which are harmless and assimilable." More recently, the agency has stated that "any safe and suitable" form of iron may be used. The term "safe and suitable" is defined in 21 CFR 130.3(d).

Section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) lists iron (salt not specified) as a required nutrient in infant formula, subject to level restrictions. FDA is reviewing all nutrient levels in infant formulas under a contract with the American Academy of Pediatrics. Any necessary modifications in the nutrient levels of iron and iron salts in infant formula will be proposed in a separate rulemaking under section 412(a)(2) of the act.

Iron and iron salts also may be used to fortify foods as described in 21 CFR Part 104 and in special dietary foods as described in 21 CFR Part 105.

III. Consumer Exposure to Iron and Iron Salts in Food

In 1971 and 1975, the National Academy of Sciences/ National Research Council (NAS/NRC) surveyed a representative cross-section of food manufacturers to determine the specific foods in which iron and iron salts were used and the levels at which they were used. NAS/NRC combined this manufacturing information with information on consumer consumption

of foods to obtain an estimate of consumer exposure to iron and iron salts. The surveys showed that the direct food uses of iron and iron salts are mainly for nutrient fortification and dietary supplement uses. Ferrous sulfate was also reported to be used as a processing aid. Additionally, the 1975 NAS/NRC survey reported that ferric sulfate is used in fats and oils, processed cheeses, and snack foods as a flavoring agent. Also, the Select Committee on GRAS Substances (the Select Committee) learned that ferric chloride is added to nonalcoholic beverages as a flavoring agent.

According to the NAS/NRC surveys, the total amounts of iron and iron salts used by food manufacturers were as follows: ferric phosphate, 639,450 pounds (1975 survey); ferric pyrophosphate, 2,426 pounds (1970 survey); ferric sodium pyrophosphate, 37,485 pounds (1975 survey); ferrous gluconate, 3,749 pounds (1970 survey); ferrous sulfate, 595,350 pounds (1975 survey); "iron reduced," 1,124,550 pounds (1975 survey); and ferric ammonium citrate, 29,988 pounds (1975 survey). During the period between 1970 and 1975, the amount of added elemental iron almost doubled, while that of ferrous sulfate, ferric phosphate, and ferric sodium pyrophosphate decreased by over 10, 40, and 90 percent, respectively.

IV. Opinions of the Select Committee on Iron and Iron Salts

Iron and iron salts have been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the searches were chosen to discover any articles that considered: (1) Chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 386 abstracts on iron and iron salts was reviewed, and 198 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

The Select Committee, which was composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB), summarized information from the scientific literature review and other sources in a report to FDA. In this report, the Select Committee also carefully evaluated all of the available safety information on iron and iron salts

(see Appendix). In the Select Committee's opinion (Ref. 1, pp. 49-50):

The body content of iron in the normal individual is regulated primarily by absorptive processes. Relatively small amounts of iron are absorbed when body stores of iron are high and relatively large amounts when body stores are low. This regulation of iron absorption is faulty in individuals with the metabolic disorder, hemochromatosis.

Although hemochromatosis is generally considered a rare, genetically transmitted disorder, several investigators believe that a latent form of hemochromatosis may be much more common. In Sweden, where food fortification with iron is at a higher level than in the United States, and where medicinal iron supplements are widely consumed, investigators reported several cases of hemochromatosis and iron overload in a sparsely populated district. The significance of these findings with respect to the general population of Sweden, or to other populations is not yet clear. However, these findings suggest that it is possible that a significant number of apparently normal and unidentified individuals might be at risk of developing liver damage from intakes of iron which are innocuous and, in fact, probably beneficial for the population at large.

It should be noted that in the United States (and probably in other industrialized countries), individuals ingesting large amounts of iron may achieve these intakes through regular consumption of iron supplements. For these individuals, food fortification contributes a relatively small fraction of total intake. The question of total intake of iron by the U.S. population and its relation to chronic iron toxicity merit further study. Monitoring of the population with respect to iron nutritional status is essential. The estimated per capita intake of 5 mg per day obtained from food fortification comprises more than one-third the total intake for much of the population.

Iron deficiency is a leading nutritional problem in the United States. Intakes of iron are below recommended levels for a large fraction of the population. Hence, it is evident that an increase in iron fortification of select foods could be an important public health measure.

The form of iron utilized to fortify foods should be of adequate bioavailability. Iron forms evaluated in this report which appear to be adequately bioavailable are elemental iron (reduced, electrolytic, carbonyl), ferrous ascorbate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric ammonium citrate, ferric chloride, and ferric citrate. In contrast, the bioavailability of ferrous carbonate ferrous oxide, ferric oxide, ferric phosphate, ferric pyrophosphate, or ferric sodium pyrophosphate is relatively low compared with ferrous sulfate. Insufficient data are available to judge the relative bioavailability of the other iron preparations considered in this report.

Experimental data are sparse for most of the forms of iron considered in this report. Animal studies have been largely confined to determination of the acute toxicity and

bioavailability of specific iron forms. Such studies have limited relevance in evaluating the possible hazards of the addition of iron to food. Few reports are available on the effects of long-term feeding experiments. An extensive literature exists on the use of certain forms given as hematinics, but the reports are largely anecdotal and their interpretation is of questionable value. Certain compounds have been employed extensively for many years both as additions to food and in the treatment of iron deficiency with no reported adverse effects. In view of the need for, and wide use of, iron compounds, it would appear prudent to place this historical and anecdotal experience on a scientifically rigorous basis in the reasonably near future. The Select Committee emphasizes the need for well-controlled chronic feeding studies with most of the individual compounds, before confident appraisal can be made of their relative merits or hazards.

In light of the considerations above, the Select Committee concluded that there is no evidence in the available information on reduced, electrolytic, and carbonyl iron, ferrous ascorbate, ferrous carbonate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric ammonium citrate, ferric citrate, ferric phosphate, or ferric pyrophosphate that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels now current and in the manner now practiced or, if deemed necessary, at somewhat higher levels to meet nutritional needs. However, the Select Committee stated that it was not possible to determine without additional data whether a major increase in consumption would constitute a dietary hazard (Ref. 1, p. 50).

The Select Committee stated that "serious deficiencies exist in the experimental data or clinical experience with a number of iron compounds employed or suggested as iron fortifying agents for foods." It concluded that because of these deficiencies, it had insufficient data upon which to base an evaluation of ferric oxide, iron peptonate, iron polyvinylpyrrolidone, sodium ferric EDTA, sodium ferricitropyrophosphate, or ferric sodium pyrophosphate when these substances are used as food ingredients (Ref. 1, p. 51).

The Select Committee also stated that "several iron compounds are used in the preparation of paper and paperboard materials contacting foods or as ingredients used to hasten the drying of films used in coating the inner surface of food cans. Neither the amounts used for these purposes nor the extent to which they might migrate to foods are known to the Select Committee. However, the

extent of their migration to food is believed to be very slight." It concluded that there is no evidence in the available information on elemental iron, ferrous sulfate, ferric chloride, ferric oxide, ferric sulfate, iron caprylate, iron linoleate, iron tallate, or the oxides of iron that demonstrates, or suggests reasonable grounds to suspect, a hazard when they are used as ingredients of paper and paperboard materials or in films coating the inner surface of cans in the manner now practiced or that might reasonably be expected in the future (Ref. 1, p. 51).

Finally, the Select Committee stated that no information was available on the metabolism or toxicity of the various substances included under the term "iron naphthenate." It concluded that in view of this deficiency, it had insufficient data upon which to base an evaluation of iron naphthenate when that substance is used as an ingredient of films that coat the inner surface of cans containing food (Ref. 1, p. 51).

V. FDA's Evaluation and Proposed Actions on Iron and Iron Salts

FDA has undertaken its own evaluation of all available information on iron and iron salts including the conclusions of the Select Committee. The agency concludes that no change in the current GRAS status of elemental iron (reduced, electrolytic, or carbonyl), ferrous ascorbate, ferrous carbonate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric ammonium citrate, ferric citrate, ferric phosphate, and ferric pyrophosphate is necessary. Therefore, in accordance with the opinion of the Select Committee, the agency proposes to affirm that the use of these substances as nutrient supplements for direct addition to conventional human food is GRAS.

Because the NAS/NRC survey did not specifically request data on dietary supplement use, FDA does not have adequate data upon which to judge the exposure from the use of iron and iron salts as dietary supplements. Without such exposure data, the agency cannot evaluate the safety of the use of these substances in dietary supplements and can take no action on the GRAS status of iron and iron salts for this use. Therefore, FDA is not taking any action on the listing of iron reduced, ferrous gluconate, ferrous lactate, ferrous sulfate, ferric phosphate, ferric pyrophosphate, and ferric sodium pyrophosphate in §§ 182.5375, 182.5308, 182.5311, 182.5315, 182.5301, 182.5304, and 182.5306, respectively, for use as dietary supplements.

FDA is also not affirming in Part 186 (21 CFR Part 186) the GRAS status of the indirect use of any of the iron compounds listed above because this use of these substances is authorized under § 184.1(a) (21 CFR 184.1(a)) (October 19, 1983; 48 FR 48456). However, in accordance with the Select Committee's opinion, and based on its own review of the available data, the agency is proposing to affirm as GRAS the use of ferric oxide and the oxides of iron as indirect food ingredients.

The agency also is proposing to affirm that the use of ferric chloride and ferric sulfate as flavoring agents for direct addition to food is GRAS. The 1975 NAS/NRC food survey reported that ferric sulfate was being used as a flavoring agent. Additionally, manufacturers reported to the Select Committee that ferric chloride is used as a flavoring agent in nonalcoholic beverages. The Select Committee did not evaluate these direct food uses of ferric chloride. However, based on its evaluation of these limited uses, FDA has tentatively concluded that these uses are safe. The agency is therefore proposing to affirm that the use of ferric chloride and ferric sulfate as flavoring agents is GRAS.

FDA is proposing to make no change on the prior-sanctioned listing in § 181.25 of iron caprylate, iron tallate, and iron linoleate when used as a component of driers. The agency is also proposing to make no change on the prior-sanctioned status of iron naphthenate for this use. Even though the Select Committee stated that it had insufficient relevant information upon which to evaluate iron naphthenate, the agency has tentatively concluded that based on the limited use, and the past history of indirect food use, of this ingredient, no health concerns exist. Additionally, the agency notes that iron naphthenate is approved for use under food additive regulations (21 CFR 175.300, 175.380, 175.390, 176.170, and 177.1210) for articles intended for use in contact with food.

Based on its review of the available data, FDA agrees with the Select Committee that there are insufficient use information and biological data upon which to base a safety evaluation of ferric oxide, iron peptonate, iron polyvinylpyrrolidone, sodium ferric EDTA, sodium ferric pyrophosphate, or ferric sodium pyrophosphate for use as direct food ingredients. Without consumer exposure data and relevant biological studies, the safety of a food ingredient cannot be evaluated. Therefore, the agency advises that unless food use information and

biological data are submitted as comments on this proposal, these ingredients will not be affirmed as GRAS for any direct food use.

However, as noted earlier in this preamble, the GRAS status of the use of iron salts in dietary supplements is not affected by this proposal. Ferric sodium pyrophosphate is listed in § 182.5306 (21 CFR 182.5306) for use in dietary supplements and in § 182.8306 (21 CFR 182.8306) for use as a nutrient. The agency is taking no action on the dietary supplement listing at the present time, but the agency is proposing to remove ferric sodium pyrophosphate from the list of nutrients in Part 182 because of the lack of information about this ingredient.

The agency notes that the 1971 and 1975 NAS/NRC survey of food manufacturers did not distinguish among the types of ferric ammonium citrate used in food but solicited information under the name "ferric ammonium citrate." Of the two types of ferric ammonium citrate (ferric ammonium citrate, brown, and ferric ammonium citrate, green), ferric ammonium citrate, green, is a regulated food additive (anticaking agent), whereas ferric ammonium citrate, brown, has been accorded GRAS status. Indications are that both are used as a nutrient and as a dietary supplement. In several of the reported biological studies, it was not clear which form of ferric ammonium citrate was used. Based on the considerations above and on the safety data available, the agency will consider both ferric ammonium citrate, brown, and ferric ammonium citrate, green, to be GRAS and has included both forms in proposed § 184.1296.

FDA is proposing to affirm the GRAS status of elemental iron, ferrous ascorbate, ferrous carbonate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferric ammonium citrate, ferric citrate, ferric phosphate, ferric pyrophosphate for use as nutrient supplements in conventional foods, of ferrous sulfite for use as a nutrient supplement in conventional foods and as a processing aid, and of ferric chloride and ferric sulfate for use as flavoring agents when they are used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1) (21 CFR 184.1(b)(1)). The agency is proposing not to include in the GRAS affirmation regulations for these substances the levels of use reported in the 1971 NAS/NRC survey. Both FASEB and the agency have concluded that a large margin of safety exists for these substances, and that a

reasonably foreseeable increase in the level of consumption of these substances will not adversely affect human health.

Furthermore, the agency believes that excessive consumption of these substances will not occur. The major use of these substances is for fortification of traditional foods, and when used for this purpose, the food standards regulations specify the amount of the substance that can be added.

Additionally, §§ 101.9(a)(2) and 104.20 (21 CFR 101.9(a)(2) and 104.20) clearly delineate the agency's policy with regards to the addition of nutrients to foods. Section 101.9(a)(2) (21 CFR 101.9(a)(2)) specifies that "If any vitamin and/or mineral is added to a food so that a single serving provides 50 percent or more of the U.S. Recommended Daily Allowance * * * unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) * * *." Section 104.20 (21 CFR 104.20) delineates the agency's policy on fortification of foods. The agency expects that there will be adherence to these guidelines and that as a result there will be no net increase in the use of these ingredients as nutrients.

The agency notes that there are numerous use situations covered by this document in which it may be possible for iron and one or more of its salts to be used interchangeably for a specific technological purpose or in a certain food class. To the extent that such substitutions are based on economic or technological considerations, the agency has no basis to object to such substitutions. The agency believes that the interchangeable nature of iron and iron salts is self-limiting (i.e., constraints are placed on the amount of iron and iron salts that can be used in various foods by production of such effects as an off-taste, solubility concerns, product deterioration, discoloration, and reduced palatability). Additionally, further constraints are placed on use by regulations promulgated in 21 CFR Parts 101, 104, and 105 and by the Infant Formula Act of 1980. Therefore, the agency is proposing to affirm the GRAS status of these ingredients when they are used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1). To

make clear, however, that the affirmation of the GRAS status of these ingredients is based on the evaluation of currently known uses, the proposed regulations set forth the technical effects that FDA evaluated.

As stated above, section 412(g) of the act authorizes the use of iron (salt not specified) in infant formula. The 1971 NAS/NRC survey reported the use of ferric sodium pyrophosphate and ferrous sulfate as nutrient supplements in infant formula. However, neither iron nor any of the other iron salts were reported being used. The agency has evaluated the use of iron and iron salts in infant formulas and has concluded that to the extent that it is technologically feasible, any iron compound affirmed as GRAS for direct food use as a nutrient can be used in infant formula. Consequently, the agency is proposing to include use in infant formula in the GRAS affirmation regulations set forth in this document.

The affirmation of GRAS status of the uses of iron and iron salts is based on the safety data available to FDA. It is not based on bioavailability. Although the issue of bioavailability of iron and iron salts is important, this issue can be separated from the evaluation of the safety of these ingredients. The agency is currently evaluating the bioavailability of nutrients, including iron and iron salts, and this issue will be addressed in a Federal Register document in the near future. In the meantime, FDA concurs with the Select Committee that all of the iron substances being affirmed as GRAS are sources of iron that are moderately or highly bioavailable.

In issuing GRAS affirmation regulations for iron and iron salts, the agency includes in paragraph (a) of each regulation a description of the identity of the substance that is being affirmed

as GRAS and, where appropriate, a description of the commercial methods of manufacture. However, in the case of many of the iron salts, the agency has been unable to list suitable methods of manufacture because of a lack of information on these processes. The agency, therefore, is specifically soliciting information and comments on the manufacturing processes for the iron and iron salts listed in the regulations.

The Select Committee stated that no food-grade specifications exist for several iron compounds, and that there is a need to establish such specifications. The agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for these compounds. When acceptable specifications are developed, the agency will incorporate them into these regulations. Until specifications are developed, FDA has determined that the public health will be adequately protected if these commercial iron compounds comply with the description in the proposed regulations and are of food-grade purity (21 CFR 170.30(h)(1) and 182.1(b)(3)).

Copies of the scientific literature review on iron and iron salts, reports of the mutagenic evaluations for ferric orthophosphate (ferric phosphate), ferric pyrophosphate, ferrous gluconate, ferrous sulfate, and sodium ferric pyrophosphate, reports of the teratogenic evaluation for ferric sodium pyrophosphate and ferric sulfate, a report on iron bioavailability, and the report of the Select Committee are available for review at the Dockets Management Branch (address above) and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

Title	Order No.	Price code	Price ¹
Iron and iron salts (scientific literature review).....	PB 221-236	A05	\$10.50
Ferrous sulfate (mutagenic evaluation).....	PB 245-435/AS	A03	7.50
Ferrous gluconate (mutagenic evaluation).....	PB 245-477/AS	A03	7.50
Ferric orthophosphate (mutagenic evaluation).....	PB 245-514/AS	A03	7.50
Ferric sodium pyrophosphate (mutagenic evaluation).....	PB 245-495/AS	A03	7.50
Ferric pyrophosphate (mutagenic evaluation).....	PB 257-876/AS	A03	7.50
Ferric sodium pyrophosphate (teratogenic evaluation).....	PB 245-524/AS	A03	7.50
Ferric Sulfate (teratogenic evaluation).....	PB 245-532/AS	A03	7.50
Iron and iron salts (Select Committee report).....	PB 178-676/AS	A05	10.50
The bioavailability of iron sources and their utilization in food enrichment.	PB 224-122	A05	10.50

¹ Price subject to change.

VI. Reference

The following information has been placed in the Dockets Management Branch (address above) and may be reviewed by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "Evaluation of the Health Aspects of Iron and Iron Salts as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD.

VII. Economic and Environmental Assessments

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substances covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if promulgated, will not be a major rule as defined by the Order.

The agency's findings that there will be no economic impact and no significant impact on a substantial number of small entities if the proposed rule is promulgated, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch.

VIII. Additional Prior Sanctions

The agency is unaware of any prior sanction for the use of these ingredients in foods under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The actions proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any

person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof that establishes the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate regulation under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before June 22, 1987, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects**21 CFR Part 182**

Food ingredients, Spices and flavorings.

21 CFR Part 184

Food ingredients.

21 CFR Part 186

Food ingredients, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Parts 182, 184, and 186 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1786 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.61.

§ 182.90 [Amended]

2. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing the entries for "Ferric sulfate," "Ferrous sulfate," "Iron, reduced," and "Oxides of iron."

§§ 182.8301, 182.8304, 182.8306, 182.8308, 182.8311, 182.8315, and 182.8375 [Removed]

3. By removing § 182.8301 *Ferric phosphate*, § 182.8304 *Ferric pyrophosphate*, § 182.8306 *Ferric sodium pyrophosphate*, § 182.8308 *Ferrous gluconate*, § 182.8311 *Ferrous lactate*,

§ 182.8315 *Ferrous sulfate*, and § 182.8375 *Iron reduced*.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

4. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1786 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.61.

5. By adding new § 184.1296, to read as follows:

§ 184.1296 Ferric ammonium citrate.

(a) Ferric ammonium citrate (iron ammonium citrate) is prepared by the reaction of ferric hydroxide with citric acid, followed by treatment with ammonium hydroxide, evaporating, and drying. The resulting product occurs in two forms depending on the stoichiometry of the initial reactants.

(1) Ferric ammonium citrate (iron ammonium citrate, CAS Reg. No. 1332-98-5) is a complex salt of undetermined structure composed of 16.5 to 18.5 percent iron, ca 9 percent ammonia, and 65 percent citric acid and occurs as reddish brown or garnet red scales or granules or as a brownish-yellow powder.

(2) Ferric ammonium citrate (iron ammonium citrate, CAS Reg. No. 1333-00-2) is a complex salt of undetermined structure composed of 14.5 to 16 percent iron, ca 7.5 percent ammonia, and 75 percent citric acid and occurs as thin transparent green scales, as granules, as a powder, or as transparent green crystals.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 116 (ferric ammonium citrate, brown) and p. 117 (ferric ammonium citrate, green), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice. The ingredients may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

6. By adding new § 184.1297, to read as follows:

§ 184.1297 Ferric chloride.

(a) Ferric chloride (iron (III) chloride, FeCl_3 , CAS Reg. No. 7705-08-0) may be prepared from iron and chlorine or from ferric oxide and hydrogen chloride. The pure material occurs as hygroscopic, hexagonal, dark crystals. Ferric chloride hexahydrate (iron (III) chloride hexahydrate, $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$, CAS Reg. No. 10025-77-1) is readily formed when ferric chloride is exposed to moisture.

(b) The Food and Drug Administration is developing food-grade specifications for ferric chloride in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

7. By adding new § 184.1298, to read as follows:

§ 184.1298 Ferric citrate.

(a) Ferric citrate (iron citrate, CAS Reg. No. 2338-05-8) is prepared from reaction of citric acid with ferric hydroxide. It is a compound of indefinite ratio of citric acid and iron.

(b) The Food and Drug Administration is developing food-grade specifications for ferric citrate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the

following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

8. By adding new § 184.1301, to read as follows:

§ 184.1301 Ferric phosphate.

(a) Ferric phosphate (ferric orthophosphate, iron phosphate, $\text{FePO}_4 \cdot x\text{H}_2\text{O}$, CAS Reg. No. 10045-86-0) is an odorless, yellowish-white to buff-colored powder and contains from one to four molecules of water of hydration. It is prepared by reacting sodium phosphate with ferric chloride or ferric citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 118, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

9. By adding new § 184.1304, to read as follows:

§ 184.1304 Ferric pyrophosphate.

(a) Ferric pyrophosphate (iron pyrophosphate, $\text{FePO}_4 \cdot x\text{H}_2\text{O}$, CAS Reg. No. 10058-44-3) is a tan or yellowish white colorless powder. It is prepared by reacting sodium pyrophosphate with ferric citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 120, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

10. By adding new § 184.1307, to read as follows:

§ 184.1307 Ferric sulfate.

(a) Ferric sulfate (iron (III) sulfate, $\text{Fe}_2(\text{SO}_4)_3$, CAS Reg. No. 10028-22-5) is a yellow substance that may be prepared by oxidizing iron (II) sulfate or by treating ferric oxide or ferric hydroxide with sulfuric acid.

(b) The Food and Drug Administration is developing food-grade specifications for ferric sulfate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

11. By adding new § 184.1307a, to read as follows:

§ 184.1307a Ferrous ascorbate.

(a) Ferrous ascorbate (CAS Reg. No. 14536-17-5) is a reaction product of

ferrous hydroxide and ascorbic acid. It is a blue-violet product containing 16 percent iron.

(b) The Food and Drug Administration is developing food-grade specifications for ferrous ascorbate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

12. By adding new § 184.1307b, to read as follows:

§ 184.1307b Ferrous carbonate.

(a) Ferrous carbonate (iron (ii) carbonate, FeCO_3 , CAS Reg. No. 563-71-3) is an odorless, white solid prepared by treating solutions of iron (II) salts with alkali carbonate salts.

(b) The Food and Drug Administration is developing food-grade specifications for ferrous carbonate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

13. By adding new § 184.1307c, to read as follows:

§ 184.1307c Ferrous citrate.

(a) Ferrous citrate ($\text{C}_6\text{H}_6\text{FeO}_7$, CAS Reg. No. 23383-11-1) is a slightly colored powder or white crystals. It is prepared from the reaction of sodium citrate with ferrous sulfate or by direct action of citric acid on iron filings.

(b) The Food and Drug Administration is developing food-grade specifications for ferrous citrate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

14. By adding new § 184.1307d, to read as follows:

§ 184.1307d Ferrous fumarate.

(a) Ferrous fumarate ($\text{C}_4\text{H}_2\text{FeO}_4$, CAS Reg. No. 141-01-5) is an odorless, reddish-orange to reddish-brown powder. It may contain soft lumps that produce a yellow streak when crushed. It is prepared by admixing hot solutions of ferrous sulfate and sodium fumarate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 120, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good

manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

15. By adding new § 184.1308, to read as follows:

§ 184.1308 Ferrous gluconate.

(a) Ferrous gluconate ($\text{C}_{12}\text{H}_{22}\text{FeO}_{14}\cdot 2\text{H}_2\text{O}$, iron (II) gluconate dihydrate, CAS Reg. No. 6047-12-7) is a fine yellowish-gray or pale greenish-yellow powder or granules. It is prepared by reacting hot solutions of barium or calcium gluconate with ferrous sulfate or by heating freshly prepared ferrous carbonate with gluconic acid in aqueous solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 122, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

16. By adding new § 184.1311, to read as follows:

§ 184.1311 Ferrous lactate.

(a) Ferrous lactate ($\text{C}_6\text{H}_{10}\text{FeO}_6$, CAS Reg. No. 590-552-2) in the trihydrate form is a greenish-white powder of crystalline mass. It is prepared by reacting calcium lactate with ferrous sulfate or by direct reaction of lactic acid with iron filings.

(b) The Food and Drug Administration is developing food-grade specifications for ferrous lactate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

17. By adding new § 184.1315, to read as follows:

§ 184.1315 Ferrous sulfate.

(a) Ferrous sulfate heptahydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$, CAS Reg. No. 7782-63-0) is prepared by the action of sulfuric acid on iron. It occurs as pale, bluish-green crystals or granules. Progressive heating of ferrous sulfate heptahydrate produces ferrous sulfate (dried). Ferrous sulfate (dried) consists primarily of ferrous sulfate monohydrate (CAS Reg. No. 17375-41-6) with varying amounts of ferrous sulfate tetrahydrate (CAS Reg. No. 20908-72-9) and occurs as a grayish-white to buff-colored powder.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 123 (ferrous sulfate heptahydrate) and p. 124 (ferrous sulfate, dried), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act

(the act) or with regulations promulgated under section 412(a)(2) of the act.

18. By adding new § 184.1375, to read as follows:

§ 184.1375 Iron, elemental.

(a) Iron, elemental (CAS Reg. No. 7439-89-6) is metallic iron obtained by any of the following processes: Reduced iron, electrolytic iron, and carbonyl iron.

(1) Reduced iron is prepared by reacting ground ferric oxide with hydrogen or carbon monoxide at an elevated temperature. The process results in a grayish-black powder, all of which should pass through a 100-mesh sieve. It is lusterless or has not more than a slight luster. When viewed under a microscope, it appears as an amorphous powder free from particles having a crystalline structure. It is stable in dry air.

(2) Electrolytic iron is prepared by electrodeposition. It is an amorphous, lusterless, grayish-black powder. It is stable in dry air.

(3) Carbonyl iron is prepared by the decomposition of iron pentacarbonyl. It occurs as a dark gray powder. When viewed under a microscope, it appears as spheres built up with concentric shells. It is stable in dry air.

(b) Iron, elemental (carbonyl, electrolytic, or reduced) meets the specifications of the Food Chemicals Codex, 3d Ed. (1981) (iron, carbonyl, p. 151; iron, electrolytic, p. 151; iron, reduced, p. 152), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

19. The authority citation for 21 CFR Part 186 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.61.

20. By adding new § 186.1300, to read as follows:

§ 186.1300 Ferric oxide.

(a) Ferric oxide (iron (III) oxide, Fe_2O_3 , CAS Reg. No. 1309-37-1) occurs naturally as the mineral hematite. It may be prepared synthetically by heating brown iron hydroxide oxide. The product is red-brown to black trigonal crystals.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of paper and paperboard used for food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

21. By adding new § 186.1374, to read as follows:

§ 186.1374 Iron oxides.

(a) Iron oxides (oxides of iron, CAS Reg. No. 97705-33-85) are undefined mixtures of iron (II) oxide (CAS Reg. No. 1345-25-1, black cubic crystals) and iron (III) oxide (CAS Reg. No. 1309-37-1, red-brown to black trigonal crystals).

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of paper and paperboard used for food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

Dated: April 15, 1987.

John M. Taylor,
Associate Commissioner for Regulatory
Affairs.

Appendix—Select Committee's Review of Selected Safety¹ Studies on Iron and Iron Salts

A. Introduction

Iron, in contrast with most other metals, is regulated in the body primarily by absorption rather than by excretion. It has long been known that little iron is excreted in the urine even when large doses are ingested. This fact led McCance and Widdowson in 1937 to conclude that iron in the body must be regulated by controlled absorption. A number of comprehensive reviews on iron absorption since that time have amply confirmed the critical importance of the gastrointestinal tract in controlling the total body iron. Absorption is strongly influenced by the status of iron stores and the erythropoietic activity in the body. Extrinsic factors such as the form of ingested iron, the nature of accompanying food, the composition of intestinal secretions, the products of digestion, and the pH of the intestinal contents can all affect the absorption of iron.

Since the normal diet contains several times the amount of iron needed to maintain iron balance, it is obvious that availability of iron, rather than its total intake, is the limiting factor in achieving adequate absorption. It is generally agreed that iron of animal origin, with the exception of eggs, is more readily available to man than the iron in plants. Heme, the principal source of iron in animal tissues and organs, is directly and rapidly absorbed, whereas nonheme iron is more slowly and less completely absorbed. The difference in bioavailability of plant and animal iron is so great that heme iron is generally considered independently of nonheme iron in iron balance studies. Bjorn-Rasmussen, *et al.* fed 32 young men meals containing both heme and nonheme (plant) iron appropriately labeled. They found that the absorption of heme iron averaged 37 percent but absorption of nonheme iron only 5 percent. Layrisse and Martinez-Torres obtained similar results with subjects fed a diet of meat, beans, maize, and rice. In this instance, absorption of heme iron was 27 percent while that of nonheme iron was 6 percent. One factor

probably contributing to the superior bioavailability of heme iron is its protection from agents which may react with nonheme iron compounds to reduce their absorption.

Although there are individual differences among the various iron compounds, ferrous salts are generally more readily absorbed in man than ferric salts. This has been observed both clinically and experimentally. Brise and Hallberg used two isotopes to study the absorption of 14 different iron salts. The absorption ratio for the various iron salts studied was as follows: Ferrous succinate, 1.22; ferrous lactate, 1.06; ferrous glycine sulfate, 1.02; ferrous fumarate, 1.01; ferrous sulfate, 1.00; ferrous glutamate, 0.96; ferrous gluconate, 0.89; ferrous citrate, 0.74; ferrous tartrate, 0.64; ferrous pyrophosphate, 0.59; ferric choline isocitrate, 0.43; ferric sulfate, 0.36; ferric citrate, 0.31; and, ferric versenate (ferric EDTA), 0.24. A partial explanation for the more rapid absorption of ferrous salts may be the greater solubility of ferrous than ferric hydroxide in the alkaline milieu of the duodenum. Insoluble salts, such as the various iron phosphates, are poorly available. The presence of precipitating agents, certain chelators, and lowered gastric acidity also significantly reduce iron absorption. Gastrectomy and achlorhydria markedly impair iron absorption.

The absorption of iron is significantly less when given after a meal than when administered to a fasting subject. Brise found that the absorption of iron (as ferrous sulfate) after a light meal was only 56 percent of that by the same subject in a fasting state. Phytates, which occur mainly in cereal foods, are often claimed to inhibit iron absorption by the formation of insoluble iron phytates during the process of digestion. However, the findings with phytate are difficult to interpret, since they depend somewhat upon the nature of the other food constituents. Phytates in some foods are bound to proteins or other plant constituents and have little effect on iron. Thus, Sharpe *et al.* found no correlation between the natural phytate content of oats and the bioavailability of iron. However, when sodium phytate was added to milk, the availability of iron to human subjects was sharply reduced. Iron utilization is also reduced when the amount of wheat bran in the diet is increased. This reduction has been attributed to the phytate content of the bran although phytin-free fiber also reduces iron utilization.

Both heme and ascorbic acid are known to enhance the absorption of

iron. When beef, a rich source of heme, was substituted for an equivalent amount of egg albumin, the absorption of nonheme iron from a test meal increased more than five-fold. Similarly, the addition of relatively small amounts of ascorbic acid has been reported to increase the absorption of iron from maize porridge. When papaya containing 66 mg of ascorbic acid was consumed with 100 g of maize, five times as much iron was absorbed than from maize alone. Ascorbic acid is thought to act both by reducing some of the ferric iron to the ferrous state, and by forming simple chelates with the remainder. Both actions increase the solubility of iron in the intestine.

The formation of iron chelates is an important factor in the regulation and facilitation of iron absorption. Iron forms complexes with a large number of organic compounds which keep the iron available for absorption by preventing the formation of poorly soluble hydroxides and phosphates. The stability of these iron complexes or chelates varies widely depending upon the size, the nature of the ligand, and other factors. Chelates with low stability will release their iron to receptor sites in the intestinal mucosa, whereas highly stable chelates will prevent this release. Chelate stability is generally expressed as a stability constant, *K*. Forth states that chelates with *K* values below 12-13 will release their iron to mucosal receptors. Most iron chelates considered in this report have *K* values well below this threshold.

Of perhaps even greater importance than extrinsic factors in modifying the absorption of iron, is a systemic regulatory mechanism dependent upon the iron status of the individual. This mechanism is poorly understood. It does stimulate iron absorption during iron deficiency, during active erythropoiesis, and during the latter half of pregnancy. Conversely, it tends to decrease the absorption of iron when erythropoiesis is depressed or when an iron overload develops. Monsen *et al.* have estimated that an individual with low iron stores absorbs approximately 20 percent of nonheme iron from a high availability meal. This was defined as meals containing more than 90 g lean meat, poultry or fish; 30 to 90 g of these foods plus 25 to 75 mg ascorbic acid; or a non-meat, non-fish meal with more than 75 mg ascorbic acid. When consuming such meals, persons with adequate iron stores absorb about 7 to 8 percent, and individuals with high iron stores absorb only about 4 percent of the dietary nonheme iron.

¹ "Evaluation of the Health Aspects of Iron and Iron Salts as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD 20014, pp. 19-48, 1980.

The detailed mechanism of iron absorption is still somewhat controversial. It is generally agreed that iron is bound by receptors in the brush border of mucosal cells in the upper small intestine; transferred across the membrane by an unknown, but presumably energy-dependent process; transported to the basal surface of the epithelium by a carrier; and finally delivered to the iron-transporting protein, transferrin, in the plasma. As already indicated, the iron status of the individual, his erythropoietic rate, and other factors regulate the amount of iron transported across the intestinal mucosa. Transferrin transports iron to the bone marrow, liver, or other tissues where it can be utilized for the synthesis of hemoglobin, cytochromes, ferritin, and other iron-containing compounds. Ferritin is an iron-storage molecule with a large iron-binding capacity. It exists as a ferric oxide complex and a protein shell (apoferritin). When saturated, each molecule can contain up to 4500 iron atoms although it usually contains less than 3000. Ferritin provides a mobile reserve of iron to meet the varying needs of the body. Large amounts are found in the liver, spleen, and hematopoietic organs, and lesser amounts in other tissues which have no apparent iron-storage function. Serum ferritin has been used as an index of total body iron because it mirrors closely the quantity of iron stored in the tissues.

Another substance which functions as an iron-storage compound is hemosiderin. Its structure is ill-defined, being a relatively amorphous compound, containing up to 35 percent iron. Hemosiderin exists in the tissues as a brown, granular, readily stainable pigment; its iron is mainly ferric hydroxide. It has been suggested, on the basis of similar physical characteristics, that hemosiderin is formed from the denaturation and proteolytic cleavage of ferritin. Up to certain levels, both ferritin and hemosiderin are deposited in liver and spleen in roughly equal amounts. Morgan and Walters concluded from human necropsy material that hemosiderin begins to predominate when total iron storage requirements exceed approximately 1 mg per g of liver or spleen.

Iron is an important but complex determinant in the susceptibility of animals to infection. On the one hand, iron deficiency impairs host defense mechanisms and reduces the animals resistance to microbial attack. On the other hand, iron is essential for microbial growth; its availability to the

invading microorganisms is reduced when blood levels are low.

The bulk of excreted iron is found in the feces, which includes not only the unabsorbed portion from ingested food but also small amounts from biliary excretion, desquamation from epithelial surfaces and gastrointestinal blood loss. These losses amount to approximately 1 mg per day or less. Virtually none is lost through the urine. Green *et al.* reported that the daily excretion of an 80 kg male subject was approximately 0.1 mg. Menstrual loss is highly variable but averages about 15 to 20 mg monthly. Because of the great differences in physiological availability of iron compounds in food, an overall absorption rate of 10 percent has been adopted in estimating the Recommended Dietary Allowance (RDA). Thus, in order to provide the necessary retention of 1 mg iron per day in men and in postmenopausal women, the RDA has been set at 10 mg. For women of childbearing age, the RDA is increased to 18 mg to allow for the extra demands imposed by menstruation, pregnancy and lactation. For infants, the recommended allowance is 1.5 mg per kg body weight. During pregnancy, daily supplements of 30 to 60 mg of iron are recommended.

Oral administration of large doses of soluble iron compounds to fasting experimental animals may cause irritation and ulceration of the gastrointestinal mucosa. Doses in the lethal range produce marked erosion and mucosal sloughing if death is delayed for 24 to 48 hours.

The acute toxicities of various iron salts for laboratory animals show wide variations among different iron salts and animal species. Thus, 150 to 305 mg iron per kg body weight has been reported as the LD₅₀ for mice given ferrous sulfate by mouth, but 3800 mg per kg is the comparable oral dose with ferrous carbonate. Species differences also appear to be great. The LD₅₀ for ferrous fumarate was reported to be 516 mg iron per kg in the mouse but more than 2300 mg per kg in rat. Dogs given lethal amounts of iron consistently displayed reduced cardiac output, increased peripheral resistance, decreased plasma volume, hemoconcentration, decreased blood volume, and lowered blood pressure. Metabolic acidosis and the accumulation of organic acids were also evident before circulatory collapse.

An estimated 2000 human cases of iron poisoning occur annually with approximately 12 deaths. Most cases occur among children, especially those in the 1 to 2 year age group, who poison themselves accidentally with oral iron

preparations prescribed for adults. In a review of 1645 cases in which children had ingested toxic agents, Greengard and McEnery reported the ferrous sulfate was responsible for 6.2 percent of the incidents. In adults, cases of acute toxicity have been observed almost exclusively among individuals with suicidal intentions.

Crotty estimated the average lethal dose for an adult male to be 200 to 250 mg per kg body weight (about 14 g of elemental iron) or approximately 1000 times the Recommended Dietary Allowance.

Large doses of iron salts cause severe gastroenteritis with hematemesis, abdominal pain, diarrhea, tachycardia, rapid respiration, depression, lassitude, and shock. Hemorrhagic necrosis and sloughing of the gastric mucosal areas with extension into the submucosa are commonly observed. The necrotic surfaces are covered with an iron-containing pigment. Similar, but less severe, changes are noted in the small intestine, with the most striking damage in the proximal portions. Metabolic acidosis is common in these cases.

Acute toxicity resulting from consumption of iron-fortified foods has not been reported. The Select Committee considers that studies of acute toxicity of the various iron forms are of limited usefulness in evaluating the safety of iron and iron salts as food ingredients.

Subchronic and chronic toxicities of iron are characterized by disorders associated with excessive iron loading or storage in the body. The storage iron is predominantly in the form of insoluble hemosiderin, and an increase in iron storage is called hemosiderosis or simply siderosis. Under certain conditions, organs may contain grossly excessive amounts of storage iron and show evidence of damage. Such a condition is termed hemochromatosis. As Jacobs has commented, a problem often encountered in interpreting iron disorders is compounded by the semantic confusion resulting from the indiscriminate use of hemochromatosis and hemosiderosis as synonyms for iron loading.

In this report, the term *hemosiderosis* is applied to conditions of increased iron stores confined mainly to the cells of the reticuloendothelial system and without obvious malfunction or disease which can be attributed to the presence of the iron. The term *hemochromatosis* is applied when the organs containing excessive amounts of storage iron show evidence of damage, usually fibrosis. It is distinguished from hemosiderosis by well characterized clinical signs and

symptoms, even though the total amount of iron in the body may be comparable in the two conditions.

Generalized hemosiderosis may result from chronic ingestion of large amounts of bioavailable iron, from repeated transfusions, and from certain microcytic hypochromic anemias, such as thalassemia major. Substantial iron overload resulting from dietary intake is rare. The most striking example of such a dietary overload is the hemosiderosis which occurs among members of the Bantu tribe in South Africa who consume large amounts of a beverage prepared in iron drums and pots. The resulting brew is of a low pH and contains 40 to 89 mg iron per liter. The iron in the beverage is well absorbed, presumably in the form of small soluble complexes produced during fermentation. The average iron intake of adult Bantu men was estimated to be about 100 mg per day and even greater intakes are possible among heavy drinkers. In the siderotic Bantu, hemosiderin is deposited in the liver parenchymal and Kupffer cells and in the spleen and bone marrow. Significant involvement of parenchymal tissues in organs other than the liver is uncommon, even in the presence of marked siderosis. The pattern of both organ and cellular deposition of iron appears to differ from that found in hemochromatosis.

Hemochromatosis is generally regarded as a disease entity characterized by extensive iron deposits in the liver, skin, heart, pancreas, and spleen. Its etiology remains controversial. The typical patient with hemochromatosis will show portal cirrhosis, bronze pigmentation, diabetes mellitus, endocrinopathy, arthropathy, and cardiac insufficiency. The normal control of iron absorption is faulty in these individuals but the basic metabolic defect has not yet been identified. The dominant view regards hemochromatosis as a rare inborn error of metabolism, and considerable evidence supports this contention. One or more abnormalities in iron metabolism have been repeatedly recognized in 25 to 75 percent of first-degree relatives of patients with this condition. Siblings are often affected and in a few cases overt disease has been detected in successive generations. McDonald, however, has argued that hemochromatosis is always secondary to dietary, toxic or other factors responsible for increased retention of iron.

The frequency of hemochromatosis has been estimated at 1 in 20,000 hospital admissions and at 1 in 7000

hospital deaths. However, this apparent low frequency has been questioned by some investigators who believe it to be a gross underestimation of the true frequency, inasmuch as diagnosis has usually been restricted to the end stage of the disease.

Crosby has been critical of the iron fortification program in the United States; he believes it may contribute to the development of hemochromatosis among susceptible individuals. This concern prompted Olsson and coworkers to search for cases in Sweden, which has fortified foods with iron for more than 30 years. The average iron intake in Sweden is considerably higher than in the United States (19 mg versus 12 mg per day); 42 percent of the Swedish intake come from food fortification. Olsson *et al.* studied the iron status of virtually all (347 of 363) persons between 30 and 39 years of age in a small rural district in Sweden. All persons with elevated serum iron levels (above 300 μg per dl) were subjected to further tests to evaluate possible iron overload. Nine men (of 197), but no women, had persistently high serum iron levels. Four of these demonstrated increased iron stores, as indicated by high transferrin iron saturation (over 70 percent), increased iron excretion induced by deferoxamine injection, and liver parenchymal iron. Phlebotomy revealed excessive mobilizable iron stores in one man. Although the investigators characterized their findings as "pre-clinical hemochromatosis," each of the four men was in good health, with no clinical signs of the disorder. Liver function and glucose tolerance tests were normal in all cases. None had laboratory signs of organ damage attributable to iron.

In a more recent report, Olsson extended to 17, his series of patients with suspected hemochromatosis. This group consisted of 14 men and 3 women between the ages of 36 to 78 years, who had been treated in a regional hospital serving approximately 133,000 inhabitants. Two of the patients had been identified as possible hemochromatotics from their clinical signs and symptoms, three from clinical and laboratory investigations of their relatives, and the remainder from routine laboratory tests or from liver biopsies performed to clarify suspected hepatic disorders. Transferrin iron saturation, serum ferritin, urinary iron excretion after deferoxamine injection, and liver iron were elevated in all cases. Cirrhosis or significant fibrosis was reported in 11, and elevated serum transaminase in 14 of the patients. Abnormal glucose tolerance curves were

present in 10 cases, but only three patients required insulin treatment. Abnormal pigmentation was noted in several of the patients, but this was seldom marked. Joint pains were reported by seven patients. Phlebotomies were performed on 12 of the patients. Only two of the 17 patients exhibited all of the typical signs and symptoms normally associated with hemochromatosis.

The most reliable method for assessing body iron stores is the chemical estimation in various tissues, especially the liver. Sheldon reported the mean concentration of liver nonheme iron in patients with hemochromatosis to be 3.6 percent dry weight (range 1.0 to 7.6 percent). The median hepatic concentrations found in 422 adult Swedish men was about 0.05 percent. The median values for Czechoslovakian males was about 0.10 and that for American males, about 0.08 percent. In a study of 3983 liver specimens from 18 different countries, only three were found to contain iron in concentrations approaching 1 percent, the lower limit of that found in hemochromatosis.

Attempts to produce hemochromatosis experimentally have been largely unsuccessful. Various iron preparations have been administered in large amount to rabbits, dogs, mice, rats, guinea pigs, and chickens. They have been given orally with normal and deficient diets, and in single or multiple doses intravenously, subcutaneously, intraperitoneally, and intramuscularly. Heavy deposits of iron in many tissues have been induced both after oral and parenteral administration, but the associated fibrosis of the liver, spleen, and pancreas, characteristic of human hemochromatosis, has not been observed.

The only study known to the Select Committee in which liver injury in animals has been reported to resemble human hemochromatosis, is that of Lisboa. This investigator administered a total of 3.5 to 5.8 g iron per kg body weight to dogs intravenously and/or intramuscularly by repeated injections of iron dextran or iron sorbitol. Of 19 dogs, six survived the experimental period of 35 to 47 months, and five developed cirrhosis. Liver histology showed disorganization of lobular architecture, with nodular regeneration, slight fibrosis, and mild inconsistent mononuclear infiltration. Massive deposits of iron were found in the parenchyma. There were no signs of diabetes.

On the other hand, Brown and coworkers also repeatedly injected iron

(as saccharated iron oxide) intravenously into dogs over a period of 6 to 10 weeks, until a total of 0.5 to 1.0 g per kg had been administered. The animals were sacrificed 81 and 84 months after the start of the experiment. Large amounts of iron were found in the liver, spleen, bone marrow, and lymph nodes, but liver function tests and histologic sections at biopsy or necropsy failed to reveal any evidence of cirrhosis. There was no diabetes or pancreatic fibrosis. Blindness developed about 3 years after the start of the experiment with lesions resembling those of retinitis pigmentosa. (Lisboa found no sign of this condition in his animals). In a subsequent experiment, Brown *et al.* injected dogs intravenously, intraperitoneally, or intramuscularly with 125 to 250 mg iron (as iron dextran or saccharated iron oxide) daily or twice weekly until the death of the animals. Death occurred in 5 to 10 months after total injections of 2.5 to 3.3 g iron per kg body weight. After about 4 months when more than 2 g iron has been injected, the animals showed a decreased serum albumin, anorexia, apathy, and weight loss. One dog developed ascites and anasarca. Except for scattered, small areas of focal necrosis and massive reticuloendothelial iron deposits, the livers of these dogs did not appear seriously damaged. There was no fibrous tissue response to the iron deposits, and no evidence of hemochromatosis, cirrhosis, or diabetes.

Feeding studies in animals also have failed to produce changes resembling hemochromatosis. Rather fed rats a diet containing 6 percent ferric citrate (about 1 g iron per kg per day) for 6 to 18 months. At necropsy, livers were engorged with hemosiderin, chiefly in the parenchymal and Kupffer cells, with large deposits also in the spleen, abdominal lymph nodes, pancreas, kidneys, and adrenals. However, cirrhosis was not observed in any of the experimental animals. Similarly, Finch *et al.* fed mice a diet containing 2 percent ferric citrate (about 500 mg iron per kg per day) for 24 days. The liver iron increased twenty-fold during this period and represented 74 percent of the total body iron, in contrast to 17 percent in the control animals. No other change was reported. Adult mongrel dogs fed about 200 mg iron per kg daily as ferric citrate for 2 to 6 months developed marked hepatic parenchymal hemosiderosis but no cirrhosis or fibrosis. Kinney *et al.* fed adult male rats a corn grit diet supplemented with 2 percent ferric citrate which provided about 300 mg iron per kg daily. After 27 to 33 days, the liver iron of the

experimental rats was 3.6 times that of controls and after 56 to 61 days it was 16.3 times. This histological picture was that of progressive hemosiderosis of the hepatic parenchyma and of the reticuloendothelial system.

B. Biological effects of individual forms of iron

1. Elemental iron powders

Included under this heading are iron particles produced by the reduction of iron oxide, by electrolysis, or by decomposition of iron pentacarbonyl. As pointed out earlier, all these forms of elemental iron have often been erroneously subsumed within the terms "reduced iron" or "ferrum reductum." However, the bioavailability of each depends upon its particle size, surface area, and purity; these properties vary with the method of preparation.

Elemental iron has certain disadvantages as a fortifying agent for flour. Its high density compared with flour makes it difficult to maintain stable blends of uniform content, and its dark color may be objectionable in some products such as pasta. Nevertheless, the chemical inertness and low cost of this form have made it an important agent in fortifying flour and other products requiring extended periods of storage. Waddell estimated that approximately 30 percent of all iron added to grain products in 1970 was elemental iron; a recent survey by NRC suggests that the percentage may be even higher today. This survey revealed that in 1975, almost 80 percent of the total fortification of foods with iron was with elemental iron.

Berg and van Pelt state that electrolytic iron of "small particle size" is currently used by all manufacturers of infant cereals. The Select Committee has no data on the relative use of the different forms of elemental iron for other food fortification.

The effectiveness of "reduced iron" in repleting hemoglobin of anemic rats or chicks was studied in a collaborative experiment among eight American and Canadian laboratories. Compared with ferrous sulfate, which was assigned a biological value of 100, the "reduced iron" has an average rating of 46, with values in the individual laboratories ranging from 27 to 100. Amine *et al.*, in similar bioassays with anemic rats and chicks, reported bioavailability of reduced iron to be 91.4 percent that of ferrous sulfate.

The importance of particle size in the absorption and utilization of powdered iron was convincingly demonstrated by Motzok *et al.* They determined the biological values of different-sized

particles in repleting the hemoglobin of anemic rats and chicks. The iron particles were 7 to 10 microns, 14 to 19 microns and 27 to 40 microns in size. The investigators found the biological values compared with ferrous sulfate were 45, 21 and 12 in the rat, and 65, 49 and 41 in the chick, respectively.

In man even higher values for the bioavailability of reduced iron have been reported by Cook *et al.* Iron reduced by hydrogen was milled to particles 5 to 10 microns in size, incorporated into dinner rolls, and consumed by human volunteers. The bioavailability of the reduced iron was 95 percent that of ferrous sulfate in rolls similarly prepared. The major determinant for the bioavailability of elemental iron appeared to be the size of the particles. Sacks and Houchin compared the ability of elemental iron powder of different particle size prepared by different techniques, to repair iron deficiency in rats. They found carbonyl iron to be the most effective of the various forms tested. This form can be obtained in extremely pure form and manufactured to rigid specifications. With particles less than 5 microns in size, carbonyl iron was 66 percent as bioavailable as ferrous sulfate. Electrolytic iron particles were somewhat larger (up to 20 microns) and have a 48 percent bioavailability, while hydrogen-reduced iron with particle size up to 149 microns had a bioavailability only 24 percent that of ferrous sulfate.

Powdered iron appears to be among the least toxic of the various preparations tested. Shanas and Boyd administered "reduced iron" intragastrically to rats. Below doses of 10 g per kg body weight there was no evidence of gastrointestinal irritation. No deaths occurred in animals receiving less than 50 g per kg and the LD₅₀ was 98.6 g per kg body weight. Death was apparently caused by bowel obstruction rather than by cellular damage. At this dosage level death usually occurred within 48 hours. When death was delayed to 60 hours, it resulted primarily from severe gastroenteritis complicated by dehydration, hemoconcentration, and electrolyte imbalance. As previously stated, the Select Committee considers such acute studies of little relevance to the questions of food fortification.

Carbonyl iron has been reported to have a comparably low acute toxicity. Volkheimer *et al.* fed massive doses (250 g) to fasting dogs without apparent harm. Sacks and Houchins gave 1 to 2 g intragastrically to 100 g rats, and Crosby fed 5 g doses to rats (weight and age not reported). No diarrhea, intestinal lesions, or other ill effects were noted.

Crosby, serving as his own subject, consumed 5 to 10 g doses without discomfort.

Sacks and Houchins fed 130 mg carbonyl iron per kg body weight daily to rats for 6 months. Upon necropsy they found no stainable iron in the duodenum, liver or pancreas. Siderosis was seen in the spleen, but the investigations claimed this to be no more marked than that observed in animals fed a laboratory ration.

2. Ferrous compounds

It has been repeatedly demonstrated that iron in the ferrous state is more readily absorbed from the intestinal tract of man than ferric iron. The difference can be explained most readily by the formation of undissociated ferric hydroxide at the pH existing in the small intestine when a ferric salt is given. Furthermore, the ferric iron is more apt than the ferrous to form other insoluble or complex compounds which further reduce absorption. Brise and Hallberg concluded that the difference in absorption between ferrous and ferric iron is of such a magnitude that "ferric iron has no place in oral iron therapy." However, in contrast to man's relative inability to absorb ferric iron, rats, dogs, and chicks appear to absorb both ferrous and ferric iron with roughly equal facility. For this reason, Narasinga Rao *et al.* have criticized the customary use of these animals in studying iron availability from human diets. They recommended the monkey as a more appropriate animal model.

Moore *et al.* in 1939, first reported that ascorbic acid increased the absorption of nonheme iron in food. It has not been confirmed repeatedly that ascorbic acid given in combination with various iron salts, both ferrous and ferric will significantly enhance the absorption of iron from the diet. The enhancing property of ascorbic acid is believed to result from its dual action of reducing the ferric iron and of forming soluble chelates. The soluble iron-ascorbate chelate maintains solubility in the neutral or alkaline milieu of the duodenum and also prevents the formation of insoluble ligands such as oxalates, carbonates, and phytates which would precipitate iron. It has a low stability constant which suggests that the chelate would readily release its iron to mucosal receptors.

As little as 60 mg ascorbic acid added to a meal of rice more than tripled the absorption of iron. Cook and Monsen tested the effect of various doses of ascorbic acid on the absorption of iron from a semisynthetic diet containing no meat. They found the absorption to be directly proportional to the amount of

added ascorbic acid over the range of 25 to 1000 mg. At these extremes, iron absorption was increased 1.65 to 9.57 times, respectively, that of the unsupplemented diet. The investigators concluded that individuals who routinely ingest large amounts of ascorbic acid may increase their iron absorption several-fold, thus posing a potential problem among persons with faulty iron-regulatory mechanisms.

Moller reported that iron given as synthetic ferrous ascorbate was much more readily absorbed in pigs of different ages than when fed as ferric ammonium citrate, iron fructose, or iron dextran. The Select Committee is aware of no other report in which the synthetic form has been employed. As stated earlier, stoichiometric or excess quantities of ascorbic acid are usually added to an iron salt and the resulting preparation considered to be ferrous ascorbate. Mikhaylova found that a ferrous ascorbate "preparation" was more effective than hydrogen-reduced iron, ferrous carbonate, or ferrous malate in raising the serum level of iron in patients with iron-deficiency anemia. Administration of 1 g of ferrous ascorbate increased the serum iron from 28 micrograms to 200 micrograms per 100 ml serum within 3 hours. The serum level remained elevated in some patients 24 hours after ingestion of ferrous ascorbate, an effect not observed with any other iron preparation tested. Beresford *et al.* administered a solution of labeled ferrous sulfate together with ascorbic acid via nasogastric tube to 19 infants and young children. The authors designated the resulting preparation as ferrous ascorbate. The average absorption of the labeled iron in children with normal temperatures was 41.2 percent of the administered dose but only 15.1 percent during their febrile states.

Twenty stock mice were injected subcutaneously with 0.2 ml of "ferrous ascorbate" containing 0.3 mg iron at weekly intervals for 43 weeks without developing tumors at any site.

Ferrous carbonate. Ferrous carbonate was the earliest preparation used in the treatment of iron deficiency anemias. It was first adopted by the French physician Pierre Bland in 1831 to treat "chlorosis" and for decades, ferrous carbonate in the form of "Bland's Pills" or "Bland's Mass" was the accepted hematinic. A mixture of 15 percent ferrous carbonate with sucrose (ferrous carbonate saccharate) forms a more soluble preparation and has also been used as a hematinic.

When given orally to dogs, the acute toxicity of ferrous carbonate was

reported to be less than that of ferrous sulfate, gluconate, or succinate and has therefore been suggested as an alternative to more commonly used therapeutic agents. D'Arcy and Howard administered as much as 1.0 g iron per kg body weight as ferrous carbonate to dogs for 15 days, with no toxic signs, or evidence of damage to the stomach or intestine at necropsy. Ferrous sulfate and ferrous gluconate caused vomiting, diarrhea, or gastrointestinal damage at iron intakes of one-fourth or less of this amount. The low toxicity of this compound probably results from its relative insolubility in the gastrointestinal tract. Its low solubility probably also explains its poor bioavailability. Fritz *et al.* found it to be 0 to 6 percent as effective as ferrous sulfate in repleting hemoglobin anemic chicks and rats.

Ferrous citrate. Little information is available on the safety of ferrous citrate. Citrate is produced in normal metabolic processes and no hazard is suspected when it is ingested in moderate amounts. Ferrous citrate is absorbed moderately well, but more poorly than some of the other ferrous compounds investigated. Brise and Hallberg compared its absorption with other iron compounds in man. In five normal subjects, the absorption of iron from ferrous citrate was 56 to 91 percent (average 74 percent) that of ferrous sulfate. It has a low stability constant which suggests that its iron should be relinquished to the mucosal receptors. Seven other ferrous salts were more readily absorbed than citrate, and only tartrate and pyrophosphate among the ferrous salts tested showed poorer absorption. Theuer *et al.*, however, reported that ferrous citrate provided the greatest iron availability of eight salts tested when added to liquid infant formulas. Anemic rats were fed supplements of a lyophilized, milk-based infant formula containing 0.25 mg iron as ferrous citrate daily. The hemoglobin increase in these rats was greater than that attained from any other iron supplement, including ferrous sulfate.

The amount of ferrous citrate used as a dietary supplement in foods is not known and the Select Committee is not aware of current use in infant formulas. It is reportedly used in a special dietary beverage at a level of 16.9 mg per liter, and in an extremely small percentage of the milk sold by dairies. The International Nutritional Anemia Consultative Group, on the basis of bioavailability and cost, lists ferrous citrate as a commercially available compound and recommends its use as a fortifying agent in beverages and sugars.

Ferrous fumarate. Ferrous fumarate is used extensively as an oral hematinic for adults and infants, but the extent of its addition to foods is not known. It is an iron supplement to certain cereals and beverages and to a corn-soy-milk blended food. It has been reported to produce unacceptable flavors in milk, but to be an acceptable additive in cocoa powder and coffee. Ferrous fumarate is relatively soluble and is readily absorbed from the gastrointestinal tract. It, too, has a relatively low stability constant. Fritz *et al.* reported that it was as effective as ferrous sulfate in repleting hemoglobin in rats and chicks made anemic on a low-iron diet. Similarly, it was absorbed as well as ferrous sulfate by normal human subjects. Its acute toxicity in animals is less than that of ferrous sulfate and of ferrous gluconate; it causes less gastric irritation in rabbits and vomiting in cats than these compounds.

Clinical studies have confirmed the effectiveness of ferrous fumarate as a hematinic. The incidence of side effects is approximately that experienced with ferrous sulfate or ferrous gluconate. A total of 118 men and women were given 74 mg iron, three times daily for 14 days, in the form of ferrous fumarate. Side-effects were reported in 26.4 percent of the cases, compared with 27.9, 31.5, and 13.9 percent from subjects receiving ferrous sulfate, ferrous gluconate, and placebo, respectively. The common complaint was constipation (10 percent), followed by diarrhea (6.4 percent) and "heartburn" (5.5 percent). Six (5.5 percent) of the subjects discontinued therapy. Ferrous fumarate enjoys one advantage in pill form over the other iron salts: It is stable without a sugar coating, thus reducing the danger of overdosing in children attracted by the sweet taste of coated pills. It is widely used in pill or liquid form as iron supplements sold over the counter. The Physicians' Desk Reference lists more than a score of such preparations currently available.

Ferrous fumarate is one of the compounds recommended by the International Nutritional Anemia Consultative Group for use in infant formulas on the basis of its bioavailability and cost.

Ferrous gluconate. Relatively large amounts of the gluconate anion are produced daily by the normal individual, and the consumption of moderate amounts poses no significant hazard. The solubility and safety of various gluconates have made it a popular vehicle with which to introduce certain metallic cations into the body as dietary

supplements. Gluconate salts are GRAS with copper (21 CFR 182.5260, and 182.8260), sodium (21 CFR 182.6757), manganese (21 CFR 182.5452, and 182.8452), zinc (21 CFR 182.5788, and 182.8988), and calcium (21 CFR 182.1199), as well as with iron (21 CFR 182.5308, and 182.8308). Ferrous gluconate is also used as a color additive in ripe olives (21 CFR 73.160).

The bioavailability of ferrous gluconate is high, approaching that of ferrous sulfate whereas its acute toxicity is significantly less. Its low stability constant should allow a rapid release of iron to intestinal receptors. When given at levels of 100 mg iron per day to male patients with iron-deficiency anemia it produced an increase in hemoglobin of about 65 percent within 4 weeks. Two of 20 patients developed abdominal pains and diarrhea within the first week and one complained of vomiting. Hallberg *et al.* gave 196 normal subjects 180 mg iron in the form of ferrous gluconate daily for 14 days. Approximately one-quarter of the subjects complained of side effects, the most common of which was constipation. No difference could be detected in the incidence or type of side effects between these subjects, and those receiving an equal amount of iron in the form of ferrous sulfate. Hoppe *et al.* in 1955 reviewed the toxicity of the various iron compounds used therapeutically and concluded that ferrous gluconate appeared to be less toxic and irritating than the other common sources of iron then used in anemia therapy. A number of ferrous gluconate preparations are available without prescription as sources of iron supplementation.

When thermally processed and freeze-dried, ferrous gluconate maintained high availability in both soy and milk infant formula products.

Ferrous gluconate was tested for mutagenic activity in a series of *in vitro* microbial assays with and without metabolic activation by mammalian systems. Both the plate and suspension test procedures were employed with *Salmonella typhimurium* strains TA-1535, -1537, and -1538 and *Saccharomyces cerevisiae*, strain D4 as the test organisms. Activating preparations were made from lung, liver, and testes of ICR random-bred mice, Sprague-Dawley rats and *Macaca mulatta* monkeys. Ferrous gluconate was mutagenic in the activation tests systems with TA-1538 and monkey liver tissue using the suspension test procedure. However, in reviewing these data, the investigator subsequently concluded that the results were variable, and no firm conclusion could be drawn.

None of the other tests was positive. Ferrous gluconate was nonmutagenic in tests with *Drosophila*.

Haddow and Horning reported that weekly subcutaneous injections of 5 mg ferrous gluconate into 20 stock mice for 13 weeks produced one fibroma at the site of injection, one thecoma, and one thymoma.

Ferrous gluconate was injected into the egg air cell and yolk at preincubation and after 96 hours of incubation. Air cell treatment at 96 hours produced a significant increase in mortality and abnormalities over the control birds. The abnormalities included anophthalmia, buphthalmia, ablepharia, eyelid dysplasia, cleft palate, and exencephaly.

Ferrous lactate. Ferrous lactate is very soluble, and its iron is readily bioavailable. No stability constant could be found for this compound, but values for other metallic lactate complexes suggest that the iron from ferrous lactate would be readily given up to mucosal receptors. The anion is produced in normal metabolic processes at levels many-fold that employed in usual iron supplementation. Brise and Halberg compared the absorption of various iron salts and found ferrous lactate to be one of the most effective studied. Its average absorption in five human subjects was 106 percent that of ferrous sulfate used as a standard. Theuer *et al.* reported similar results when ferrous lactate was added to milk- or soy-based infant formula products and then heated and freeze-dried. The relative biological value (RBV) based on the hemoglobin repletion test was 104 in the soy isolate base and 118 in the milk base compared with ferrous sulfate. The addition of this salt as a fortifying agent in beverages has been recommended by the International Nutritional Anemia Consultative Group, on the basis of its bioavailability and cost.

Weekly subcutaneous injections of 5 mg of ferrous lactate trihydrate (1.0 mg iron) into 20 albino mice were associated with two carcinomas and one fibrosarcoma at the injection sites within the 21 week test period.

Alterman investigated the teratogenic effects of ferrous lactate to the developing chick embryo. Various scattered abnormalities occurred, but serious abnormalities were not significantly greater or different from controls. The investigator concluded that ferrous lactate was nonteratogenic under the test conditions employed.

Ferrous sulfate. Ferrous sulfate has been the most thoroughly investigated of the iron salts and has become recognized as the standard against

which other compounds are evaluated. It appears to be the most acutely toxic of the iron salts currently used in foods. However, it is difficult to place these salts in rank order, for as Hoskins has pointed out, the LD₅₀ values may reflect variations in strain specificity or prior treatment of the animals rather than intrinsic toxicity of the iron salt. Further, it is the opinion of the Select Committee that acute toxicity has little relevance to the safety of iron fortification of foods.

Rats receiving 100 to 300 mg iron per kg body weight intragastrically as ferrous sulfate survived and showed no gross evidence of liver necrosis. Four of six rats receiving 400 mg per kg died within 40 hours and 39 of 55 rats receiving 500 mg per kg within 12 hours. The latter animals suffered periportal or midzonal liver cells necrosis. The surviving animals developed peripheral vasoconstriction and diarrhea within 1 hour following iron ingestion.

They were listless but exhibited only moderate decreases in blood pressure. Electron microscopic examination of the liver cells revealed stainable iron in swollen or necrotic hepatocytes although these cells appeared normal by light microscopy. The parenchymal cells were irreversibly injured and became greatly swollen prior to necrosis. All animals receiving iron, including those with no other evidence of cell injury, had characteristic granules in the intracristal lumina of liver cell mitochondria. These mitochondrial changes appear to be the first observable effects of acute iron toxicity.

Dogs given 150 to 400 mg iron per kg as ferrous sulfate by gavage or by enema, or 10 mg per kg intravenously, began to hyperventilate within an hour after administration. Marked metabolic acidosis developed with blood pH values as low as 6.7 after 6 hours. The severity of the acidosis was roughly proportional to the amount of ferrous sulfate administered. The cardiac output decreased progressively because of diminished venous return, but arteriolar constriction maintained normal blood pressure until final collapse. When animals survived the acute phase of iron intoxication, their blood pH returned to normal within 24 hours. The direct cause of death in most cases was respiratory failure.

Acute toxicity of ferrous sulfate in man is highly variable. As little as 1 g (about 3 mg iron per kg body weight) has proved fatal in an adult, whereas recovery has been reported in a 30-month-old child who had ingested 15 g (about 250 mg iron per kg body weight). The extensive experience with therapeutic doses of ferrous sulfate and other iron salts in the treatment of iron

deficiency in all age groups indicates a low toxicity. Thus, adults in many cases have taken 300 mg ferrous sulfate three times daily for years without apparent ill effects. Murphy reported a woman who had taken over 4.5 kg of ferrous sulfate over a 19-year period with no clinical or biochemical evidence of hemochromatosis or other pathology. For most of this period, she had taken three 200 mg tablets of ferrous sulfate daily and for approximately 12 months had taken six tablets daily. Her serum iron, total iron-binding capacity, and liver function tests were within normal limits. Liver biopsy was not performed. Wallerstein and Robbins reported hemochromatosis in a patient with chronic hemolytic anemia who had ingested about 500 g iron in the form of ferrous sulfate over a period of 12 years.

Ferrous sulfate was found not to be teratogenic to the developing chick embryo. The administration of up to 200 mg per kg of ferrous sulfate orally to pregnant rats or of 160 mg per kg to pregnant mice for 10 consecutive days had no clearly discernible effect on nidation or on maternal or fetal survival. The number of abnormalities seen in either soft or skeletal tissues did not differ from controls.

Ferrous sulfate was tested for mutagenic activity with *S. cerevisiae*, strain D4, and *S. typhimurium*, strains TA-1535, -1537, and -1538 with and without activation. Mutagenicity was evaluated by both plate and suspension assay procedures. According to the investigators, the results from the Salmonella suspension assay "strongly suggest" some mutagenic activity after metabolic activation. No mutagenicity was observed using the plate assay procedure with or without metabolic activation. Results with the yeast indicator organisms showed no mutagenic activity. Ferrous sulfate showed no mutagenic activity when tested in *Drosophila*.

No tumors were reported among 10 mice (strains A and FAIC) receiving single intradermal injections of 0.05 ml of 0.05 M ferrous sulfate (about 0.15 mg iron). Weekly subcutaneous injection of 2.5 mg of ferrous sulfate (0.5 mg iron) into 20 stock mice for 16 weeks produced one fibroma at the injection site.

Ferrous sulfate promotes the oxidation of fat, producing undesirable effects on color, flavor, and aroma during storage of fat-containing products. To prevent the induction of rancidity in enriched flours, an encapsulated ferrous sulfate has been developed, which significantly lengthens the storage life. It has the added advantage of possessing a density

similar to flours, thus eliminating the settling problem encountered with elemental iron.

As mentioned earlier, ferrous sulfate is the standard against which other iron compounds are compared for bioavailability and has been so recommended by the Association of Official Analytical Chemists. Although its relative biological value (RBV) thus becomes 100 by definition, this does not imply that it is completely utilized. Actually, the absorption in man may vary widely from less than 1 to more than 50 percent, depending on the individual and various other factors.

3. Ferric compounds

References have already been made to the greater bioavailability of iron in ferrous than in ferric compounds. This has been demonstrated both in laboratory and clinical studies. Clinical investigators report that patients with hypochromic anemia generally require about five times as much ferric iron as ferrous iron to achieve maximal hemoglobin production. The difference in effectiveness is attributed in large part to the lesser solubility of ferric compounds in the intestine. However, Viteri *et al.* claim that aqueous solutions of ferrous salts are rapidly oxidized to the ferric state unless strict reducing conditions are maintained. In any event, ferric compounds remain a major source of food fortification, although they appear to be relinquishing their preeminence in flavor of elemental iron. In 1970, according to the NRC survey, more than twice as much ferric phosphate and ferric sodium pyrophosphate were used to fortify foods as elemental iron. By 1975, this ratio had been reversed, because of a marked increase in the use of elemental iron and a precipitous decline in that of ferric sodium pyrophosphate.

Ferric ammonium citrate. Ferric ammonium citrate is an unpublished GRAS substance of uncertain structure. It is prepared by adding ferric hydroxide to an aqueous solution of citric acid and ammonia, neutralizing the mixture and then drying. It has enjoyed some popularity as a medication, for it is relatively well utilized by the body and lacks the objectionable astringent properties found in other ferric salts.

Heath used it successfully to treat "hypochromic anemia." He recommended that patients be given 2 g per day (0.4 g iron) initially, with gradual increases to 6 g daily (1.2 g iron). Patients were successfully treated on this regimen for many months. He claimed this dosage schedule could be tolerated with ease by the majority of

the patients. Only occasional cramps or diarrhea developed and these symptoms disappeared during the course of the treatment.

The acute toxicity of ferric ammonium citrate is low, with oral LD₅₀ values ranging from 1.75 (guinea pig) to 5.0 (mouse) g per kg body weight. One fatality has been reported in a woman who consumed 15 g of this compound (with an unknown quantity of whiskey). She died three days later with toxic hepatitis. In another case, a 58 year-old woman received 10 g ferric ammonium citrate per day for 23 days and 12.5 g on the 24th day. On the 25th day, the patient lost consciousness, but recovered when the medication was discontinued.

The use of ferric ammonium citrate in food is minor and was estimated at 1400 kg in 1974. The reported levels of this usage were 10 mg per liter in milk and frozen dairy products, and 15 mg per kg in cheese. It was stated that in recent years, as much as 150 millions of liters of milk nationwide had been fortified with ferric ammonium citrate although accurate figures are not available.

The availability of iron in ferric ammonium citrate compares favorably with that of ferrous sulfate when fed to animals. Fritz *et al.* reported its RBV as 98 to 115 as measured by hemoglobin repletion in anemic chicks and rats. Hinton and Moran reported it to be as effective as ferrous sulfate when baked in bread, in the regeneration of hemoglobin in anemic rats. However, in severely anemic patients, the iron was poorly available when baked in bread. Similarly, when used to fortify chappatti made from wheat flour, only 2 to 4 percent of the iron was absorbed.

Ferric chloride. The NRC survey of food processors indicated that ferric chloride was not widely used as a food additive. It was reportedly added only to nonalcoholic beverages and at levels less than 0.01 percent. It is authorized as a component of paper and paperboard in contact with aqueous and fatty foods (21 CFR 176.170) and with dry foods (21 CFR 176.180).

The acute toxicity for ferric chloride in animals appears to be comparable with that of ferrous sulfate, based on their respective iron content. Hoppe *et al.*, in their extensive review of the acute toxicity of iron compounds, reported five cases in which a tincture of ferric chloride has been taken. The ingestion of 45 ml (about 6 g of the salt) proved fatal to a male adult but as much as twice this amount has been taken by the other four patients without fatality.

Ferric chloride is readily soluble and efficiently absorbed. Blumberg and Arnold compared the bioavailability of

ferric chloride and ferrous sulfate in enriched breads. When fed at two levels, both preparations were equally effective in producing hemoglobin regeneration in anemic rats. The iron from each of these compounds was four to five times as available as the iron in ferric phosphate.

Pirzio-Biroli *et al.* administered labeled ferric chloride to subjects during a standard meal. They reported an absorption of 5 percent in normal and 22 percent in iron-deficient subjects. Layrisse and Martinez-Torres obtained similar results when ferric chloride was incorporated in pancakes made from maize. The average absorption in 8 normal subjects was 4.2 percent. When heme (veal muscle) was added to the diet, iron absorption increased to 7.5 percent.

Ammerman *et al.* fed radioactive iron in the form of ferric oxide, ferric chloride, ferrous carbonate or ferrous sulfate to calves and lambs. The availability of iron from ferric chloride, as measured by the levels of ⁵⁹Fe in the serum and red blood cells did not differ significantly from that of ferrous sulfate. A more recent study, however, indicates that although the bioavailability of iron in ferric chloride is reasonably good, it is significantly less than that of ferrous sulfate.

Ferric citrate. Ferric citrate is unpublished GRAS, and is generally referred to as iron citrate. No data are available on the use of this compound as a fortifying agent in food. The citrate ion is widely distributed in plants and animals and is a naturally occurring component of the diet. Relatively large amounts are produced and oxidized by normal metabolic processes in man. The iron from ferric citrate is more readily available than from most of the ferric compounds. Its bioavailability in anemic chicks and rats averaged 73 percent that of ferrous sulfate.

Rather, in an attempt to induce hemochromatosis, fed large amount of ferric citrate to rats for most of their normal life spans. Diets containing 16 and 4 percent protein and 6 percent ferric citrate were fed to 90-day-old male Addis rats for up to 521 days. The daily intake of ferric citrate was approximately 6 g per kg body weight or about 1 g per kg of elemental iron daily. The iron content of the liver per 100 g dry weight increased from 38.5 to 1070 mg in the rats on the high protein diet (average duration 352 days) and from 73.9 to 1775 mg per 100 g dry weight among those on the low protein diet (average duration 434 days). Despite extensive hemosiderin deposits in the liver and pancreas for both groups, equivalent to those observed in

hemochromatosis, no fibrosis of either organ was observed.

Twenty stock mice were injected subcutaneously with 5 mg ferric citrate (about 40 mg iron per kg body weight) weekly for 33 weeks. Thirteen mice survived the experimental period. No tumors were reported.

Ferric phosphate. Ferric phosphate (ferric orthophosphate) has been one of the major sources of iron for the fortification of breakfast cereals and flour, because its relative chemical inertness and inconspicuous white color minimize changes in the appearance and taste of the fortified product. These properties have made ferric phosphate attractive to the food processors. However, the use of ferric phosphate is declining, having dropped by 40 percent between 1970 and 1975. This decline has been attributed to the high cost and low RBV of this compound.

The low absorption of ferric phosphate has been demonstrated repeatedly. Pla and Fritz, employing their hemoglobin repletion assay in rats and chicks, reported ferric phosphate to be only 12 percent as effective as ferrous sulfate. It fared even more poorly when the increase in plasma iron in man was used as an index of absorption. With this criteria, ferric phosphate was only 7 percent as effective as ferrous sulfate. When baked in dinner rolls, less than 1 percent of the iron in ferric phosphate was available, contrasting with 8.6 percent of reduced iron and 5.7 percent of ferrous sulfate.

Hodson suggest that storage of foods fortified with ferric phosphate may convert the iron to the ferrous state and improve its absorbability. He analyzed canned liquid dietary foods to which ferric phosphate has been added and found up to 90 percent of the iron to be in the ferrous form after 5 to 6 months storage. However, the product had also been fortified with ascorbic acid, and the cans had limited headspace, conditions favorable to a reducing environment. The storage conditions and thermal processing procedures were not described.

Food grade ferric phosphate was tested for mutagenicity against *S. cerevisiae*, strain D4 and *S. Typhimurium*, strains TA-1535, -1537, and -1538. The tests were conducted with and without addition of metabolic activation preparations derived from lung, liver and testes of ICR random-bred mice, Sprague-Dawley rats, and *M. mulatta* monkeys. None of the tests revealed mutagenic activity.

Ferric pyrophosphate. Ferric pyrophosphate is very insoluble in water and is generally added to fat-

containing foods, where more soluble sources of iron might induce rancidity. Its use, however, is quite limited, and estimates indicate that only about one metric ton was used by American food processors in 1970. A 1975 survey failed to reveal any use.

The relative biological value (RBV) of ferric pyrophosphate was only 7 percent that of ferrous sulfate, as determined by the chick hemoglobin repletion assay. However, when the diet was subjected to heat and pressure processing (1055 g per cm² and 121° for 15 minutes), the RBV increased to 90 percent and did not differ significantly from that of ferrous sulfate. Theurer *et al.* also found ferric pyrophosphate to be an excellent iron source when infant formulas containing this salt were subjected to commercial sterilization processes.

No acute or chronic toxicity data for ferric pyrophosphate, either with animals or man are available for the Select Committee. This compound has been tested for mutagenic activity in a series of *in vitro* microbial assays with and without metabolic activation. The organisms employed were *S. typhimurium*, strains TA-1535, -1537 and -1538 and *S. cerevisiae*, strain D4. Activating preparations were made from lung, liver and testes of ICR random-bred mice, Sprague-Dawley rats, and *M. mulatta* monkeys. Ferric pyrophosphate induced no mutagenic activity in these tests. It showed little toxicity to the developing chick embryo when administered via the air sac before incubation at levels up to 200 mg per kg (10 mg per egg). Air cell treatment after a 96-hour incubation gave a calculated LD₅₀ of 43 per kg (2.2 mg per egg). The observed abnormalities did not differ in kind or number from controls.

Ferric sodium pyrophosphate. Ferric sodium pyrophosphate shares with ferric phosphate the light color and the chemical inertness desired by industry as an iron fortifying agent for grain products. In 1970 it comprised about 16 percent of all iron products used for fortification and, together with ferric phosphate, was the major iron source for the enrichment of cereals, rice, macaroni, and similar products. A 1975 survey, however, revealed a drop of approximately 95 percent in the use of ferric sodium pyrophosphate as a fortifying agent. It is more costly and less biologically available than ferric phosphate, which probably contributed to its reduced use. The iron provided by this compound in 1970 was estimated to be about 0.7 mg per person day, but this value has dropped to less than 0.05 mg in 1975.

The bioavailability of ferric sodium pyrophosphate has been determined by

various techniques and has been shown to be poor. Pla and Fritz found its iron availability to be only 13 percent of ferric sulfate as determined by the hemoglobin repletion method in rats and chicks. When measured by an increase of plasma iron in man, it was rated as 7 with ferrous sulfate as 100. When baked in dinner rolls, less than 1 percent was absorbed. It was only 15 percent as efficient as ferrous sulfate when fed to anemic rats in iron-fortified cereal milk diets. Rois *et al.* confirmed the poor absorption from infant cereal and stated it was an undependable source of iron to meet the nutritional needs of the infant. However, sterilization of infant formulas and heat and pressure processing of diets have been reported to convert ferric sodium pyrophosphate from a poor to a relatively good supplemental iron source. The reason for this increase is not known. Wood *et al.* speculated that processing may enhance the formation of soluble chelates which are more readily absorbed than the inorganic salt.

At a concentration of 1.25 percent, ferric sodium pyrophosphate was tested for mutagenicity in several *in vitro* microbial assays, with and without metabolic activation. The organisms employed were *S. typhimurium*, strains TA-1535, -1537, and -1538 and *S. cerevisiae*, strain D4. Activating preparations were made from lung, liver and testes of ICR random-bred mice, Sprague-Dawley rats, and *M. mulatta* monkeys. No mutagenic activity was observed in these tests.

Intraperitoneal injection of 1600 mg per kg of ferric sodium pyrophosphate (about 300 mg iron) into pregnant rats and mice for 10 consecutive days, had no discernible effect on nidation, on maternal or fetal survival, or on fetal abnormalities.

Ferric sulfate. Ferric sulfate is GRAS for use in paper and paperboard food packaging materials. No data are available to the Select Committee on the amounts used for this purpose. Ferric sulfate is slowly soluble in water. Brise and Hallberg reported its absorption in man to be 36 percent that of ferrous sulfate while Fritz *et al.* found it to be 83 percent as effective in hemoglobin repletion in chicks and rats.

Viteri *et al.* state that ferrous sulfate, added to solutions as an enrichment agent, is actually ingested in most cases as ferric sulfate. According to these investigators, 80 percent of the ferrous iron is rapidly oxidized in aqueous solutions to the ferric state unless strict reducing conditions are maintained. They compared the absorption of iron from ferric sulfate with that from sodium ferric EDTA and from hemoglobin.

When 5 mg labeled iron in these forms were given to children (mostly iron deficient) with a milk-rice-sugar formula, 34.4 percent of hemoglobin iron, 8.6 percent of sodium ferric EDTA iron, and only 3.3 percent of ferric sulfate iron were absorbed. Normal and iron-deficient men also showed a similar pattern of absorption. Addition of ascorbic acid and of sodium ferric EDTA enhances the absorption of iron from ferric sulfate.

Oxides of Iron. Ferrous and ferric oxides are categorized as "oxides of iron" (21 CFR 182.90) which accords them GRAS status as substances migrating to food from paper and paperboard products used in food packaging. Ferric oxide, in addition, has been given unpublished GRAS status as a dietary supplement. "Synthetic iron oxide" is also authorized as a color additive in pet food, not to exceed 0.25 percent by weight of food (21 CFR 73.200). Ferrous oxide is practically insoluble in water but readily soluble in acids. It is readily oxidized to the ferric state in the presence of air. No biological data are available to the Select Committee for this compound.

Ferric oxide is poorly absorbed from the gastrointestinal tract. Doty *et al.* introduced (⁵⁹Fe) ferric oxide into the stomach of rats by gavage. Four hours after administration, 99.3 percent of the labeled material could be recovered, indicating an absorption of less than 1 percent. Tests for bioavailability reflect this poor solubility. Fritz *et al.* reported a bioavailability in anemic chicks and rats of 0 to 6 percent for ferric oxide compared with that of ferrous sulfate. Of the 19 iron preparations tested for their ability to regenerate hemoglobin in anemic animals, only ferric oxide and ferrous carbonate showed relative biological values below 10 percent.

No tumors were produced when dialyzed 5 percent colloidal ferric oxide was injected subcutaneously into 20 CBA mice in doses of 0.2 ml weekly for 16 weeks. Single intraperitoneal injections of 0.5 mg of ferric oxide suspension (concentration not reported) into 15 albino mice also failed to produce tumors during an observation period of 5 months.

Epidemiologic evidence suggests that exposure to hematite dust (mainly ferric oxide) increases the risk of lung cancer in man, but the role of ferric oxide in its development is still uncertain. Ferric oxide given intratracheally or by inhalation has not been found carcinogenic in hamsters, mouse, or guinea pig. Stenback *et al.*, however, claimed that ferric oxide given intratracheally increased the

carcinogenic potential of subcutaneously injected dimethylnitrosamine (DMN) on respiratory tissues. With DMN alone, 12 of 24 Syrian golden hamsters developed tumors, none of which was in the respiratory system. With DMN injection followed by repeated endotracheal instillations of ferric oxide, 14 of 30 animals showed tumors, including four in the respiratory system.

Sodium ferricitropyrophosphate. Sodium ferricitropyrophosphate is a mixed salt of uncertain composition produced by combining sodium pyrophosphate with ferric citrate. According to industry representatives it is soluble and leaves no off-flavor, properties which make it a useful source of iron in the fortification of milk. Between 1955 and 1967, it was used in the preparation of multivitamin and mineral concentrates for the dairy industry. There is no evidence that it is not used for this purpose.

No data are available on the biological or toxicological properties of sodium ferricitropyrophosphate.

4. Iron Complexes

Iron caprylate. The Select Committee was unable to obtain any production data on iron caprylate or on the other iron compounds used to hasten the drying of films which coat the inner surfaces of food containing cans. The film coating a no. 303 can (capacity about 0.5 kg) weighs approximately 170 mg, of which 10 percent is dryer. The dryer in turn contains, 6 to 7 percent iron, or about 0.1 mg iron per can for a total of 0.2 mg iron per kg of contents. It is not known how much would migrate into the food, but the amount is believed to be very small.

Caprylic acid is a naturally occurring constituent of many foods, readily metabolized and utilized by man. Few biological data are available for 2-ethyl hexanoic acid, whose iron salt would also be found in the film coating. It has been reported that the minimal lethal dose of this compound by mouth for rats was 1600 mg per kg body weight.

Iron linoleate. The possible exposure to iron from iron linoleate would be roughly the same as that discussed for iron caprylate; namely, a maximum of 0.2 mg per kg canned contents. Linoleic acid and the other fatty acids in linseed oil, which might form iron salts are naturally occurring food components readily metabolized and utilized by man.

Iron naphthenate. Iron naphthenate encompasses a mixture of iron salts and acids of variable composition. The Select Committee is unaware of biological studies on naphthenic acids

or on iron naphthenates. The possible migration into food might be similar to that described above for the other iron salts in can coatings.

Iron peptonate. Iron peptonate is an iron complex which is unpublished GRAS as a dietary supplement. There is no evidence that it has any current usage. The Grocery Manufacturers of America surveyed its membership in 1976 and reported that none of the firms queried was using iron peptonate for iron supplementation. No information on its biological effects is available to the Select Committee.

Iron polyvinylpyrrolidone. As indicated earlier iron or iron salts with polyvinylpyrrolidone (PVP) are used as mixtures of variable proportions, authorized as tableting adjuvants or stabilizers in various mineral and vitamin concentrates (21 CFR 75.355). The Select Committee is not aware of the use of any chemically defined iron-PVP complex as an iron fortifying agent in foods, nor of the biological properties of such a complex.

Iron tallate. The fatty acid fractions of tall oil comprises about half the total acid content and consist mainly of oleic and linoleic acids. Both are naturally occurring constituents of many edible oils, and are consumed without ill effect in relatively large amounts. Acute toxicity tests of the resin fraction have given LD₅₀ values of 4.6 g per kg for mice and guinea pigs and 7.6 g per kg for rats. Tall oil resins have been fed at levels of 50 mg per kg per day to rats and 40 mg per kg per day to beagle dogs for 2 years with no significant differences from controls in their hematology, urinalyses, and liver and kidney function tests.

Sodium ferric EDTA. Ethylene diamine tetraacetic acid (EDTA) forms water-soluble chelates with many metallic ions, including iron, and this property has been widely exploited. Its disodium salt is used to solubilize trace minerals in animal feeds (21 CFR 573.360) and to stabilize iron salts in liquid multivitamin preparations (21 CFR 172.135). It is also used as a preservative or to promote color retention in a variety of food products in concentrations of 36 to 500 ppm (21 CFR 172.135).

Ferric EDTA is a very stable complex with a stability constant well above the threshold for release of iron to mucosal receptors. Helbook and Saltman present evidence that the iron chelate is transported intact across the intestinal mucosa. In the plasma, the iron is relinquished very slowly to plasma transferrin, so that most of the chelate is eliminated in the urine.

Ferric EDTA has been shown to be an effective source of iron for animals and for iron-deficient patients. Anderson *et*

al. fed cereal-milk diets supplemented with 100 mg iron per 100 g diet in the form of sodium ferric EDTA to 5-day old Pitman-Moore miniature pigs for 28 days. Efficient utilization of iron from this source was observed. It was significantly greater than that obtained with equivalent amounts of catalytically reduced iron or sodium iron pyrophosphate. Iron absorption from the EDTA complex was 90 percent that of ferrous sulfate.

Will and Vilter administered sodium ferric EDTA containing 100 mg iron three times daily to three anemic patients for 35 to 59 days. The total doses of elemental iron administered were 10.5 to 17.7 g. The hematologic response was comparable to that from equivalent doses of ferrous sulfate.

Brise and Hallberg found the absorption of iron from sodium ferric EDTA to be the least of 14 iron salts tested and only 20 percent that of ferrous sulfate. This finding may be misleading, for the investigators added 10 mg ascorbic acid to the ferrous sulfate solution to prevent oxidation of the ferrous ion. Since ascorbic acid promotes iron absorption, the net result of such differential treatment would be to decrease the percentage absorption of sodium ferric EDTA compared with ferrous sulfate.

Cook and Mosen reported that the absorption of iron from test meals was reduced by 28 percent at a 1:1 molar ratio of EDTA with iron and by half at a 2:1 molar ratio. The authors estimated that American diets may contain 50 to 100 mg EDTA daily, amounts shown by this study to impair significantly the absorption of nonheme iron.

Layrisse and Martinez-Torres, on the other hand, claim that sodium ferric EDTA possesses certain advantages over other iron salts, including ferrous sulfate. They reported that iron absorption in human subjects from maize or milk enriched with this compound was consistently greater than from ferrous sulfate enrichment. Iron absorption from sodium ferric EDTA or from ferrous sulfate-fortified sugar was comparable, but the chelated form was considered preferable since it precipitated more slowly from tannin-containing beverages, thus allowing better absorption of the iron.

A recent study from the same laboratory suggested that ferric EDTA was a more reliable salt than ferrous sulfate as an enrichment agent in foods. These investigators added either ferric EDTA or ferrous sulfate to six different foods (sugar, cane syrup, milk, sweet manioc, wheat, or maize) and determined the iron absorption in man.

The mean iron absorption from ferrous sulfate ranged from 2.0 percent from maize to 30.0 percent from refined sugar. On the other hand, no significant difference could be detected in the iron absorption from these foods enriched with ferric EDTA (range 8.2 to 13.1 percent); these results indicate that ferric EDTA is less affected than ferrous sulfate by substances in food which inhibit iron absorption.

Viteri *et al.* have also demonstrated excellent bioavailability of iron from sodium ferric EDTA when given to infants and adults. They, too, claim this chelated form is superior to ferrous sulfate as a source of available iron. Referring to unpublished studies in their laboratory, they reported preliminary findings which showed that infants absorbed labeled iron in milk fortified with sodium ferric EDTA 2.5 times better than iron from ferrous sulfate. They suggested that one reason for the greater availability of iron in this form than from most iron salts may be due to the solubility of the iron EDTA complex at the pH characteristic of the duodenum and upper jejunum. The affinity of EDTA for iron is very strong at these pHs and tends to protect it from forming insoluble and unabsorbable complexes. No adverse effects were reported in any of these studies from the administration of sodium ferric EDTA.

Ascorbic acid and EDTA appear to display opposing effects on the absorption of iron. Ferrous sulfate labeled with ⁵⁹Fe was placed in an isolated rat intestinal loop together with various amounts of ascorbic acid and/or EDTA. Iron absorption was significantly higher in the presence of ascorbic acid. When both compounds were added, EDTA was capable of negating the enhancing effects of ascorbic acid even at molar ratios of ascorbates: EDTA as high as 4:1.

The variable results obtained with the iron EDTA complex are confusing, and suggest that the experimental conditions or the presence or absence of other substances are critical in evaluating its effectiveness as an iron source.

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21 CFR Part 310

[Docket No. 86N-0337]

Oral Contraceptives; Patient Package Insert Requirement

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the requirements for patient package inserts for oral contraceptive drug products. FDA is taking this action to adopt recommendations made by FDA's Advisory Committee on Fertility and Maternal Health Drugs. The revised requirements will enable patient package inserts to reflect more expeditiously current information about this class of drug products.

FDA is also proposing to remove the labeling regulations for oral postcoital contraceptives and medroxyprogesterone acetate injectable for contraception.

DATE: Comments by July 20, 1987.

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

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drugs and Biologics (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 11, 1970 (35 FR 9001), FDA first required manufacturers and dispensers of oral contraceptives to make information available to patients about the use of these products. The regulation adopted at that time required that oral contraceptives be dispensed with a brief informational leaflet describing the product's benefits and risks. The leaflet—now called a patient package insert—contained information about side effects associated with use of oral contraceptives and emphasized the importance of patients discussing use of these drugs with their physicians. The leaflet noted that a booklet containing more information about the drug product was available from the patient's physician.

In 1978, in response to new information on the benefits and risks of oral contraceptive use, FDA revised its patient package insert requirements for oral contraceptives (see the Federal Register of January 31, 1978 (43 FR 4214)). As revised, the patient package insert regulation significantly expanded the amount of information required to be provided to patients. The revised patient package insert regulation contained detailed requirements on the content of the patient package insert and on the ways they were to be prepared and distributed. At the same time, the agency also made available a guideline patient package insert text that reflected these expanded informational requirements. Manufacturers could

adopt the guideline text to comply with the regulatory requirements.

Elsewhere in this issue of the Federal Register, FDA is announcing the availability of revised guideline texts for physician labeling and patient labeling for oral contraceptives. The revisions are intended to ensure that the latest and most accurate information on the benefits and risks of oral contraceptive use is brought to the attention of drug users. The revisions are the result of a combined effort by FDA's Advisory Committee on Fertility and Maternal Health Drugs, FDA scientists from the Center for Drugs and Biologics, and representatives of the drug industry, health care professions, and consumer advocacy organizations to update and improve oral contraceptive drug product labeling. Transcripts of the advisory committee meetings have been placed on file in the Dockets Management Branch (address above).

In addition, FDA is proposing to revise the oral contraceptive patient labeling rule. The proposed rule changes would simplify the content and format of the patient package insert to make the document more understandable and to enable the inserts to reflect current information about this class of drugs in a more timely fashion.

Under the proposed rule, the oral contraceptive patient package insert regulation would be amended from a listing of specific items to be included in the patient package insert to an enumeration of general categories of information. The current regulation details not only the kind of information to be included in the patient package insert, but also the specific conclusions the patient package insert is required to reach. This specificity means that any significant new information learned about the drug's benefits and risks can only be reflected in the patient package insert text after the oral contraceptive patient package insert regulation has been revised, i.e., on completion of notice and comment rulemaking. This procedural obligation may delay communication of important new information about oral contraceptives to drug product users. The proposed revision would make it easier for manufacturers to update patient package inserts to reflect new information about oral contraceptives.

The agency is proposing several other changes to simplify the oral contraceptive patient package insert and to allow manufacturers and other labelers greater flexibility in developing patient package inserts. First, the proposal would eliminate the current requirement that a summary patient

package insert be included in the drug package in addition to the required separate detailed patient package insert leaflet. Under the proposed revision, the summary can be combined with the more detailed patient package insert into a single leaflet. The proposal would require that each leaflet accompany or be placed in each package dispensed to the patient.

In addition, to enhance manufacturers' flexibility in preparing patient package inserts, the agency is proposing to eliminate current requirements with respect to printing specifications for the patient package insert. Except in the regulations imposing patient package insert requirements for specific drug products, FDA has not established printing specifications for drug labeling. FDA has found that its routine review of final printed labeling for drugs subject to new drug applications (this would include all oral contraceptives) and its other compliance activities have been adequate to ensure that drug labeling is legible and readable for its intended audiences. FDA now believes that this kind of monitoring of labeling practices obviates the need to mandate printing specifications for patient labeling.

Finally, FDA proposes to establish more flexible distribution requirements for oral contraceptive patient package inserts. Under current requirements, the patient package insert must physically accompany the drug product from the manufacturer or labeler through the wholesaler to the dispenser of the product. The proposal would permit distributors of oral contraceptives to adopt whatever distribution method they choose, provided all persons in the distribution chain receive an adequate number of the patient package inserts to meet their responsibilities.

As noted, FDA is making available a revised guideline text for oral contraceptive patient package inserts. It should be emphasized that this revised guideline applies only to combination estrogen-progestogen oral contraceptives. Manufacturers of such products may rely on that guideline to meet the requirements of the current regulation. Manufacturers of progestogen-only oral contraceptive drug products may continue to rely on the guideline text published in the *Federal Register* of January 31, 1978 (43 FR 4223). The agency intends to issue a revised guideline text for progestogen-only products in the near future.

FDA is also proposing to remove the regulations in 21 CFR 310.501(b) for oral postcoital contraceptives and § 310.501a for injectable medroxyprogesterone acetate for contraception because there

are no marketed drug products currently approved for these uses.

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The agency has examined the economic impact of this proposed rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96-354). The proposed rule would modify the format and style of the oral contraceptive labeling regulation to make it more easily understood and readable. In addition, the proposal would amend the regulations from a listing of specific items to be included in the patient package insert to an enumeration of general categories of information. No additional burdens are imposed upon manufacturers. Therefore, the agency concludes that this proposed rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that this proposed rule, if promulgated, will not have a significant economic impact on small entities as defined by the Regulatory Flexibility Act.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 310 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR Part 310 continues to read as follows:

Authority: Secs. 502, 503, 505, 701, 52 Stat. 1051, 1052, 1053, 1055 as amended (21 U.S.C. 352, 353, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

2. By revising § 310.501 to read as follows:

§ 310.501 Patient package inserts for oral contraceptives.

(a) *Requirement for a patient package insert.* The safe and effective use of oral contraceptive drug products requires that patients be fully informed of the benefits and the risks involved in their use. An oral contraceptive drug product that does not comply with the requirements of this section is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352). Each dispenser of an

oral contraceptive drug product shall provide a patient package insert to each patient (or to an agent of the patient) to whom the product is dispensed, except that the dispenser may provide the insert to the parent or legal guardian of a legally incompetent patient (or to the agent of either). The patient package insert is required to be placed in or accompany each package dispensed to the patient.

(b) *Distribution requirements.* (1) Each manufacturer and distributor of an oral contraceptive drug product shall provide sufficient numbers of patient package inserts to each person to whom it ships the product to permit the dispenser to give one insert to each patient receiving the drug.

(2) Patient package inserts for oral contraceptives dispensed in acute care hospitals or long-term care facilities will be considered to have been provided in accordance with this section if provided to the patient before administration of the first oral contraceptive and every 30 days thereafter, as long as the therapy continues.

(c) *Patient package insert contents.* A patient package insert for an oral contraceptive drug product is required to contain the following:

(1) The name of the drug.

(2) A summary section including a statement concerning the effectiveness of oral contraceptives in preventing pregnancy, the contraindications to the drug's use, and a statement of the risks and benefits associated with the drug's use.

(3) A statement of the effectiveness of oral contraceptives.

(4) Information that the patient should provide to the prescriber before taking the drug.

(5) A statement of medical conditions that deserve special consideration in connection with oral contraceptive use and about which the patient should inform the prescriber.

(6) A warning regarding the serious side effects of oral contraceptives.

(7) A boxed warning concerning the risks associated with cigarette smoking and oral contraceptive use.

(8) A statement of other serious adverse reactions and potential safety hazards that may result from the use of oral contraceptives.

(9) Information on precautions the patients should observe while taking oral contraceptives, including the following:

(i) A statement that identifies activities and drugs, foods, or other substances the patient should avoid because their interactions with oral contraceptives are known, likely to

occur, and likely to have clinical significance; and

(ii) A statement of risks to the mother and unborn child from the use of oral contraceptives before or during early pregnancy; and

(iii) A statement concerning excretion of the drug in human milk and associated risks to the nursing infant.

(10) A statement concerning possible side effects which may help the patient evaluate the benefits and risks from the use of oral contraceptives.

(11) A statement of possible benefits associated with oral contraceptive use.

(12) Information about how to take oral contraceptives properly, including information about what to do if the patient forgets to take the product, information about becoming pregnant after discontinuing use of the drug, a statement that the drug product has been prescribed for the use of the patient and should not be used for other conditions or given to others, and a statement that the patient's pharmacist or practitioner may have a more technical leaflet about the drug product that the patient may ask to review.

(13) The following information about the drug product and the patient package insert:

(i) The name and place of business of the manufacturer, packer, or distributor, or the name and place of business of the dispenser of the product.

(ii) The date, identified as such, of the most recent revision of the patient package insert placed prominently immediately after the last section of the labeling.

(d) *Other indications.* The patient package insert may identify indications in addition to contraception that are identified in the professional labeling for the drug product.

(e) *Guidelines.* The Food and Drug Administration has made available guidelines for patient package inserts for oral contraceptive drug products. A guideline is available for the class of combination estrogen-progestogen oral contraceptive and a separate guideline is available for the progestogen-only oral contraceptives. Any person may use the appropriate guideline to meet the requirements of this section.

(f) *Requirement to supplement new drug application.* Holders of approved applications for oral contraceptive drug products that are subject to the requirements of this section are required to submit supplements under § 314.70(c) of this chapter to provide for the labeling required by this section. Such labeling may be put into use without advance approval by the Food and Drug Administration.

§ 310.501a [Removed]

3. By removing § 310.501a *Medroxyprogesterone acetate injectable for contraception.*

Dated: March 30, 1987.

Frank E. Young,
Commissioner of Food and Drugs.

[FR Doc. 87-8848 Filed 4-20-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

Pennsylvania Permanent Regulatory Program; Modification; Public Comment and Opportunity for Public Hearing

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Proposed rule.

SUMMARY: OSMRE is announcing procedures for the public comment period and for hearing on the substantive adequacy of program amendments submitted by the Commonwealth of Pennsylvania as modifications to the Pennsylvania Permanent Regulatory Program (hereinafter referred to as the Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment revises the Pennsylvania Surface Mining Conservation and Reclamation Act to (1) clarify information needs concerning access to properties for purposes of coal refuse disposal, coal prep plants and for underground mining activities and (2) to establish a fund to provide loans to deep mine operators unable to obtain surety bond. This notice sets forth the times and locations that the Pennsylvania program and the proposed amendment are available for public inspection, the comment period during which interested persons may submit written comments on the proposed program elements, and the procedures that will be followed regarding the public hearing.

DATES: Written comments not received on or before 4:00 p.m. May 21, 1987, will not necessarily be considered.

If requested, a public hearing on the proposed modifications will be held on May 18, 1987, beginning at 9:00 a.m. at the location shown below under "ADDRESSES".

ADDRESS: Written comments should be mailed or hand delivered to: Mr. Robert Biggi, Harrisburg Field Office, Office of Surface Mining, 101 South 2nd Street,

Suite L-4, Harrisburg, Pennsylvania 17101.

If a public hearing is held its location will be: Penn Harris Motor Inn and Convention Center at the Camp Hill Bypass and U.S. 11 and 15, Camp Hill, Pennsylvania.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Biggi, Harrisburg Field Office, Office of Surface Mining Reclamation and Enforcement, 101 South 2nd Street, Suite L-4, Harrisburg, Pennsylvania 17101; Telephone: (717) 782-4036

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

Availability of Copies

Copies of the Pennsylvania program, the proposed modifications to the program, a listing of any scheduled public meeting and all written comments received in response to this notice will be available for review at the OSMRE offices and the office of the State regulatory authority listed below, Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding holidays. Each person may receive, free of charge, one single copy of the proposed modifications by contracting the Harrisburg Field Office.

Harrisburg Field Office, Office of Surface Mining Reclamation and Enforcement, 101 South 2nd Street, Suite L-4 Harrisburg, Pennsylvania 17101

Office of Surface Mining Reclamation and Enforcement, Room 5124, 1100 "L" Street, NW., Washington, DC 20240
Pennsylvania Department of Environmental Resources, Fulton Bank Building, Third and Locust Streets, Harrisburg, Pennsylvania 17120

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanation of support of the commenter's recommendations. Comments received after the time indicated under "DATES" or at location other than Harrisburg, Pennsylvania, will not necessarily be considered and included in the Administrative Record for this final rulemaking.

Public Hearing

Persons wishing to comment at a public hearing should contact the person listed under "FOR FURTHER INFORMATION CONTACT" by the close of business May 6, 1987. If no one requests to comment at a public hearing, the hearing will not be held.

If only one person requests to comment, a public meeting, rather than

a public hearing, may be held and the results of the meeting included in the Administrative Record.

Public Meeting

Persons wishing to meet with OSMRE representatives to discuss the proposed amendments may request a meeting at the OSMRE office listed under "ADDRESSES" by contacting the person listed under "FOR FURTHER INFORMATION CONTACT"

All such meetings are open to the public and, if possible, notices of meetings will be posted in advance in the Administrative Record. A written summary of each public meeting will be made a part of the Administrative Record.

II. Background on the Pennsylvania State Program

On February 29, 1980, the Secretary of the Interior received a proposed regulatory program from the State of Pennsylvania. On October 22, 1980, following a review of the proposed program as outlined in 30 CFR Part 732, the Secretary disapproved the Pennsylvania program. The State resubmitted its program on January 25, 1982, and subsequently the Secretary approved the program subject to the correction of minor deficiencies. Information pertinent to the general background, revisions, modifications, and amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval of the Pennsylvania program can be found in the July 30, 1982 Federal Register notice (47 FR 33050). Subsequent action concerning the conditions of approval and program amendments are identified at 30 CFR 938.15 and 938.16.

III. Submission of Program Amendment

On January 22, 1987, Pennsylvania submitted for OSMRE's approval an amendment to the State program which revises the Pennsylvania Surface Mining Conservation and Reclamation Act. Two specific sections of the legislation modify the approved regulatory program:

(1) Section 4.2(F)(II) of the State Act has been modified to clarify information needs concerning access to properties for purposes of coal refuse disposal, coal prep plants and for underground mining activities. The amended language provides that in the case of permit applications for coal refuse disposal areas, coal preparation facilities not situated on a permit area and the surface activities of underground mines,

the applicant shall submit a description of the documents upon which the applicant bases the right to enter upon the surface land and conduct mining activities. It further provides that the State regulatory authority shall have access to permitted areas for a period of five years after completion or abandonment of mining and reclamation activities.

(2) A new Section 4.7 has been created to establish an Anthracite Deep Mine Operators' Bond Fund to provide loans to anthracite deep mine operators unable to obtain surety bond. The following categories of anthracite deep mine operators would be eligible to use the fund to meet their bond obligation: (1) Operators who have sought and been denied a bond by three separate bonding companies and (2) operators whose bonds are cancelled due to the insolvency or bankruptcy of any insurance company or surety company.

Operators who use the fund to meet their bond obligations will be required to pay a fee of twenty-five cents for each ton of coal extracted from mining operations for which the required bond has not been posted. In addition each operator must file with the regulatory authority one thousand dollars toward the bond obligation.

The per ton fee is to be continued until the fund has reached a level that equals the number of acres for which no bond has been posted multiplied by the per-acre bonding requirement established by the regulations of the Department. The fees paid by an operator may be used only to secure the reclamation obligations of the operator.

The Director is seeking comment on the adequacy of the proposed amendment in satisfying the criteria for approval of State program amendments set forth at 30 CFR 732.15 and 732.17. The Director must find that the amendment provisions are consistent with SMCRA and no less effective than the Federal regulations. The full text of the proposed amendment is available for review in the OSMRE Administrative Record under No. PA 631 at the addresses listed above.

IV. Additional Determinations

1. *Compliance with the National Environmental Policy Act:* The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. *Executive Order No. 12291 and the Regulatory Flexibility Act:* On August 28, 1981, the Office of Management and Budget (OMB) granted OSMRE an exemption from sections 3, 4, 7, and 8 of

Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a Regulatory Impact Analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule would not impose any new requirements; rather, it would ensure that existing requirements established by SMCRA and the Federal rules would be met by the State.

3. *Paperwork Reduction Act:* This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 938

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: April 14, 1987.

James W. Workman,

Deputy Director, Operations and Technical Services, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 87-8899 Filed 4-20-87; 8:45 am]

BILLING CODE 4310-05-M

VETERANS ADMINISTRATION

38 CFR Part 21

Veterans Education; Term-by-Term Enrollment Certifications

AGENCY: Veterans Administration.

ACTION: Withdrawal of proposed regulations.

SUMMARY: On page 30151 and 30152 of the Federal Register of June 30, 1983 there was published a notice of intent to amend part 21 to require that certifications of enrollment be made each term, quarter or semester. Interested people were given 30 days in which to submit comments, suggestions or objections regarding the proposal. The VA (Veterans Administration) is withdrawing that proposal.

FOR FURTHER INFORMATION CONTACT: June C. Schaeffer (225), Assistant Director for Education Policy and Program Administration, Vocational Rehabilitation and Education Service, Department of Veterans Benefits, Veterans Administration, 810 Vermont Avenue NW., Washington, DC 20420 (202) 233-2092.

SUPPLEMENTARY INFORMATION: The VA received one telephone call and 273 letters, many containing more than one comment, suggestion or objection. Veterans and other VA beneficiaries submitted 155 letters. There were also six letters in the form of petitions which were signed by an additional 334 people. Officials of educational institutions submitted 95 letters. Officials of educational and other organizations wrote 13 letters. Two officials of State

approving agencies submitted letters, as did one Federal official and one interested citizen. Three of the veterans, five college officials and one educational organization supported the proposal and urged that it be adopted. The remainder of the letter writers had various objections and suggestions.

While the VA was reviewing the letters, the Veterans' Benefits Improvement and Health-Care Authorization Act of 1986 was enacted.

Section 319 of that Act generally prohibits the VA from requiring that educational institutions certify enrollments on a term, quarter or semester basis. Accordingly, the VA is withdrawing its proposal which would have required them to do so.

Approved: April 2, 1987.

Thomas K. Turnage,
Administrator.

[FR Doc. 87-8898 Filed 4-20-87; 8:45 am]

BILLING CODE 8320-01-M

Notices

Federal Register

Vol. 52, No. 76

Tuesday, April 21, 1987

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Committee on Regulation; Public Meetings

SUMMARY: Pursuant to the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of two meetings of the Committee on Regulation of the Administrative Conference of the United States. The committee has scheduled these meetings to consider further the Administrative Conference study of federal user fees and a draft committee recommendation on the subject.

DATES: *First Meeting*—Thursday, May 7, 1987; 9:30 a.m. until noon; *Second Meeting*—Friday, May 15, 1987; 9:30 a.m. until noon.

Location: Offices of Steptoe & Johnson, 1330 Connecticut Avenue, NW., Washington, DC.

Public Participation: The committee meeting is open to the interested public, but limited to the space available. Persons wishing to attend should notify the contact person at least two days before the meeting. The committee chairman may permit members of the public to present oral statements at the meeting. Any member of the public may file a written statement with the committee before, during, or after the meeting. Minutes of the meeting will be available on request.

FOR FURTHER INFORMATION CONTACT: Michael W. Bowers, Office of the Chairman, Administrative Conference of the United States, 2120 L Street, NW., Suite 500, Washington, DC 20037. Telephone: (202) 254-7065.

SUPPLEMENTARY INFORMATION: The Committee on Regulation will discuss and take action on a draft recommendation on user fees that was published for comment on March 12 and discussed at a public hearing on April 2 (see FR 7814). The meeting scheduled for May 15 will not be held if the committee

completes its consideration of this matter on May 7. If the committee adopts a proposed recommendation on user fees, it will be presented to the Assembly of the Administrative Conference at a meeting on June 11-12, 1987.

Dated: April 16, 1986.

Jeffery S. Lubbers,
Research Director.

[FR Doc. 87-8934 Filed 4-20-87; 8:45 am]

BILLING CODE 6110-01-M

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

1987 Price Support Levels for Fire-Cured (Type 21), Fire-Cured (Types 22-23), Dark Air-Cured (Types 35-36), Virginia Sun-Cured (Type 37), Cigar-Filler and Binder (Types 42-44, 53-55) and Cigar-Filler (Type 46) Tobaccos

AGENCY: Commodity Credit Corporation (CCC), USDA.

ACTION: Notice of Proposed Determination of 1987 Price Support Levels for Six Kinds of Tobacco.

SUMMARY: The purpose of this Notice of Proposed Determination is to request comments with respect to levels of price support for fire-cured (type 21), tobacco, (2) fire-cured (types 22-23), (3) dark air-cured (types 35-36), (4) Virginia sun-cured (type 37), tobacco, (5) cigar-filler and binder (types 42-44, 53-55) tobacco, and (6) cigar-filler (type 46) kinds of tobacco for the 1986 marketing year. The levels of price support for these kinds of tobacco are required to be determined under the provisions of section 106 of the Agricultural Act of 1949, as amended.

DATE: Comments must be received on or before May 21, 1987 to be assured of consideration.

ADDRESS: Written comments should be sent to the Director, Commodity Analysis Division, ASCS, U.S. Department of Agriculture, P.O. Box 2415, Washington, DC 20013. All written submissions made pursuant to this notice will be made available for public inspection from 8:15 a.m. to 4:45 p.m. Monday through Friday, in Room 3741, USDA South Building, 14th and Independence Avenue, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Robert H. Miller, (202) 447-8839 or Kenneth Robison, (202) 447-5188. A Preliminary Regulatory Impact Analysis describing the options considered in developing this notice and the impact of implementing each option is available on request from Mr. Robison.

SUPPLEMENTARY INFORMATION: This notice has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Departmental Regulation 1512-1, and has been classified as "not major." The provisions of this notice will not result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individuals industries, Federal, State or local Governments, or geographical regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, the environment, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The title and number of the Federal Assistance Program to which this notice applies are: Title—Commodity Loans and Purchases; Number—10.051, as set forth in the Catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a noticed of proposed rulemaking with respect to the subject of this notice.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983). It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Determination of Price Support

Price support is required to be made available for each crop of a kind of tobacco for which marketing quotas are

in effect or for which marketing quotas have not been disapproved by producers. With respect to the 1986 crop of the six kinds of tobacco covered by the notice, the respective maximum level of support is determined in accordance with section 106 of the Agricultural Act of 1949, as amended (the "Act").

Section 106(f)(6)(A) of the Act provides that the level of support for the 1987 crop of a kind of tobacco shall be the level in cents per pound at which the 1986 crop of such kind of tobacco was supported, plus or minus, respectively, the amount by which (i) the support level for the 1987 crop, as determined under section 106(b) of the Act, is greater or less than (ii) the support level for the 1986 crop, as determined under section 106(b) of the Act, as that difference may be adjusted by the Secretary under section 106(d) of the Act if the support level under clause (i) is greater than the support level under clause (ii). Accordingly, under section 106(f)(6)(A) of the Act, the support level for the 1987 crop of such kind of tobacco will be the 1986 level, adjusted by the difference between (plus or minus) the 1987 "basic support level" and the 1986 "basic support level".

In addition, section 106(f)(6)(B) provides that to the extent requested by the board of directors of an association through which price support is made available to producers ("producer association") the Secretary may reduce the support level determined under section 106(f)(6)(A) for any kind of tobacco (except flue-cured and burley) to more accurately reflect the market value and improve the marketability of tobacco.

The levels of price support for the 1986 crops of various kinds of tobacco, which are determined in accordance with sections 106(f)(6)(A) are as follows:

Kind and type	Support (cents per pound)
Virginia fire-cured, type 21.....	120.0
KY-TN fire-cured, types 22-23.....	124.2
Dark air-cured, types 35-36.....	105.8

Kind and type	Support (cents per pound)
Virginia sun-cured, type 37.....	106.0
Cigar-filler and binder, types 42-44, 53-55.....	91.6
Puerto Rican, type 46.....	75.0

Section 106(b) of the Act provides that the "basic support level" for any year is determined by multiplying the support level for the 1959 crop of such kind of tobacco by the ratio of the average of the index of prices paid by farmers including wage rates, interest, and taxes (referred to as the "parity index") for the three previous calendar years to the average index of such prices paid by farmers, including wage rates, interest, and taxes for the 1959 calendar year (298). For the 1987-crop year, the average parity indexes for the three previous years are: 1984—1130; 1985—1120; and 1986—1097. The average of the parity indexes for these years is 1116 and the ratio of the 1984-86 index to the 1959 index is 3.74. For the 1986-crop year, the average parity indexes used to calculate the 1986 "basic support level" were: 1983—1104; 1984—1130; 1985—1120. The ratio of the 1983-85 index to the 1959 index equaled 3.75. Thus, the "basic support level" for the 1986 and 1987 crops of the various kinds of tobaccos and the annual decrease are as shown in the following table:

Kind and type	Basic support level		Decrease in 1987 from 1986
	1986	1987	
	Cents per pound		
Virginia fire-cured, type 21.....	145.5	145.1	.4
Kentucky-Tennessee fire-cured, types 22-23.....	145.5	145.1	.4
Dark air-cured, types 35-36.....	129.4	129.0	.4
Virginia sun-cured, type 37.....	129.4	129.0	.4

Kind and type	Basic support level		Decrease in 1987 from 1986
	1986	1987	
Cigar-filler and binder, types 42-44, 54-55.....	107.2	107.0	.2
Puerto Rican, type 46.....	111.4	111.1	.3

Section 106(d) of the Act provides the Secretary of Agriculture may reduce the level of support which would otherwise be established for any grade of such kind of tobacco which the Secretary determines will likely be in excess supply. In addition, the weighted average of the level of support for all eligible grades of such tobacco must, after such reduction, reflect not less than 65 percent of the increase in the support level for such kind of tobacco which would otherwise be established under section 106 of the Act if the support level is higher than the support level for the preceding crop. Before any such reduction is made, the Secretary must consult with the associations handling price support loans and consideration must be given to the supply and anticipated demand of such tobacco, including the effect of such reduction on other kinds of quota tobacco. In determining whether the supply of any grade of any kind of tobacco of a crop will be excessive, the Secretary shall take into consideration the domestic supply, including domestic inventories, the amount of such tobacco pledged as security for price support loans, and anticipated domestic and export demand, based on the maturity, uniformity and stalk position of such tobacco. Since the 1987 "basic support level" is below the 1986 "basic support level", section 106(d) is not applicable for the 1987 crop.

As noted in the following table, the supplies of all these kinds of tobacco for which price support is made available are currently at, or in excess of, the supply deemed adequate to meet domestic use and export needs. As a result of these increased supplies of tobacco, the quantity to tobacco pledged as collateral for CCC price support loans has also become ample to excessive.

Kind and type	Million Pounds				
	1986/87 production	1986/87 Total Supply	1986/87 Reserve Supply	1986- Crop CCC Loan Collateral	1986/87 CCC Loans as percent of production
Virginia fire-cured, type 21	3.6	9.5	12.5	1.0	29.0
Kentucky-Tennessee fire-cured types, 22-23.....	35.1	131.4	118.0	9.0	28.0
Dark air-cured types 35-36.....	11.1	62.0	57.6	3.0	30.2
Virginia sun-cured, type 37.....	.1	1.0	1.5	²	5.5
Cigar-filler, and binder, types 42-44, 53-55.....	12.2	72.7	75.2	3.5	28.7
Puerto Rican, type 46.....	.2	5.8	2.4 ¹	.2	100

¹ Three times annual disappearance past 3 marketing years.

² Less than 50,000 pounds.

Because of the oversupply situation for fire-cured (type 21), fire-cured (type 22-23), dark air-cured, Virginia sun-cured, Puerto Rican filler, and cigar-filler and binder (types 42-44; 53-55), the proposed 1987 maximum support level for each kind consists of the 1986 level of support decreased by the difference between the 1987 "basic support level" and the 1986 "basic support level". However, this level could be reduced further if any of the producer associations request that the support level for their respective kind be reduced.

Proposed Determinations

Accordingly, the Secretary of Agriculture proposes to determine and announce the maximum price support level for the following kinds of tobacco (1987-crop) at the levels set forth below:

Kind and type	Amount (maximum (cents per pound)
Virginia fire-cured, type 21	119.6
KY-TN fire-cured, types 22-23.....	123.8
Dark air-cured, types 35-36.....	105.4
Virginia sun-cured, type 37.....	105.6
Cigar-filler and binder, types 42-44, 53-55.....	91.4
Puerto Rican filler (type 46).....	74.7

Comments are requested with respect to the appropriate level of price support of such kinds of tobacco.

Authority: Secs. 4 and 5, Stat. 1070, 1072, as amended, (15 U.S.C. 714b, 714c); Secs. 101, 106, 401, 403, 406, 63 Stat. 1051, as amended, 74 Stat. 6, as amended, 63 Stat. 1054, as amended, 1055, (7 U.S.C. 1441, 1445, 1421, 1423, 1426).

Signed at Washington, DC, on April 16, 1987.

Milton J. Hertz,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 87-8847 Filed 4-20-87; 8:45 am]

BILLING CODE 3410-05-M

Forest Service

Columbia River Gorge National Scenic Area; Interim Guidelines; Availability

The Columbia River Gorge National Scenic Area Act of November 17, 1986, requires that the Secretary of Agriculture develop Interim Guidelines for the Scenic Area outside of Urban Areas. These Guidelines will identify land use activities which are inconsistent with the Act and govern the authority to acquire land without consent of the owner. The Interim Guidelines establish the standards by which proposed facilities and land uses will be evaluated for consistency with the Scenic Area Act.

Draft Interim Guidelines have been prepared and are available for review from the National Scenic Area, 902 Wasco Avenue, Suite 301, Hood River, OR 97031. Comments of the Interim Guidelines must be received by the Scenic Area Manager no later than May 13, 1987. For further information, contact Katherine Jesch, Scenic Area Planner, (503) 386-2333.

Arthur W. DuFault,

National Scenic Area Manager.

[FR Doc. 87-8839 Filed 4-20-87; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE

Presidential Board of Advisors on Private Sector Initiatives; Open Meeting

AGENCY: Office of the Secretary, Office of the General Counsel and Office of Business Liaison, Commerce.

SUMMARY: The Presidential Board of Advisors on Private Sector Initiatives will hold a meeting on April 27, 1987. Committee meetings will also be held on this date. Public comment is welcome.

TIME AND PLACE: Presidential Board of Advisors on Private Sector Initiatives.

Monday, April 27, 1987, 11:15 a.m.-1:00 p.m., at the American Red Cross National Headquarters, Rooms to be Posted, 17 and E Streets, NW., Washington, DC 20006.

Committee Meetings

Monday, April 27, 1987, 10:00 a.m.-11:00 a.m., at the American Red Cross National Headquarters, Rooms to be Posted, 17 and E Streets, NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT:

The Committee Control Officer, Mr. Robert H. Brumley, Deputy General Counsel, U.S. Department of Commerce, (202/377-4772) or the Alternate Control Officer, Nancy J. Olson, Director, Office of Business Liaison, U.S. Department of Commerce, (202/377-3942), Main Commerce Building, Washington, DC 20230.

Robert R. Brumley,

Deputy General Counsel.

April 16, 1987.

[FR Doc. 87-9056 Filed 4-20-87; 8:45 am]

BILLING CODE 3510-BP-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Bangladesh

April 16, 1987.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on April 21, 1987. For further information contact

Janet Heinzen, International Trade Specialist (202) 377-4212. For information on the quota status of these limits, please refer to the Quota Status Reports which are posted on the bulletin boards of each Customs port. For information on embargoes and quota reopenings, please call (202) 377-3715.

Background

CITA directives dated October 17, 1986 and January 28, 1987 (51 FR 37625 and 52 FR 3327) established import restraint limits for certain cotton and man-made fiber textile products, produced or manufactured in Bangladesh and exported during the twelve-month periods which begin, in the case of Category 641, on May 29, 1986; and, in the case of Category 341, on February 1, 1987.

On March 27, 1987, the Governments of the United States and the People's Republic of Bangladesh exchanged diplomatic notes to further amend the Bilateral Cotton and Man-Made Fiber Textile Agreement of February 19 and 24, 1986, as amended, to establish the specific limits for man-made fiber textile products in Categories 641 and 647/648, produced or manufactured in Bangladesh and exported during the four-month period which began on October 1, 1986 and extended through January 31, 1987.

The agreement also establishes specific limits for cotton and man-made fiber textile products in Categories 336, 341pt. (sublimit of Category 341), 641 and 647/648, produced or manufactured in Bangladesh and exported during the twelve-month period which began on February 1, 1987 and extends through January 31, 1988.

In the letter which follows this notice the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to control imports in Categories 336, 341pt., 641 and 647/648 at the agreed limits for the twelve-month period which began on February 1, 1987 and extends through January 31, 1988.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the *Federal Register* on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 18, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), July 14, 1986 (51 FR 25386), July 29, 1986 (51 FR 27068) and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1987).

This letter and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Donald R. Foote,

Acting Chairman, Committee for the Implementation of Textile Agreements.
April 16, 1987.

Committee for the Implementation of Textile Agreements

Commissioner of Customs
Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner: This directive cancels and supersedes the directive of October 17, 1986, issued to you by the Chairman, Committee for the Implementation of Textile Agreements, which directed you to prohibit entry for consumption or withdrawal from warehouse for consumption of man-made fiber textile products in Category 641, produced or manufactured in Bangladesh and exported during the twelve-month period which began on May 29, 1986 and extends through May 28, 1987.

In addition, this directive amends, but does not cancel, the directive of January 28, 1987 concerning cotton and man-made fiber textile products, produced or manufactured in Bangladesh and exported during the twelve-month period which began on February 1, 1987 and extends through January 31, 1988.

Effective on April 21, 1987, the directive of January 28, 1987 is amended to include the following import restraint limits for cotton and man-made fiber textile products, produced or manufactured in Bangladesh and exported during the twelve-month period which began on February 1, 1987 and extends through January 31, 1988.

Category	12-Month restraint limit ¹
336.....	60,000 dozen.
341pt. ²	408,100 dozen.
641.....	500,000 dozen of which not more than 175,000 dozen shall be in Category 641pt. ³
647/648.....	636,000 dozen of which not more than 413,400 dozen shall be in Category 647pt./648pt. ⁴

¹ The limits have not been adjusted to account for any imports exported after January 31, 1987.

² A sublimit of Category 341—1,166,000 of which not more than 408,100 dozen shall be in TSUSA numbers 384.4608, 384.4610 and 384.4612.

³ In Category 641, blouses made from fabric with two or more colors in the warp and/or the filling in TSUSA numbers 384.9110 and 384.9120.

⁴ In Category 647/648, long trousers and slacks in TSUSA numbers 381.2370, 381.2375, 381.2859, 381.3190, 381.3335, 381.3549, 381.6679, 381.6984, 381.8531, 381.8672, 381.8835, 381.8840, 381.9234, 381.9310, 381.9575, 381.9580, 381.9846, 381.9974, 384.1950, 384.2010, 384.2015, 384.2017, 384.2030, 384.2040, 384.2050, 384.2267, 384.2345, 384.2348, 384.2351, 384.2355, 384.2667, 384.2783, 384.5482, 384.5684, 384.7756, 384.7858, 384.8241, 384.8242, 384.8244, 384.8245, 384.8247, 384.8256, 384.8258, 384.9000, 384.9172, 384.9174, 384.9176, 384.9372 and 384.9678.

Textile products in Category 336 which have been exported to the United States prior to February 1, 1987 shall not be subject to this directive.

Textile products in Category 336 which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1)(A) prior to the

effective date of this directive shall not be denied entry under this directive.

In carrying out this directive, man-made fiber textile products in Categories 641 and 647/648, produced or manufactured in Bangladesh and exported to the United States during the four-month period which began on October 1, 1986 and extended through January 31, 1987, shall, to the extent of any unfilled balances be charged against the restraint limits established for such goods during that period. In the event the limits established for that period have been exhausted by previous entries, such goods shall be charged to the limits established in this directive.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

Sincerely,

Donald R. Foote,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 87-8988 Filed 4-20-87; 8:45 am]

BILLING CODE 3510-DR-M

Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in the People's Republic of China

April 17, 1987.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on April 23, 1987. For further information contact Diana Solkoff, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, please refer to the Quota Status Reports which are posted on the bulletin boards of each Customs port or call (202) 566-5810. For information on embargoes and quota reopenings, please call (202) 377-3715.

Background

CITA directives dated July 18, 1986 (FR 26459), August 25, 1986 (51 FR 30692), October 24, 1986 (51 FR 39408) and January 27, 1987 (52 FR 3160) established restraint limits for cotton, wool and man-made fiber textile products, produced or manufactured in the People's Republic of China and exported during the twelve-month periods beginning on July 24, 1986,

August 28, 1986, October 27, 1986 and January 28, 1987, respectively.

During consultations held February 23-27, 1987 between the Governments of the United States and the People's Republic of China, agreement was reached to establish specific limits for the Categories 319, 637, 650 and 659-S, produced or manufactured in China and exported during the period which began on January 1, 1987 and extends through December 31, 1987.

In addition, the two governments also agreed that overshipments of the limit for the July 24, 1986 through July 23, 1987 period of 5,000 dozen would be charged to the restraint limits established for Category 637, starting with the twelve-month period which began on January 1, 1987 and each of the subsequent four-year periods to be established under a new bilateral agreement. Category 637 is subject to phased entry procedures for goods exported in excess of the limit established for the period which began on July 24, 1986.

In the letter published below, the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to prohibit entry, or withdrawal from warehouse, for consumption in the United States of cotton and man-made fiber textile products in Categories 319, 637, 650 and 659-S, produced or manufactured in the People's Republic of China and exported during the twelve-month period which began on January 1, 1987 and extends through December 31, 1987, in excess of the specified limits.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the *Federal Register* on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983 (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), July 14, 1986 (51 FR 25386) and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1987).

This letter and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Donald R. Foote,

Acting Chairman, Committee for the Implementation of Textile Agreements.

April 17, 1987.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,

Department of the Treasury,
Washington, D.C. 20229

Dear Mr. Commissioner: This directive cancels and supersedes those portions of the directives of July 18, 1986, August 25, 1986 and October 24, 1986 issued to you by the Chairman of the Committee for the Implementation of Textile Agreements, which directed you to prohibit entry for consumption or withdrawal from warehouse for cotton and man-made fiber textile products in Categories 637, 659-S¹ and 319/320pt.² produced or manufactured in the People's Republic of China and exported during the twelve-month periods which began, in the case of Category 637, on July 24, 1986; in the case of Category 659-S, on August 28, 1986; and, in the case of Category 319/320pt., on October 27, 1986.

This directive cancels and supersedes the directive of January 27, 1987 concerning imports of man-made fiber textile products in Category 650, produced or manufactured in the People's Republic of China and exported during the twelve-month period which began on January 28, 1987.

In carrying out this directive, entry of goods exported during the July 24, 1986 through December 31, 1986 period and in excess of the limit established for Category 637 for the period July 24, 1986 through July 23, 1987 shall be permitted entry, but shall not be charged to the 1987 restraint limit, for consumption in the United States in the following amounts during the indicated thirty-day periods.

Period	Amount to be entered (dozen)
April 23-May 22, 1987	90,000
May 26-June 25, 1987	90,000
June 26-July 27, 1987	90,000

Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on July 31, 1986; pursuant to the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of August 19, 1983, as amended, between the Governments of the United States and the People's Republic of China; and in accordance with the provisions of Executive Order 11851 of March 3, 1972, as amended, you are directed to prohibit, effective on April 23, 1987, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton and man-made fiber textile products in Categories 319, 637, 650 and 659-S, produced or manufactured in the People's Republic of China and exported during the twelve-month period which began on January 1, 1987 and extends through December 31,

¹ In Category 659, only TSUSA numbers 381.2340, 381.3170, 381.9100, 381.9570, 384.1920, 384.2339, 384.8300, 384.8400 and 384.9353.

² In Category 320, only TSUS items 320, 321, 322, 326, 327 and 328 with statistical suffix 66.

1987, in excess of the following restraint limits³:

Category	Twelve-month restraint limit
319	¹ 2,150,000
637	² 270,000
650	² 88,000
659-S	³ 1,050,000

¹ Square yards.

² Dozen.

³ Pounds.

Also effective on April 23, 1987, you are directed to charge the following amounts to the restraint limits established for Categories 319, 637, 650 and 659-S for the period which began on January 1, 1987 and extends through December 31, 1987.

Category	Amount to be charged	Import period
319	¹ 134,300	Jan. 1, 1987-Mar. 28, 1987.
637	² 5,000	Jan. 1, 1987-April 22, 1987.
650	² 800	Jan. 1, 1987-Jan. 31, 1987.
659-S	-0-	Jan. 1, 1987-April 22, 1987.

¹ Square yards.

² Dozen.

The limits set forth above are subject to adjustment in the future according to the provisions of the bilateral agreement of August 19, 1983, as amended, which provide, in part, that: (1) Certain specific limits may be exceeded by not more than 5 percent of its square yard equivalent total, provided that the amount of the increase is compensated for by an equivalent square yard decrease in one or more other specific limit in that agreement year; (2) subject to consultations, specific limits may be increased for carryover and carryforward up to 10 percent of the applicable category limit in any agreement year according to the terms specified in the agreement; and (3) administrative arrangements or adjustments may be made to resolve minor problems arising in the implementation of the agreement. Any appropriate adjustments under the provisions of the bilateral agreement will be made to you by letter.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the *Federal Register* on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), July 14, 1986 (51 FR 25386), July 29, 1986 (51 FR 27068) and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1986).

In Carrying out the above directions, the Commission of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs

³ The limits have not been adjusted to account for any imports exported after December 31, 1986.

exception to the rule-making provisions of 5 U.S.C. 553 (a)(1).

Sincerely,

Donald R. Foote,

Acting Chairman, Committee for the
Implementation of Textile Agreements.

[FR Doc. 87-8973 Filed 4-20-87; 8:45 am]

BILLING CODE 3510-DR-M

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 87-C0002]

Whirlpool Corp., a Corporation; Provisional Acceptance of a Settlement Agreement

AGENCY: Consumer Product Safety
Commission.

ACTION: Provisional acceptance of a
settlement agreement under the
Consumer Product Safety Act.

SUMMARY: It is the policy of the
Commission to publish settlements
which it provisionally accepts under the
Consumer Product Safety Act in the
Federal Register in accordance with the
terms of 16 CFR 1118.20(e). Published
below is a provisionally-accepted
Settlement Agreement with Whirlpool
Corporation, a corporation.

DATE: Any interested person may ask
the Commission not to accept this
agreement or otherwise comment on its
contents by filing a written request with
the Office of the Secretary by May 6,
1987.

ADDRESS: Persons wishing to comment
on this Settlement Agreement should
send written comments to the Office of
the Secretary, Consumer Product Safety
Commission, Washington, DC 20207.

FOR FURTHER INFORMATION CONTACT:
Leonard H. Goldstein, Directorate for
Compliance and Administrative
Litigation, Consumer Product Safety
Commission, Washington, DC 20207;
telephone (301) 492-6626.

SUPPLEMENTARY INFORMATION:

Dated: April 15, 1987.

Sheldon D. Butts,
Deputy Secretary.

Settlement Agreement and Order

[CPSC Docket No. 87-C0002]

In the matter of Whirlpool Corp., a
corporation.

1. This Settlement Agreement and
Order, entered into between Whirlpool
Corporation, a corporation (hereinafter,
"Whirlpool"), and the staff of the
Consumer Product Safety Commission
(hereinafter, "staff"), is a compromise

resolution of the matter described
herein, without a hearing or
determination of issues of law and fact.

I. The Parties

2. Whirlpool is a corporation
organized and existing under the laws of
the State of Delaware with its principal
corporate offices located at Benton
Harbor, Michigan 49022.

3. Whirlpool has manufactured certain
canister vacuum cleaners, identified
further in paragraph 6 and 7 below
(hereinafter, "canister vacuum
cleaners"), (a) for sale to a consumer for
use in or around a permanent or
temporary household or residence, or (b)
for the personal use, consumption or
enjoyment of a consumer in or around a
permanent or temporary household or
residence. These canister vacuum
cleaners are "consumer products"
within the meaning of section 3(a)(1) of
the Consumer Product Safety Act
(hereinafter, "CPSC"), 15 U.S.C.
2052(a)(1).

4. Whirlpool manufactured and sold
these canister vacuum cleaners to Sears,
Roebuck and Co. (hereinafter, "Sears")
for resale in stores located throughout
the United States. Whirlpool, therefore,
is a "manufacturer" of a "consumer
product" which is "distributed in
commerce," as those terms are defined
in sections 3(a)(1), (4) and (11) of the
CPSC, 15 U.S.C. 2052(a)(1), (4) and (11).

5. The "staff" is the staff of the
Consumer Product Safety Commission,
an independent regulatory agency
established by Congress pursuant to
section 4 of the CPSA, 15 U.S.C. 2053.

II. The Product

6. Whirlpool manufactured
approximately 1,240,000 canister
vacuum cleaners from 1976 through 1983.
Sears sold the vacuum cleaners to
consumers under its "Kenmore" brand
name.

7. The inside compartment of the
canister vacuum cleaner contains a dust
bag, motor filter and motor fan housing.
The motor filter fits directly over the
motor fan housing, and prevents dust
from entering into an air intake opening
at the top of the motor fan housing
(hereinafter, "air intake opening").

III. Staff Allegations of a Defect in the Canister Vacuum Cleaner and of a Failure by Whirlpool To Comply With the Reporting Requirements of Section 15(b) of the CPSA

8. The defect in the canister vacuum
cleaner consists of the potential
accessibility consumers of rotating
motor fan blades contained within the
air intake opening.

9. If the lid of the canister vacuum
cleaner is open for any reason while the
motor is operating, and if a consumer
removes the motor filter and
accidentally inserts a finger or fingers
into the air intake opening, the rotating
motor fan blades within the air intake
opening can cause severe finger
lacerations or amputations.

10. During the period prior to May
1986, when Whirlpool asked the
Commission staff for an advisory
opinion concerning the vacuum cleaners
in question, the company has received
19 reports from consumers alleging
finger lacerations or amputations within
the air intake opening of the canister
vacuum cleaner.

11. In June 1983, Whirlpool placed a
guard over the air intake opening
thereby eliminating the laceration and
amputation hazard as to those canister
vacuum cleaners having a guard.

12. Whirlpool knew or should have
known by June 1983 that the air intake
opening was accessible to users of the
canister vacuum cleaner, and could
cause severe lacerations or amputations
if accessed while the vacuum cleaner
was operating.

13. Whirlpool had received sufficient
information by June 1983 to reasonably
support the conclusion that canister
vacuum cleaners, described in
paragraphs 6 and 7 hereof, contained a
defect which could create a substantial
product hazard, but the company failed
to report such information to the
Commission in a timely manner as
required by section 15(b) of the CPSA,
15 U.S.C. 2064(b).

IV. Allegations of Whirlpool Corp.

14. Whirlpool denies each and all of
the staff allegations with respect to its
canister vacuum cleaners. It further and
specifically denies that its canister
vacuum cleaners contain a defect which
creates or which could create a
substantial product hazard within the
meaning of section 15(a) of the CPSA, 15
U.S.C. 2064(a), and further specifically
denies an obligation to report
information to the Commission under
section 15(b) of the CPSA, 15 U.S.C.
2064(b) with respect to these canister
vacuum cleaners.

V. Agreement of the Parties

15. Whirlpool and the staff agree that
the Commission has jurisdiction in this
matter for purposes of entry and
enforcement of this Settlement
Agreement and Order.

16. Whirlpool agrees to settle the
Commission's claim for a civil penalty
by payment of the amount of \$75,000
within 30 days of final acceptance of

this Settlement Agreement by the Commission and service of the Commission's Order on Whirlpool. This payment is made in settlement of disputed allegations by the staff that Whirlpool violated the reporting requirements of section 15(b) of the CPSA, 15 U.S.C. 2064(b), with regard to canister vacuum cleaners manufactured by Whirlpool between 1976 and 1983. Whirlpool makes no admission of any fault, liability or statutory violation and expressly denies any fault, liability or statutory violation. The Commission does not make any determination that such canister vacuum cleaners described in paragraphs 6 and 7 hereof, contain a defect which could create a substantial product hazard or that a violation of the CPSA has occurred.

17. For purposes of section 6(b) of the CPSA, 15 U.S.C. 2055(b), this matter shall be treated as if a complaint had issued.

18. Upon final acceptance of this Settlement Agreement by the Commission, Whirlpool knowingly, voluntarily and completely waives any rights it may have (1) to an administrative or judicial hearing with respect to the Commission's claim for a civil penalty, (2) to judicial review or other challenge or contest of the validity of the Commission's action with regard to its claim for a civil penalty, (3) to a determination by the Commission as to whether a violation of section 15(b) of the CPSA, 15 U.S.C. 2064(b), has occurred, and (4) to a statement of findings of fact and conclusions of law with regard to the Commission's claim for a civil penalty. By making this waiver, Whirlpool does not concede that its canister vacuum cleaners contain a defect which creates or could create a substantial product hazard within the meaning of section 15(a) of the CPSA, 15 U.S.C. 2064(a).

19. Upon final acceptance of this Settlement Agreement and Order by the Commission and payment of the \$75,000 settlement amount by Whirlpool, the Commission agrees to waive its right to pursue any penalty proceeding for a violation of section 15(b) of the CPSA, 15 U.S.C. 2064(b), relating to the matters encompassed by this Settlement Agreement and Order.

20. Upon provisional acceptance of this Settlement Agreement and Order by the Commission, this Settlement Agreement and Order shall be placed on the public record and shall be published in the *Federal Register* in accordance with the procedure set forth in 15 CFR 1118.20(e). If the Commission does not receive any written request not to accept the Settlement agreement and Order within 15 days, the Settlement

Agreement and Order will be deemed finally accepted on the 16th day after the date it is published in the *Federal Register*, in accordance with 16 CFR 1118.20(f).

21. The parties further agree that the incorporated Order be issued under the CPSA, 15 U.S.C. 2051 *et seq.*, and that a violation of the Order will subject Whirlpool to appropriate legal action.

22. No agreement, understanding, representation, or interpretation not contained in this Settlement Agreement and Order may be used to vary or to contradict its terms.

Whirlpool Corporation.

Dated: March 6, 1987.

By:

Stephen E. Upton,
Senior Vice President, Corporate
Communications, Education and Government
Affairs.

Dated: April 15, 1987.

Consented to by:

David Schmeltzer,
Associate Executive Director, Directorate for
Compliance and Administrative
Litigation.

Order

Upon consideration of the Settlement Agreement of the parties, it is hereby

Ordered that Whirlpool Corporation shall pay within 30 days of final acceptance of this Settlement Agreement and service of this Order, a civil penalty in the sum of \$75,000 to the Consumer Product Safety Commission.

Provisionally accepted on the 15th day of April, 1987.

By Order of the Commission.

Sayde E. Dunn,
Secretary, Consumer Product Safety
Commission.

[FR Doc. 87-8876 Filed 4-20-87; 8:45 am]

BILLING CODE 6355-01-M

COPYRIGHT ROYALTY TRIBUNAL

[Docket No. CRT 87-2-85CD]

Commencing 1985 Cable Distribution Proceeding and Setting Certain Procedural Dates

AGENCY: Copyright Royalty Tribunal.

ACTION: Notice of commencement of proceeding; Notice of certain procedural dates.

SUMMARY: The Copyright Royalty Tribunal announces that a controversy exists regarding the distribution of the royalties paid by cable operators for the calendar year 1985. The Tribunal also announces certain procedures and an

initial schedule which will govern the 1985 cable distribution proceeding.

DATES: The 1985 cable distribution controversy is declared as of April 22, 1987. Parties shall submit prehearing statements June 1, 1987. Written direct cases shall be submitted for Phase I on June 22, 1987.

FOR FURTHER INFORMATION CONTACT: Robert Cassler, General Counsel, Copyright Royalty Tribunal, 1111 20th Street NW., Suite 450, Washington, DC 20036, (202) 653-5175.

SUPPLEMENTARY INFORMATION: On January 13, 1987, the Copyright Royalty Tribunal (Tribunal) solicited public comments as to whether a controversy exists concerning distribution of the 1985 cable copyright royalty fees. 52 FR 1373. Comments were initially due March 2, 1987, but by Order dated February 27, 1987, the Tribunal extended the comment period to April 1, 1987. Based upon the written comments, the Tribunal concludes that a controversy exists as to the distribution of the 1985 cable copyright royalty fees, both in Phase I and in Phase II of the proceeding, effective April 22, 1987.

The Tribunal will initiate a proceeding to determine the proper distribution of the 1985 cable fund. The procedures for the proceeding will be the same as those governing the 1983 and 1984 cable distribution proceedings. See, *Notice of Commencement of Proceeding; Notice of Adoption of Procedures*, 50 FR 13845 (April 8, 1985).

The initial schedule for the 1985 cable distribution proceeding is as follows:

June 1, 1987—Parties submit Prehearing Statements. The statement shall include (1) Notice of intent to Participate in Phase I, Phase II or both; (2) A brief description of the nature of the works for which claims are made; (3) Identification of Phase I categories against which any Phase II claims are asserted; and (4) Identification of parties encompassed within a claimant group.

June 22, 1987—Parties exchange and file with the Tribunal their written direct cases in Phase I.

The Tribunal expects that settlement negotiations will continue during this period, and that it and all affected parties will be informed immediately of any successful conclusion of negotiations. Further procedural dates will be issued by Order to the parties involved.

Dated: April 16, 1987.

J.C. Argetsinger,
Chairman.

[FR Doc. 87-8884 Filed 4-20-87; 8:45 am]

BILLING CODE 1410-09-M

DEPARTMENT OF DEFENSE**Department of the Air Force****USAF Scientific Advisory Board; Meeting**

April 15, 1987.

The meeting location for the USAF Scientific Advisory Board Ad Hoc Committee on Airships, announced in Federal Register 52 FR 11529, has changed. The USAF Scientific Advisory Board Ad Hoc Committee on Airships will now meet on May 6th and 7th, 1987. All other information remains the same.

This meeting will involve discussions of classified defense matters listed in section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202-697-4811.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 87-8891 Filed 4-20-87; 8:45 am]

BILLING CODE 3910-01-M

DEPARTMENT OF ENERGY**International Research Center for Energy Economic Development Energy Conferences; Solicitation for a Grant Application**

AGENCY: Department of Energy (DOE).

ACTION: Notice of solicitation for a grant application.

SUMMARY: DOE announces that it is conducting negotiations with the International Research Center for Energy Economic Development (ICEED) to support the conduct of two international energy conferences. These negotiations are expected to result in the renewal of Grant No. DE-FG01-86IE10538 in which DOE will provide \$23,000 of the total estimated cost of \$136,828 for the performance period of fourteen months estimated to begin April 21, 1987.

Scope of Study: The grant will provide assistance for two international conferences. The first conference, "Issues in the Canadian-U.S. Energy Relationship", will discuss such topics as; interaction of Canadian and U.S. energy policies, U.S. petroleum industry in Canada, imports of Canadian natural gas by the United States, the role of the electric power sector, revival of the

concept of North American energy market, and energy in the Canadian-U.S. trade relationship. The second conference, "Managing Energy Uncertainty", will examine the impact of the December 1986 OPEC production agreement on the petroleum industries of various nations, the fate of netback arrangements, the effects of the new pricing system on Japan, rising U.S. Congressional protectionist attitudes, the \$18 price level and downstream operations, Pacific Basin energy trade patterns, methods to reduce downside risks, increasing cost advantages and efficiency in production, and changes in exploration and production levels.

Dated: April 16, 1987.

Stephan J. Michelsen,

Contract Operations Division "B", Office of Procurement Operations.

[FR Doc. 87-9138 Filed 4-20-87; 11:38 am]

BILLING CODE 6450-01-M

Announcement of Extension of Comment Period on the Draft Environmental Impact Statement for Remedial Action at the Weldon Spring Site

The Department of Energy (DOE) published an announcement of availability of a draft environmental impact statement (DOE/EIS-117D), Remedial Action at the Weldon Spring Site on March 9, 1987 (52 FR 7190). Written comments were requested by April 20, 1987. As a result of a request from the Environmental Protection Agency, Region VII, dated April 15, 1987, the DOE has decided to extend the comment period for the draft EIS until May 5, 1987. Written comments should be received by May 5, 1987 in order to ensure consideration in preparation of the final EIS. Comments received after that date will be considered to the extent practicable.

For further information, contact: Rodney R. Nelson, U.S. Department of Energy, Weldon Spring Site Remedial Action Office, Route 2, Highway 94, South, St. Charles, Missouri 63303, telephone: (314) 441-8978.

Issued at Washington, DC April 17, 1987.

Grover A. Smithwick,

Principal Deputy Assistant Secretary, Environment, Safety and Health.

[FR Doc. 87-9142 Filed 4-20-87; 11:43 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

[Docket No. ERA C&E-87-48; OFP Case No. 61071-9366-20-22]

Acceptance of Petition for Exemption and Availability of Certification by City of Anaheim, CA

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of acceptance.

SUMMARY: On March 30, 1987, City of Anaheim, California (Anaheim or petitioner) filed a petition with the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) requesting a permanent exemption from the provisions of the Powerplant and Industrial Fuel Use Act of 1978 ("FUA" or "the Act") (42 U.S.C. 8301, *et seq.*) for a peakload powerplant to be located in Anaheim, California.

Title II of the Act prohibits the use of petroleum or natural gas as a primary energy source in a new powerplant and prohibits the construction of any such facility without the capability to use an alternate fuel as a primary energy source. The exemption petition was based on peakload. Final rules containing the criteria and procedures for petitioning for exemptions from the prohibitions of Title II of FUA are found in 10 CFR Parts 500, 501, and 503. Final rules setting forth criteria and procedures are found at 10 CFR 503.41.

ERA has determined that the petition appears to include sufficient evidence to support an ERA determination on the exemption request and it is therefore accepted pursuant to 10 CFR 501.3. A review of the petition is provided in the **SUPPLEMENTARY INFORMATION** section below.

As provided for in sections 701 (c) and (d) of FUA and 10 CFR 501.31 and 501.33, interested persons are invited to submit written comments in regard to this petition and any interested person may submit a written request that ERA convene a public hearing.

The public file containing a copy of this Notice of Acceptance and Availability of Certification as well as other documents and supporting materials on this proceeding is available upon request through DOE, Freedom of Information Reading Room, 1000 Independence Avenue, SW., Room 1E-190, Washington DC 20585, from 9:00 a.m. to 4:00 p.m., Monday through Friday, except Federal holidays.

ERA will issue a final order granting or denying the petition for exemption

from the prohibitions of the Act within six months after the end of the period for public comment and hearing, unless ERA extends such period. Notice of any such extension, together with a statement of reasons therefor, would be published in the **Federal Register**.

DATES: Written comments are due on or before June 5, 1987. A request for a public hearing must be made within this same 45-day period.

ADDRESSES: Fifteen copies of written comments or a request for a public hearing shall be submitted to: Case Control Unit, Office of Fuels Programs, Room GA-093, Forrestal Building, 1000 Independence Ave., SW., Washington, DC 20585.

Docket No. ERA C&E-87-48 should be printed on the outside of the envelope and the document contained therein.

FOR FURTHER INFORMATION CONTACT:

Myra Couch, Coal and Electricity Division, Office of Fuels Programs, Economic Regulatory Administration, 1000 Independence Avenue, SW., Room GA-093, Washington DC 20585, Telephone (202) 586-6769

Steven E Ferguson, Esq., Office of General Counsel, Department of Energy, Room 6A-113, 1000 Independence Avenue, SW., Washington, DC 20585, Telephone (202) 586-6947

SUPPLEMENTARY INFORMATION: The peakload facility will consist of a 45 MW combustion turbine and auxiliary equipment.

Under the requirements of 10 CFR 503.41(a)(2)(ii), if a petitioner proposes to use natural gas or to construct a powerplant to use natural gas in lieu of an alternate fuel as a primary energy source, the Administrator of the Environmental Protection Agency or the director of the appropriate state air pollution control agency must certify to ERA that the use by the powerplant of any available alternate fuel as a primary energy source will cause or contribute to a concentration, in an air quality control region or any area within the region, of a pollutant for which any national air quality standard is or would be exceeded. However, since ERA has determined that there are no presently available alternate fuels which may be used in the proposed powerplant, no such certification can be made. The certification requirement is therefore waived with respect to the petitioner's petition.

The petitioner submitted a certified statement by a duly authorized officer to the effect that the proposed oil and/or gas-fired combustion turbine generators will be operated as a peakload powerplant.

On February 23, 1982, DOE published in the **Federal Register** (47 FR 7676) a notice of the amendment to its guidelines for compliance with the National Environmental Policy Act of 1969 (NEPA). Pursuant to the amended guidelines, the grant or denial of certain FUA permanent exemptions, is among the classes of actions that DOE has categorically excluded from the requirement to prepare an Environmental Impact Statement or an Environmental Assessment pursuant to NEPA (categorical exclusion).

This classification raises a rebuttable presumption that the grant or denial of the exemption will not significantly affect the quality of the human environment. The petitioner has certified that it will secure all applicable permits and approvals prior to commencement of operation of the new unit under exemption.

DOE's Office of Environment, in consultation with the Office of General Counsel, will review the completed environmental checklist submitted by the petitioner pursuant to 10 CFR 503.13, together with other relevant information. Unless it appears during the proceeding on the petitioner's petition that the grant or denial of exemption will significantly affect the quality of the human environment, it is expected that no additional environmental review will be required.

As provided in 10 CFR 501.3(b)(4), the acceptance of the petition by ERA does not constitute a determination that the petitioner is entitled to the exemption requested. That determination will be made on the basis of the entire record of these proceedings, including any comments received in response to this document.

Issued in Washington, DC, on April 13, 1987.

Robert L. Davies,

Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 87-8885 Filed 4-20-87; 8:45 am]

BILLING CODE 6450-01-M

Energy Information Administration

Publication of Alternative Fuel Price Ceilings and Incremental Price Threshold for High Cost Natural Gas

The Natural Gas Policy Act of 1978 (NGPA) (Pub. L. 95-621) signed into law on November 9, 1978, mandated a new framework for the regulation of most facets of the natural gas industry. In general, under Title II of the NGPA, interstate natural gas pipeline companies are required to pass through certain portions of their acquisition

costs for natural gas to industrial users in the form of a surcharge. The statute requires that the ultimate costs of gas to the industrial facility should not exceed the cost of fuel oil which the facility could use as an alternative.

Pursuant to Title II of the NGPA, section 204(e), the Energy Information Administration (EIA) herewith publishes for the Federal Energy Regulatory Commission (FERC) computed natural gas ceiling prices and the high cost gas incremental pricing threshold which are to be effective May 1, 1987. These prices are based on the prices of alternative fuels.

For further information contact: Leroy Brown, Jr., Department of Energy Energy, Information Administration, 1000 Independence Avenue, S.W., Room BE-034, Washington, DC 20585, Telephone: (202) 586-6077.

Section I

As required by FERC Order No. 50, computed prices are shown for the 48 contiguous States. The District of Columbia's ceiling is included with the ceiling for the State of Maryland. FERC, by an Interim Rule issued on April 2, 1981, in Docket No. RM79-21, revised the methodology for calculating the monthly alternative fuel price ceilings for State regions. Under the revised methodology, the applicable alternative fuel price ceiling published for each of the contiguous States shall be the lower of the alternative fuel price ceiling for the State or the alternative fuel price ceiling for the multistate region in which the State is located.

The price ceiling is expressed in dollars per million British Thermal Units (BTU's). The method used to determine the price ceilings is described in Section III.

	<i>Per million BTU's</i>
State:	
Alabama.....	\$2.06
Arizona ¹	2.13
Arkansas ¹	2.65
California ¹	2.13
Colorado ²	2.12
Connecticut ¹	2.21
Delaware ¹	2.29
Florida.....	2.16
Georgia.....	2.30
Idaho ²	2.12
Illinois.....	1.90
Indiana.....	2.02
Iowa ¹	1.93
Kansas ¹	1.93
Kentucky ¹	2.09
Louisiana.....	2.64
Maine.....	2.19
Maryland ¹	2.29
Massachusetts.....	2.18
Michigan ¹	2.09
Minnesota.....	1.84

	Per million BTU's
Mississippi.....	2.29
Missouri ¹	1.93
Montana ²	2.12
Nebraska ¹	1.93
Nevada ¹	2.13
New Hampshire ¹	2.21
New Jersey ¹	2.29
New Mexico ¹	2.65
New York.....	2.24
North Carolina ¹	2.33
North Dakota ¹	1.93
Ohio.....	2.06
Oklahoma ¹	2.65
Oregon.....	2.01
Pennsylvania ¹	2.29
Rhode Island ¹	2.21
South Carolina ¹	2.33
South Dakota ¹	1.93
Tennessee ¹	2.33
Texas.....	2.55
Utah ²	2.12
Vermont ¹	2.21
Virginia.....	2.21
Washington.....	2.07
West Virginia ¹	2.09
Wisconsin ¹	2.09
Wyoming ²	2.12

¹ Region based price as required by FERC Interim Rule, issued on April 2, 1981, in Docket No. RM-79-21.

² Region based price computed as the weighted average price of Regions E, F, G and H.

Section II.—Incremental Pricing Threshold for High Cost Natural Gas

The EIA has determined that the volume-weighted average price for No. 2 distillate fuel oil landed in the greater New York City Metropolitan area during February 1987 was \$19.72 per barrel. The EIA has implemented a procedure to partially compensate for the two-month lag between the end of the month for which data are collected and the beginning of the month for which the incremental pricing threshold becomes effective. The prices found in *Platt's Oilgram Price Report* are given for each trading day in the form of high and low prices for No. 2 fuel oil in Metropolitan New York and Northern New Jersey. A lag adjustment factor was calculated using the average of the low posted price for these two areas for the ten trading days ending April 14, 1987, and dividing that price by the corresponding average price computed from prices published by *Platt's* for the month of February 1987. This lag adjustment factor was applied to the February price yielding \$19.83 per barrel. In order to establish the incremental pricing threshold for high cost natural gas, as identified in the NGPA, Title II, section 203(a)(7), this price was multiplied by 1.3 and converted to its equivalent in

millions of BTU's by dividing by 5.8. Therefore, the incremental pricing threshold for high cost natural gas, effective May 1, 1987, is \$4.45 per million BTU's.

Section III.—Method Used to Compute Price Ceilings

The FERC, by Order No. 50, issued on September 29, 1979, in Docket No. RM79-21, established the basis for determining the price ceilings required by the NGPA. FERC also, by Order No. 167, issued in Docket No. RM81-27 on July 24, 1981, made permanent the rule that established that only the price paid for No. 6 high sulfur content residual fuel oil would be used to determine the price ceilings. In addition, the FERC, by Order No. 181, issued on November 6, 1981, in Docket No. RM81-28, established that price ceilings should be published for only the 48 contiguous States on a permanent basis.

A. Data Collected

The following data were required from all companies identified by the EIA as sellers of No. 6 high sulfur content (greater than 1 percent sulfur content by weight) residual fuel oil: For each selling price, the number of gallons sold to large industrial users in the months of December 1986, January 1987, and February 1987.³ All reports of volume sold and price were identified by the State into which the oil was sold.

B. Method Used to Determine Alternative Price Ceilings

(1) Calculation of Volume-Weighted Average Price

The prices which will become effective May 1, 1987, (shown in Section I) are based on the reported price of No. 6 high sulfur content residual fuel oil, for each of the 48 contiguous States, for each of the 3 months, December 1986, January 1987, and February 1987. Reported prices for sales in December 1986 were adjusted by the percent change in the nationwide volume-weighted average price from December 1986 to February 1987. Prices for January 1987 were similarly adjusted by the percent change in the nationwide volume-weighted average price from January 1987 to February 1987. The volume-weighted 3-month average of the adjusted December 1986 and January 1987, and the reported February 1987

³ Large Industrial User—A person/firm which purchases No. 6 fuel oil in quantities of 4,000 gallons or greater for consumption in a business, including the space heating of the business premises. Electric Utilities, governmental bodies (Federal, State, and Local), and the military are excluded.

prices were then computed for each State.

(2) Adjustment for Price Variation

States were grouped into the regions identified by the FERC (see Section III.C). Using the adjusted prices and associated prices and associated volumes reported in a region during the 3-month period, the volume-weighted standard deviation of prices was calculated for each region. The volume-weighted 3-month average price (as calculated in Section III.B.(1) above) for each State was adjusted downward by two times this standard deviation for the region to form the adjusted weighted average price for the State.

(3) Calculation of Ceiling Price

The lowest selling price within the State was determined for each month of the 3-month period (after adjusting up or down by the percent change in oil prices at the national level as discussed in Section III.B(1) above). The products of the adjusted low price for each month times the State's total reported sales volume for each month were summed over the 3-month period for each State and divided by the State's total sales volume during the 3 months to determine the State's average low price. The adjusted weighted average price (as calculated in Section III.B.(2)) was compared to this average low price, and the higher of the values was selected as the base for determining the alternative fuel price ceiling for each State. For those States which had no reported sales during one or more months of the 3-month period, the appropriate regional volume-weighted alternative fuel price was computed and used in combination with the available State data to calculate the State alternative fuel price ceiling base. The State's alternative fuel price ceiling base was compared to the alternative fuel price ceiling base for the multistate region in which the State is located and the lower of these two prices was selected as the final alternative fuel price ceiling base for the State. The appropriate lag adjustment factor (as discussed in Section III.B.4) was then applied to the alternative fuel price ceiling base. The alternative fuel price (expressed in dollars per gallon) was multiplied by 42 and divided by 6.3 to estimate the alternative fuel price ceiling for the State (expressed in dollars per million BTU's).

There were insufficient sales reported in Region G for the months of December 1986, January 1987, and February 1987. The alternative fuel price ceilings for the States in Region G were determined by calculating the volume-weighted

average price ceilings for Region E, Region F, Region G, and Region H.

(4) Lag Adjustment

The EIA has implemented a procedure to partially compensate for the two-month lag between the end of the month for which data are collected and the beginning of the month for which ceiling prices become effective. It was determined that *Platt's Oilgram Price Report* provides timely information relative to the subject. The prices found in *Platt's Oilgram Price Report* are given for each trading day in the form of high and low prices for No. 6 residual oil in 19 cities throughout the United States. The low posted prices for No. 6 residual oil in these cities were used to calculate a national and a regional lag adjustment factor. The national lag adjustment factor was obtained by calculating a weighted average price for No. 6 high sulfur residual fuel oil for the ten trading days ending April 14, 1987, and dividing that price by the corresponding weighted average price computed from prices published by Platt's for the month of February 1987. A regional lag adjustment factor was similarly calculated for four regions. There are: One for FERC Regions A and B combined; one for FERC Region C; one for FERC Regions D, E, and G combined; and one for FERC Regions F and H combined. The lower of the national or regional lag factor was then applied to the alternative fuel price ceiling for each State in a given region as calculated in Section III.B.(3).

Listing of States by Region

States were grouped by the FERC to form eight distinct regions as follows:

Region A: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Region B: Delaware, Maryland, New Jersey, New York, Pennsylvania.

Region C: Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, Tennessee, Virginia.

Region D: Illinois, Indiana, Kentucky, Michigan, Ohio, West Virginia, Wisconsin.

Region E: Iowa, Kansas, Missouri, Minnesota, Nebraska, North Dakota, South Dakota.

Region F: Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Region G: Colorado, Idaho, Montana, Utah, Wyoming.

Region H: Arizona, California, Nevada, Oregon, Washington.

Issued in Washington, DC, April 17, 1987.

L.A. Pettis,

Deputy Administrator, Energy Information Administration.

[FR Doc. 87-9004 Filed 4-20-87; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. RP87-55-000]

Columbia Gas Transmission Corp.; Proposed Changes in FERC Gas Tariff

April 15, 1987.

Take notice that on April 10, 1987, Columbia Gas Transmission Corporation (Columbia) tendered for filing One Hundred and Seventeenth Revised Sheet No. 16 to its FERC Gas Tariff, Original Volume No. 1, to be effective April 1, 1987. The revised tariff sheet reflects an adjustment to Columbia's current non-gas commodity sales rates effective April 1, 1987 to recognize the amortization of certain costs incurred by Columbia to reform its high-cost contracts with certain Southwest producers. Columbia proposes an annual amortization of such costs of \$79,153,545, which results in an impact on Columbia's non-gas commodity sales rate of 15.74¢ per Dth.

The instant filing is contingent upon Commission action on Columbia's April 6, 1987 Request for Rehearing of the Commission's March 30, 1987 order issued in Dockets Nos. TA87-4-21, *et al.* In the underlying PGA filing in that docket, Columbia had included \$18,092,620 in its projected current cost of gas representing the amortization of the aforementioned contract reformation costs for the subject PGA period (April 1, 1987 through August 31, 1987). The Commission's March 30 order rejected the inclusion of the \$18,092,620 in the cost of purchased gas without prejudice to Columbia filing to collect such costs, on a prospective basis, in a proceeding pursuant to section 4 of the Natural Gas Act. Columbia's Request for Rehearing asked the Commission, *inter alia*, to permit recovery of those contract reformation costs as gas costs, or alternatively, to consolidate such filing with Columbia's general rate filing in Docket No. RP86-168, and permit Columbia to recover the subject contract reformation costs effective April 1, 1987, subject to refund. In the event the Commission grants rehearing of Columbia's Request in Docket Nos. TA87-4-21, *et al.*, Columbia will withdraw the instant filing.

As support for the cost of service, exclusive of the contract reformation

costs, Columbia incorporates by reference its September 30, 1986 section 4(e) filing in Docket No. RP86-168, *et al.*, as revised by Motion on February 27, 1987, as well as Columbia Gulf Transmission Company's initial and revised filings in Docket No. RP86-167-000.

Pursuant to § 388.110 of the Commission's Regulations, Columbia has requested that the Commission treat certain contract reformation information and data as commercially sensitive and confidential data, the disclosure of which would be harmful to Columbia. Due to the highly confidential and proprietary nature of the information contained in "Confidential Binder A" Columbia submits that access to the contents thereof be limited to parties other than producers and interstate pipelines to this proceeding. Columbia will maintain copies of the Confidential Binder A at its Charleston, West Virginia and Washington, DC offices for parties other than producers and interstate pipelines to review, which will be subject to appropriate protective conditions. Columbia submits that a protective order of the nature of the one issued by the Presiding Judge in Columbia's ongoing section 4 rate case in Docket No. RP86-168, *et al.* would be appropriate.

Columbia requested such waivers of the Commission's Regulations as may be necessary to make the instant filing, subject to refund, effective April 1, 1987.

Copies of the filing, exclusive of Confidential Binder A, were served by Columbia upon each of its jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, Union Center Plaza Building, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 22, 1987. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing, exclusive of Confidential Binder A, are on file with the Commission and are available for public inspection. A copy of this filing,

including Confidential Binder A, is in the non-public file with the Commission.
Kenneth F. Plumb,
Secretary.

[FR Doc. 87-8869 Filed 4-20-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CI87-289-000]

El Paso Production Co. and El Paso Natural Gas Co.; Application for Certificates of Public Convenience and Necessity

April 14, 1987.

Take notice that on February 6, 1987, El Paso Production Company ("Production Company") and El Paso Natural Gas Company ("El Paso") filed with the Commission an Application for Certificates of Public Convenience and Necessity to continue sales of gas to Northwest Pipeline Company ("Northwest") as successors-in-interest to Beta Development Company ("Beta"). They state that El Paso acquired an undivided fifty percent (50%) interest in certain wells and leases owned by Beta, the production from which was sold to Northwest. El Paso subsequently transferred the properties to its subsidiary Production Company which was organized to consolidate the production functions of the company.

El Paso seeks a certificate of public convenience and necessity applicable to the sales made from the properties to Northwest during the interim period before transfer of the properties to Production Company. Production Company seeks a certificate for the continued sales to Northwest. The sales are conducted under the same terms and conditions as applied when Beta was the interest owner, in accordance with orders, rules, and regulations of the Commission.

El Paso acquired from Beta one-half (½) of its leasehold interest in certain wells located in San Juan County, New Mexico by Assignment of Oil and Gas Leases dated September 11, 1983. Beta previously was making sales in interstate commerce of natural gas for resale at these wellheads to Northwest pursuant to the small producer exemption certificate issued at Docket No. CS76-612. Therefore, El Paso is requesting authorization, effective August 19, 1983, and continuing through June 10, 1986, for the continuation of the sale to Northwest of natural gas produced from the one-half (½) leasehold interest acquired by El Paso, all as more fully set forth in the application. The natural gas produced from those leasehold interests continued to be sold under the same terms and

conditions as applied when Beta held the interests.

Effective July 1, 1986, El Paso transferred its interest in the Beta properties to Production Company by Conveyance dated July 16, 1986. Thus, effective July 1, 1986, Production Company requests issuance of a certificate of public convenience and necessity authorizing the continued sale of gas from those properties to Northwest as successor in interest to El Paso.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 27, 1987, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or to be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 87-8870 Filed 4-20-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA87-6-51-000, 001]

Great Lakes Gas Transmission Co.; Tariff Filing

April 14, 1987.

Take notice that Great Lakes Gas Transmission Company (Great Lakes) on April 9, 1987, tendered for filing Sixth-A Revised Sheet Nos. 57(i) and 57(ii) and Substitute Seventh Revised Sheet Nos. 57(i) and 57(ii) to its FERC Gas Tariff, First Revised Volume No. 1.

Sixth-A Revised Sheet Nos. 57(i) and 57(ii) reflect changes in the gas purchased prices applicable to Northern Minnesota Utilities ("NMU"), the abovementioned filing reflects a significant price decrease in the purchased gas component of the commodity charge for deliveries within contract demand from \$1.80774 to \$1.60 per MMBtu and a reduction in the purchased gas component of the overrun rate from \$1.60 to \$1.56 per MMBtu for the month of April, 1987. These gas

purchase price changes result from recent negotiations between TransCanada Pipelines Limited ("TransCanada") and NMU, which Great Lakes is hereby implementing. NMU and TransCanada have agreed that the commodity charges for gas purchased by NMU will be negotiated on a monthly basis and that if such negotiations are unsuccessful, the prices under the pre-existing contractual arrangements that would have become effective except for these new contractual arrangements, would become effective on the first day of the month for which the new price negotiations are unsuccessful. These arrangements have been reflected in an amendment dated March 25, 1987 to the Gas Purchase Contract between TransCanada and Great Lakes dated October 9, 1970.

On March 30, 1987, Great Lakes filed Seventh Revised Sheet Nos. 57(i) and 57(ii) to be effective May 1, 1987 which reflects its semi-annual change in the surcharge rate and a PGA adjustment to reflect the gas purchase costs at the time of the filing. Therefore, Great Lakes has also filed six copies of Substitute Seventh Revised Sheet Nos. 57(i) and 57(ii), to be effective May 1, 1987, which reflect the gas purchase price changes for NMU resulting from the filing herewith.

Great Lakes requests waiver of the 30 day notice requirement of the Commission's Regulations and any other necessary waivers so as to permit the above mentioned tariff sheets to become effective as requested.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211). All such motions or protests should be filed on or before April 21, 1987. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 87-8871 Filed 4-20-87; 8:45]

BILLING CODE 6717-01-M

[Docket No. RP84-13-004]

**Michigan Consolidated Gas Co.,
Interstate Storage Division; Proposed
Changes in FERC Gas Tariff**

April 14, 1987.

Take notice that on April 2, 1987, Michigan Consolidated Gas Company—Interstate Storage Division (ISD) tendered for filing proposed changes to the following tariff sheets in its FERC Gas Tariff, Original Volume No. 1, Original Volume No. 2 and Original Volume No. 3:

	Rate schedule
Original Volume No. 1:	
Sixth Revised Sheet Nos. 63 & 64	X-7
Sixth Revised Sheet Nos. 87 & 94	X-9
Sixth Revised Sheet Nos. 110 & 111	X-11
Sixth Revised Sheet Nos. 132 & 139	X-13
Sixth Revised Sheet Nos. 155 & 162	X-15
Tenth Revised Sheet No. 192	X-19
Eighth Revised Sheet No. 193	X-19
Ninth Revised Sheet No. 216	X-20
Seventh Revised Sheet No. 217	X-20
First Revised Sheet No. 282	X-20-1
First Revised Sheet No. 283	X-20-1
Original Volume No. 2:	
Fifth Revised Sheet Nos. 6 & 7	X-23
Fifth Revised Sheet No. 29	X-23
Fifth Revised Sheet No. 30	X-24
Fifth Revised Sheet Nos. 51 & 52	X-25
Fifth Revised Sheet Nos. 73 & 74	X-26
Fifth Revised Sheet No. 96	X-27
Fifth Revised Sheet Nos. 117 & 118	X-28
Fourth Revised Sheet No. 154	X-30
Original Volume No. 3:	
Second Revised Sheet No. 2	S-1, S-2, S-3, S-4, S-5, S-6,

The proposed changes reflect a decrease of \$2,607,240 in the cost of service that underlies ISD's presently effective rates.

ISD states that the proposed rate reduction is required by Article V of the Stipulation and Agreement in Docket No. RP84-13-000, which was accepted and approved by the Commission in its letter order dated January 11, 1985. Article V requires ISD to make an appropriate rate filing if the Federal income tax rate (46%) upon which ISD's rates are predicated is increased or decreased. The Tax Reform Act of 1986 reduces the Federal corporate income tax rate to 34%, effective July 1, 1987. Consequently, the Federal income tax amount embodied in ISD's cost of service is to be reduced by \$2,607,240. This amount is calculated pursuant to Article V by multiplying \$217,270 times each 1 percent change in Federal corporate income tax rate.

ISD requests that this proposed rate reduction become effective on July 1, 1987, which is the effective date of the new Federal corporate income tax rate

and thus the effective date required by Article V. ISD states that copies of its filing have been served upon its customers and the Michigan Public Service Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such motions of protests should be filed on or before April 21, 1987. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 87-8872 Filed 4-20-87; 8:45 am]

BILLING CODE 6717-01-M

FARM CREDIT ADMINISTRATION**Performance Review Board;
Designation of Members**

AGENCY: Farm Credit Administration.

ACTION: Notice.

SUMMARY: In accordance with the provisions in Title 5, U.S.C. 4314(c)(4), the Farm Credit Administration hereby publishes the names of the executives who are designated as members of the Agency's Performance Review Board. The members of the Board are as follows:

1. Francis J. Boyd, Jr.
2. David C. Baer.
3. Frederick R. Medero.
4. Larry W. Edwards.
5. Thomas G. McKenzie.
6. Dennis L. Barringer.
7. Michael J. Powers.
8. George D. Irwin.
9. Harold D. Schuler.
10. Paul C. Redmer.
11. Eldon W. Stoehr.

William A. Sanders, Jr.,

Secretary, Farm Credit Administration Board.

[FR Doc. 87-8900 Filed 4-20-87; 8:45 am]

BILLING CODE 6705-01-M

FEDERAL HOME LOAN BANK BOARD

[No. AC-593]

**The Cumberland Federal Savings and
Loan Association, Louisville, KY; Final
Action Approval of Conversion
Application**

Dated: April 8, 1987.

Notice is hereby given that on April 2, 1987, the Office of General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of The Cumberland Federal Savings and Loan Association, Louisville, Kentucky for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Office of Secretariat at the Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, and at the Office of the Supervisory Agent at the Federal Home Loan Bank of Cincinnati, 2000 Atrium Two, Cincinnati, Ohio 45202.

By the Federal Home Loan Bank Board.

Jeff Sconyers,*Secretary.*

[FR Doc. 87-8856 Filed 4-20-87; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-591]

**Maryland Federal Savings and Loan
Association, Hyattsville, MD; Final
Action Approval of Conversion
Application**

Dated: April 8, 1987.

Notice is hereby given that on March 26, 1987, the Office of General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of Maryland Federal Savings and Loan Association, Hyattsville, Maryland for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Office of the Secretariat at the Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, and at the Office of the Supervisory Agent at the Federal Home Loan Bank of Atlanta, 1475 Peachtree Street, NE., Atlanta, Georgia 30309.

By the Federal Home Loan Bank Board.

Jeff Sconyers,*Secretary.*

[FR Doc. 87-8857 Filed 4-20-87; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-592]

Washington Federal Savings and Loan Association, Washington, D.C.; Final Action Approval of Conversion Application

Dated: April 8, 1987.

Notice is hereby given that on April 2, 1987, the Office of General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of Washington Federal Savings and Loan Association, Washington, DC for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Secretariat of said Corporation, 1700 G Street, NW., Washington, DC 20552, and at the Office of the Supervisory Agent of said Corporation at the Federal Home Loan Bank of Atlanta, P.O. Box 105565, Atlanta, Georgia 30348.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 87-8858 Filed 4-20-87; 8:45 am]

BILLING CODE 6720-01-M

[No. 87-463]

Application for Unlisted Trading Privileges and Opportunity for Hearing Cincinnati Stock Exchange

Dated: April 16, 1987.

AGENCY: Federal Home Loan Bank Board.**ACTION:** Notice.

SUMMARY: The Cincinnati Stock Exchange has filed, pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1, an application with the Federal Home Loan Bank Board ("Board") for Unlisted trading privileges in the following securities: Home Federal Savings and Loan Association, San Diego, California (FHLBB No. 3143), Common Stock, \$0.01 Par Value.

These securities are listed and registered on one or more other national securities exchanges and are reported in the consolidated transaction reporting system.

Comments: Any interested person may inspect the application at the Board, and, within 15 days of publication of this notice in the **Federal Register**, submit to the Corporate and Securities Division, Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, written data, views and

arguments bearing upon whether the extensions of unlisted trading privileges pursuant to such application are consistent with the maintenance of fair and orderly markets and the protection of investors. Following this opportunity for hearing, the Board will approve the application after the date mentioned above if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such application are consistent with the maintenance of fair and orderly markets and the protection of investors.

FOR FURTHER INFORMATION CONTACT:

John P. Harootunian, Assistant General Counsel for Securities Policy, Corporate and Securities Division, Office of General Counsel, at (202-377-6415) or at the above address.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 87-8897 Filed 4-20-87; 8:45 am]

BILLING CODE 6720-01-M

Southern Floridabanc Savings Association, Boca Raton, FL; Appointment of Receiver

Notice is hereby given that pursuant to the authority contained in section 406(c)(2) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(2) (1982), the Federal Home Loan Bank Board appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Southern Floridabanc Savings Association, Boca Raton, Florida, on April 16, 1987.

Dated: April 16, 1987.

Jeff Sconyers,

Secretary.

[FR Doc. 87-8923 Filed 4-20-87; 8:45 am]

BILLING CODE 6720-01-M

Southern Floridabanc Savings Association, Boca Raton, FL; Appointment of Receiver

Notice is hereby given that the Circuit Court of the State of Florida for the County of West Palm Beach has confirmed the appointment by the Comptroller of the State of Florida ("Florida") of a receiver for Southern Floridabanc Savings Association, Boca Raton, Florida ("Southern Floridabanc"), and that pursuant to the authority contained in section 406(c)(1) of the National Housing Act, as amended (12 U.S.C. 1729(c)(1) (1982), the Federal Savings and Loan Insurance Corporation accepted the tender of the Comptroller of the appointment as

receiver for Southern Floridabanc, for the purpose of liquidation, effective April 16, 1987.

Dated: April 16, 1987.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary

[FR Doc. 87-8924 Filed 4-20-87; 8:45 am]

BILLING CODE 6720-01-M

FEDERAL MARITIME COMMISSION**Agreement(s) Filed**

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-007690-020

Title: The India, Pakistan, Bangladesh, Ceylon & Burma Outward Freight Conference

Parties:

The Scindia Steam Navigation Co., Ltd.

The Shipping Corporation of India, Ltd.

Waterman Isthmian Line

Synopsis: The proposed amendment would increase the conference admission fee from \$5,000 to \$25,000. The parties have requested a shortened review period.

Agreement No: 202-010656-019

Title: North Europe-U.S. Gulf Freight Association

Parties:

Compagnie Generale Maritime (CGM)

Lykes Bros. Steamship Company, Inc.

Gulf Container Line (GCL), B.V. (GCL)

Sea-Land Service, Inc.

Hapag-Lloyd AG

Trans Freight Lines

Nedlloyd Lijnen, B.V.

Synopsis: The proposed amendment would permit the continued independent operations in the agreement trade of Wallenius Line (a carrier associated with GCL) or

any other carrier organized under the terms of Agreement No. 207-009498 with respect to vehicular and non-containerizable cargo as described in Agreement No. 202-010656.

By Order of the Federal Maritime Commission.

Dated: April 16, 1987.

Joseph C. Polking,

Secretary.

[FR Doc. 87-8896 Filed 4-20-87; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The noticants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 6, 1987.

A. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Bank of Philadelphia Employee Stock Ownership Stock Bonus Plan and Trust*, Philadelphia, Mississippi; to retain 18.6 percent of the voting shares of Philadelphia Capital Corporation, Philadelphia, Mississippi, and thereby retain Bank of Philadelphia, Philadelphia, Mississippi.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. LT Corporation, Inc., James I. Tims, and Robert L. Tims, all of Cleveland, Mississippi; to acquire 51.3 percent of the voting shares of First Bolivar Capital Corporation, Cleveland, Mississippi, and thereby indirectly acquire First National Bank of Bolivar County, Cleveland, Mississippi.

Board of Governors of the Federal Reserve System, April 15, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-8855 Filed 4-20-87; 8:45 am]

BILLING CODE 6210-01-M

Branch Corp. et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments, regarding each of these applications must be received not later than May 13, 1987.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Branch Corporation*, Wilson, North Carolina; to acquire 100 percent of the voting shares of Community Bancorporation, Inc., Greenville, South Carolina, and thereby indirectly acquire Community Bank, Greenville, South Carolina.

2. *Branch Corporation of South Carolina*, Wilson, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of Community Bank, Greenville, South Carolina.

B. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *CB Bancshares, Inc.*, Fort Valley, Georgia; to acquire 100 percent of the voting shares of Cook Banking Company, Cochran, Georgia. Comments

on this application must be received by May 10, 1987.

2. *First National Bancorp*, Gainesville, Georgia; to merge with Banks County Financial Corporation, Homer, Georgia, and thereby indirectly acquire Bank of Banks County, Homer, Georgia.

Comments on this application must be received by May 10, 1987.

3. *Randolph Bancshares, Inc.*, Oxford, Alabama; to become a bank holding company by acquiring 100 percent of the voting shares of Alabanc, Inc., Wadley, Alabama, and thereby indirectly acquire First Bank, Wadley, Alabama.

C. Federal Reserve Bank of Chicago (David S. Epstein, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Illinois Regional Bancorp, Inc.*, Elmhurst, Illinois; to acquire 100 percent of the voting shares of Plum Grove Bancorporation, Inc., Rolling Meadows, Illinois, and thereby indirectly acquire First Commercial Bank of Rolling Meadows, Rolling Meadows, Illinois. Comments on this application must be received by May 7, 1987.

Board of Governors of the Federal Reserve System, April 15, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-8854 Filed 4-20-87; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Cooperative Agreements To Support School Health Education To Prevent the Spread of Acquired Immunodeficiency Syndrome (AIDS); Availability of Funds for Fiscal Year 1987

Introduction

The Centers for Disease Control (CDC) announces the availability of funds for Fiscal Year 1987 for cooperative agreements to support the development and implementation of effective health education about AIDS for youth, school, and college populations (elementary through college-age youth, parents, and relevant school, health, and education personnel). Funds will be available to national private-sector education and health organizations and other national agencies that serve youth. These organizations must be able to help increase the number of schools, colleges, or agencies that serve youths who do not attend school, providing effective AIDS education that is locally

determined, consistent with community values, and appropriate to community needs.

Authorizing Legislation

These programs are authorized under section 301 (a) of the Public Health Service Act (42 U.S.C. 241(a)), as amended, and section 311 (b) and (c) of the Public Health Service Act (42 U.S.C. 243 (b)), as amended. The Catalog of Federal Domestic Assistance Number is 13.118.

Program Background and Objectives

As of 3/2/87, approximately 32,000 cases of AIDS, as defined by the CDC surveillance case definition, had been reported. Although the vast majority of AIDS cases and documented infections have occurred among homosexual and bisexual men and intravenous drug abusers, infection with the AIDS virus is also spreading among heterosexuals (from infected men to women or from infected women to men) and perinatally (from infected mothers to newborn infants).

An estimated 1-1.5 million Americans already are infected and cases resulting from heterosexual transmission of the virus are expected to increase. By the end of 1991, the cumulative total of AIDS cases in the United States is estimated to reach 270,000 with over 179,000 deaths due to AIDS. Because infected persons are capable of spreading the virus to others for years before experiencing signs or symptoms of disease, the Public Health Service (PHS) has recommended major public health education efforts to inform the public, especially youth, school, and college populations, about AIDS and how to prevent becoming infected with the AIDS virus.

Every school day, more than 47 million students attend 90,000 elementary and secondary schools in 15,500 school districts across the Nation. A significant proportion of these students (and youths who do not attend school) may make behavior choices that unknowingly place them at increased risk for contracting and spreading the AIDS virus. These young persons need to be informed about AIDS before making these choices.

The Nation's schools could inform 90-95% of our young people about the increasing number of infected individuals, the fatal nature of the disease, the lack of a preventive vaccine or cure for the disease, and specific means by which individuals can protect themselves now and in the future from becoming infected.

The objective of these cooperative agreements is to help increase the

number of schools, colleges and other organizations that serve youth, providing effective education about AIDS that is locally determined, consistent with community values, and appropriate to community needs. Assistance provided by national organizations will provide a wide range of educational options from which local educators and others can choose in determining the most effective and appropriate strategies to teach young people about AIDS.

The effectiveness of AIDS education in schools may be influenced by the extent to which it is integrated within a more comprehensive program of school health education that establishes a foundation for understanding the relationships between personal behaviors and health. For example, education about AIDS may be more effective if students at appropriate ages were knowledgeable about community health, communicable diseases, such as sexually transmitted diseases, and drug abuse; and have opportunities to learn peer resistance skills, communication skills, building self-esteem, etc.

These cooperative agreements thus will stress the importance of providing immediate education about behaviors that increase the risk of AIDS for junior high, high school, and college-age youths, and the importance of providing such education within a more comprehensive program of kindergarten through grade twelve school health education that establishes a foundation for understanding the relationships between personal behaviors and health. Education about AIDS in the early elementary grades principally should be provided to allay excessive fears of young children about the AIDS epidemic and contracting the disease.

I. National Programs for School Health Education To Prevent the Spread of AIDS

A. Purpose

The purpose of these programs is to assist national education, health, and social service organizations that serve youth to increase the number of schools and other organizations providing effective AIDS education for youth, school, and college populations in communities throughout the U.S.; and to facilitate collaboration between public and private sector agencies to implement a coordinated national program to help schools nationwide provide effective education about AIDS.

There is a strong need to provide effective education about AIDS for school-age youth. Cooperative agreements with national organizations

are intended to utilize and integrate each organization's unique and complementary organizational capabilities and constituencies to help with the implementation and diffusion of such programs.

B. Cooperative Activities

1. *Recipient Activities*—(a) Use organizational capacities and constituencies to help with the implementation and diffusion of effective AIDS education for school or college populations, or for youths who do not attend school; and to promote educational programs that are locally determined, consistent with community values, and appropriate to community needs.

(b) Establish specific, measurable, and realistic program objectives at national, State, and local levels to increase the number of schools, colleges, or other institutions providing effective AIDS education; and develop a plan of operation to meet the objectives.

(c) Develop a plan of operation, including but not limited to: Influencing changes in policies, actions, knowledge/attitudes/beliefs, skills, or availability/accessibility of resources and services that will help to increase the number of schools, colleges, or institutions providing effective AIDS education.

(d) Develop, diffuse, and disseminate educational strategies, materials, and resources that will help schools, colleges, or other institutions in providing effective AIDS education.

(e) Assess progress in achieving objectives and in carrying out activities.

(f) Involve official education and health agencies and other relevant organizations in the planning, implementation, and evaluation of the program.

(g) Provide copies of AIDS education curricula, program descriptions, progress reports, and educational materials to be included in CDC's Combined Health Information Database, and use the Database to avoid duplication of efforts in developing needed resources.

(h) Participate with CDC and other national organizations in an annual conference and one workshop about AIDS education for youth, school, and college populations.

2. *Centers for Disease Control Activities*—(a) Provide information about AIDS and the prevention of infection with the AIDS virus, guidance on the development or selection of curricula and materials, and other guidance, recommendations, and standards that may be used as a basis for planning, implementing, and

assessing effective AIDS education for youth, school, and college populations.

(b) Identify and develop prototype educational materials and assessment instruments that can be adopted for use by students, parents, and school personnel.

(c) Provide information about resources relevant to AIDS education in schools, including program descriptions, educational materials, policies, and curricula; and assure the availability of such information through CDC's Combined Health Information Database (CHID).

(d) Provide technical assistance related to attainment and assessment of program objectives, development of educational materials and strategies, and dissemination of successful strategies, experiences, and evaluations.

(e) Plan meetings of national, State, and local education agencies to address issues and program activities related to improving AIDS education for youth, school and college populations.

C. Eligible Applicants

Eligible applicants are *national* organizations which may be private, non-profit, health, education, social service, professional, or voluntary organizations with organizational capacities and experience to help schools and other organizations that serve school-age youth to provide effective education about AIDS.

D. Availability of Funds

Approximately \$1,400,000 will be available in Fiscal Year 1987 to fund approximately 12 cooperative agreements.

Up to 7 cooperative agreements will be awarded to *national organizations that propose programs to increase the number of schools* (public and private, elementary, middle/junior high, and/or high schools) *and/or agencies serving youths who do not attend school providing effective AIDS education.* Each of these cooperative agreements will receive an average award of approximately \$100,000.

One cooperative agreement may be awarded to a *national organization that represents colleges of education* to increase the number of colleges providing preservice and inservice training to help teachers provide effective education about AIDS. This cooperative agreement will be funded at a level of approximately \$100,000.

One cooperative agreement may be awarded to a *national organization that represents college and university health services* to increase the number of colleges and universities providing effective AIDS education for college

students and personnel. This cooperative agreement will be funded at a level of approximately \$100,000.

One cooperative agreement may be awarded to a *national organization that proposes a program intended to increase the availability of AIDS education to Black youths* in schools and/or in organizations that serve the needs of Black youths who do not attend school. This cooperative agreement will be funded at a level of approximately \$100,000.

One cooperative agreement may be awarded to a *national organization that proposes a program intended to increase the availability of effective AIDS education to Hispanic youths* in schools and/or in organizations that serve the needs of Hispanic youths who do not attend school. This cooperative agreement will be funded at a level of approximately \$100,000.

One cooperative agreement may be awarded to a *national organization that represents State education agencies* to help these agencies increase the number of schools providing effective AIDS education. This cooperative agreement will be funded at a level of approximately \$300,000.

It is expected that the initial cooperative agreements will be awarded on or about September 15, 1987, and will be funded for a 12 month budget period with a project period of 1 to 5 years. Funding estimates outlined above may vary and are subject to change.

E. Use of Funds

Funds may be used to support personnel, their training and travel, and to purchase supplies and services directly related to planning, organizing, and conducting the activities described in this announcement.

Funds may be expended for written materials, pictorials, audiovisuals, questionnaires or survey instruments, and educational group sessions related to AIDS education for youth, school, and college populations if approved in accordance with paragraph G. below, entitled *Review of Materials*. Funds from the project may not be spent for research activities, for surveys, or for questionnaires except as may be needed to collect the basic evaluation requirements of this announcement.

Funds shall not be used for purchasing computer equipment, office equipment or furnishings, renting or leasing office space, or to support construction or renovation, unless specifically approved.

F. Reporting Requirements

An annual progress report which includes data and activities related to

the achievement of measurable objectives will be required. Annual financial status and performance reports are required 90 days after the end of a budget period.

G. Review of Materials

The applicant must plan to use a panel of education and public health professionals and representatives of target populations (e.g. students, parents, teachers, administrators, etc.) to review the appropriateness of educational materials (written materials, pictorials, audiovisuals, questionnaires, etc.) developed or used in the proposed program. The panel should be guided by the extent to which materials are consistent with scientific and technical information published in various CDC and PHS recommendations and guidelines, and the extent to which the content is appropriate for its intended purpose and target group(s).

Specifically, applicants for cooperative agreements will be required to include in the application the following:

(1) Identification of a panel of no less than five persons including education and public health professionals and representatives of target populations (e.g. students, parents, teachers, administrators, etc.). The identity of proposed members of the panel, including their names, occupations, and any organizational affiliations that were considered in their selection for the panel;

(2) A letter or memorandum from the proposed project director, countersigned by the business office, which includes concurrence with this guidance and assurance that its provisions will be observed.

(3) When a cooperative agreement is awarded, the recipient will:

(a) Convene the panel and present for its assessment actual copies of written materials, pictorials, and audiovisuals proposed to be used;

(b) Provide for assessment by the panel, draft text, scripts, or detailed descriptions for written materials, pictorials, or audiovisuals proposed to be used;

(c) Prior to expenditure of funds for use of these materials, assure that project files are documented with a statement of approval signed by the panel.

(d) Provide to CDC the approval statements of the panel for all proposed written materials, audiovisual materials, and pictorials approved during the quarter.

This page should be no longer than one typed, single-spaced page.

H. Review and Evaluation Criteria

1. The initial application for a project period will be reviewed and evaluated according to the following criteria:

- a. The magnitude of, and likelihood of the applicant achieving, during this budget period: (1) Proposed increases in the number of schools, colleges, and universities, and other agencies that serve school-age youth who do not attend school, providing effective AIDS education as a result of the applicant's proposed activities; (2) and/or estimated increases, in the numbers of youths, school, or college populations receiving effective AIDS education as a result of the applicant's proposed activities;
- b. The applicant's demonstrated ability to help schools, colleges, or agencies that serve school-age youth who do not attend school in communities across the Nation provide effective education about health; the scope and efficiency of its national network and constituencies for rapidly disseminating information and activities; current and previous activities (if any) that have successfully contributed to the implementation and diffusion of effective health education in schools, colleges, or agencies that serve the needs of youths who do not attend school; and its unique sensitivity, experience, awareness, or skills that will help the applicant to achieve proposed program objectives;
- c. The applicant's demonstrated ability to coordinate efforts with other national organizations; and to plan and carry out complementary, collaborative, and organized national education efforts;
- d. The quality of proposed objectives for this budget period in terms of importance, specificity, measurability, and feasibility; and the specificity and feasibility of the applicants timetable for implementation of program activities.
- e. The extent to which the applicant's activities reflect: (1) The immediate and urgent need for educating youths of junior high school-age and above, and/or youths who do not attend school, about how to protect themselves from infection with the AIDS virus; and (2) the need for integrating education about AIDS into a more comprehensive program of school health education that establishes a foundation for understanding the relationships between personal behaviors and health;
- f. The usefulness of assessment data that will be obtained to measure program objectives and monitor program activities during the first program year, and the feasibility of obtaining and using that data to improve programs;

g. The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds; and

h. The number and qualifications of proposed staff, and time allotted for them to accomplish program activities.

2. Continuation awards within the project period will be made on the basis of the following criteria:

a. The accomplishments of the current budget period show that the applicant is meeting its objectives and carrying out activities as planned, including incorporating effective AIDS education within comprehensive school health education programs;

b. The objectives for the new budget period are realistic, specific, and measurable;

c. The budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of cooperative agreement funds; and

d. Program activities are modified to resolve problems and improve effectiveness and efficiency.

I. Special Guidelines for Application Preparation

A one and one-half day preapplication meeting will be held in the Washington, D.C. area in the latter part of May.

The purpose of this meeting is to help potential applicants to:

1. Understand the scope and intents of the National Programs for School Health Education to Prevent AIDS;

2. Understand the scope and intents of the State and Local Programs for School Health Education to Prevent AIDS;

3. Plan coordinated, complementary approaches to increasing the number of schools, colleges, organizations providing effective AIDS education for school-age youth; and

4. Become familiar with the Public Health Service grants policies, and application and review procedures.

Each potential applicant may send not more than 2 representatives to this meeting.

Please provide to the Grants Management Officer by May 1, 1987 the full names, titles, agency, street address, city, state, zip code, and telephone numbers of the persons that are planning to attend this meeting.

Attendees will be notified of the specific dates and times of the meeting as soon as possible.

While the information is intended to assist all potential applicants in preparing their applications, attendance at this meeting is not mandatory for the submission of an application, nor will such attendance or non-attendance be used in any way in the evaluation of

applications and in the selection of potential awardees.

Applications

A. Application Content

(1) The initial application for a new project period must include a narrative for the part of this announcement under which funds are requested that describes the following:

(a) *Need.* The applicant should briefly describe the need to increase the number of schools, colleges, and other agencies providing effective AIDS education for school-age populations.

The applicant also should identify specific modifiable barriers that its organization can resolve to help with the implementation and diffusion of AIDS education programs for youth, school, and college populations.

This section should be no longer than three typed, single-spaced pages.

(b) *Capacities.* The applicant should describe its organization's capacity to achieve the proposed increase in the number of schools, colleges, or other organizations providing effective AIDS education.

The description should address the organization's structure, the interests and constituencies it represents (e.g., parents, students, teachers, health organizations, religious organizations, etc.), its demonstrated ability to help schools, colleges, or other organizations provide education about health for school-age populations; the scope and efficiency of its national network for rapidly disseminating information and other communications; and current and previous activities (if any) that have successfully reduced barriers that hinder the provision of effective AIDS education in schools, colleges, or organizations that serve the needs of youths who do not attend school.

This section should be no longer than three typed, single-spaced pages.

(c) *Coordination.* The applicant should describe its organization's demonstrated ability to coordinate efforts with other national organizations; and its capacity to plan and carry out collaborative, complementary, and organized national efforts for effective AIDS education. The applicant's description should demonstrate a recognition of relevant activities (current or planned) of local and State education agencies and/or of other national organizations.

This section should be no longer than two typed, single-spaced pages.

(d) *Objectives.* The applicant should identify objectives that are specific, measurable, and feasible to be accomplished during the first program

year. The objectives should clearly identify outcomes intended (e.g. increases in the number of schools, colleges, or other organizations providing effective AIDS education; specific changes in policy, actions, knowledge/ attitudes/beliefs, skills, and availability of resources or services; increases in the number of youths, school, or college populations receiving effective AIDS education as a result of the applicants proposed activities; etc.).

This section should be no longer than two typed, single-spaced pages.

(e) *Activities.* The applicant should identify the specific activities that will be undertaken to achieve each of the program's objectives during the first program year. The applicant's workplan should describe who will do what, when, and where to implement the activities.

Activities related to helping schools should clearly reflect: (1) The immediate and urgent need for educating junior high and high school students about how to protect themselves from infection with the AIDS virus; and (2) the need for integrating education about AIDS into a more comprehensive program of school health education that establishes a foundation for understanding the relationships between personal behaviors and health.

This section should be no longer than ten typed, single-spaced pages.

(f) *Assessment.* The applicant should identify the specific data that it will obtain to assess progress in meeting its objectives and conducting its activities during the first program year. The applicant also should describe how that information will be obtained, and how it will be used to improve the program.

This section should be no longer than five typed, single-spaced pages.

(g) *Evidence of Support.* The applicant should identify the extent to which relevant organizations (e.g., education and health agencies) support the proposal. If the program requires the participation or collaboration of other education or health organizations, evidence of support and agreement to participate must be provided by appropriate officials of those organizations.

This section should be no longer than one typed, single-spaced page with copies of letters of support attached.

(h) *Transfer of Technology.* The applicant should plan to share a description of the program and evidence of effectiveness with other agencies interested in AIDS education for youth, school, or college populations. The applicant should submit a description of the program and all educational materials developed by the program to

be included in CDC's Combined Health Information Database.

The applicant should include plans to utilize the database in avoiding duplication of efforts and incorporating available programs/materials as the database grows.

This section should be no longer than one typed, single-spaced page.

(2) *Continued Funding.* An application for continuing funding of these activities within an approved project period should contain the following information:

a. Description of activities performed and results achieved during the prior budget period;

b. Short-term objectives for the new budget period;

c. A description of the method of operation that will be used to accomplish any new objectives;

d. An evaluation plan which will help determine if the methods are effective and the objectives are being achieved; and

e. A budget and accompanying justification consistent with the purpose and objectives of the project.

(3) *Index.* Each application must contain an index specifically directing the reviewers to each section of the application that corresponds with Recipient Activities.

B. Application Submission and Deadline Date

The original and two copies of the application must be submitted to Leo A. Sanders, Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305, on or before July 15, 1987.

(1) *Deadline.* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date, or

b. Sent on or before the deadline date and received in time for submission to the independent review group.

(Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing).

(2) *Late Applications.* Applications which do not meet the criteria in 1.a or b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

C. Other Submission and Review Requirements

Applications are not subject to review as governed by Executive Order 12372, entitled "Intergovernmental Review of Federal Programs."

Where to Obtain Additional Information

Information on application procedures, copies of application forms, and other material may be obtained from Marsha Driggans, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305, or by calling (404) 262-6575 or FTS 236-6575. Technical assistance may be obtained from Jack Jones, Public Health Advisor, Division of Health Education, Center for Health Promotion and Education, Centers for Disease Control, Atlanta, Georgia 30333, Telephone (404) 329-3824 or FTS 236-3824.

Dated: April 15, 1987.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 87-8851 Filed 4-20-87; 8:45 am]

BILLING CODE 4160-18-M

Cooperative Agreements To Support School Health Education To Prevent the Spread of Acquired Immunodeficiency Syndrome; State and Local Programs and Demonstration/Training Programs for School Health Education To Prevent the Spread of AIDS; Availability of Funds for Fiscal Year 1987

Introduction

The Centers for Disease Control (CDC) announces the availability of funds for Fiscal Year 1987 for cooperative agreements to support the development and implementation of effective health education about AIDS for school populations (elementary through high school-age youth, parents, and relevant school, health, and education personnel). Funds will be available to assist State and local education agencies (SEAs and LEAs) in areas with a cumulative total of 200 and 150 or more AIDS cases respectively. These agencies must be able to carry out and promote appropriate actions to help increase the number of schools, and agencies that serve school-age youth who do not attend school, providing effective education about AIDS that is locally determined, consistent with community values, and appropriate to community needs.

Authorizing Legislation

These programs are authorized under section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)), as amended, and section 311(b)(c) of the Public Health Service Act (42 U.S.C. 243 (b)), as amended. The Catalog of Federal Domestic Assistance Number is 13.118.

Program Background and Objectives

AIDS constitutes a significant and growing threat to the health of all people in the United States. Although the vast majority of AIDS cases and documented infections have occurred among homosexual and bisexual men and intravenous drug abusers, infection with the AIDS virus also is spreading among heterosexuals (from infected men to women or from infected women to men) and perinatally (from infected mothers to newborn infants).

An estimated 1-1.5 million Americans already are infected and cases resulting from heterosexual transmission of the virus are expected to increase. Because infected persons are capable of spreading the virus to others for years before experiencing signs or symptoms of disease, the Public Health Service (PHS) has recommended the initiation of major public education efforts to inform the public, especially youth, school, and college populations, about AIDS- and how to prevent becoming infected with the AIDS virus.

The objective of these cooperative agreements is to help increase the number of schools, and other agencies that serve school-age youth who do not attend school, that provide effective AIDS education that is locally determined, consistent with community values, and appropriate to community needs.

These cooperative agreements will stress both the importance of providing immediate education for junior high, high school, and college-age youths about behaviors that increase the risk of AIDS, and the importance of providing such education within a more comprehensive program of kindergarten through grade twelve school health education that establishes a foundation for understanding the relationships between personal behaviors and health. Education about AIDS in the early elementary grades principally should be provided to allay excessive fears of young children about the AIDS epidemic and contracting the disease.

A. Eligible Applicants

Eligible applicants are the official State education agency (SEA) in states from which a cumulative total of 200 or more AIDS cases, as defined by the

CDC case definition, were reported to CDC as of 12/29/86; and local education agencies (LEAs) of cities from which a cumulative total of 150 or more AIDS cases, as defined by the CDC case definition, were reported to CDC as of 12/29/86. For the purpose of this agreement, the term "state" includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, the Northern Mariana Islands, and American Samoa.

SEA proposals must give priority to assisting local education agencies in cities with a high reported incidence of AIDS that do not receive funding directly from CDC for purposes described in this cooperative agreement.

LEAs that receive funding directly from CDC for purposes described in the announcement will not be eligible for fiscal support that may be provided directly from CDC to their SEA unless specifically requested and approved.

Applications submitted by the SEA and LEAs from the same state must be coordinated to assure that unnecessary duplication of activities (e.g., data collection, teacher training, materials development) does not occur. No more than one LEA application will be funded in each city. In a city served by more than one LEA, the LEAs are encouraged to collaborate in proposing coordinated, complementary activities; to submit one application with one LEA identified as the coordinating agency and recipient of the award; and to submit a discrete and individually justified budget, narrative, and workplan for each LEA collaborating in the proposal.

B. Availability of Funds

A total of approximately \$5,100,000 will be available in Fiscal Year 1987 to fund approximately 10 cooperative agreements with SEAs and 12 cooperative agreements with LEAs, as follows:

1. Approximately \$4,100,000 will be available to fund approximately 10 cooperative agreements with SEAs and 12 cooperative agreements with LEAs to increase the number of schools, and number of agencies that serve school-age youths who do not attend school, that provide effective AIDS education.

Priority funding will be given to approved applications from SEAs and LEAs in states and cities from which a cumulative total of over 1500 AIDS cases, as defined by the CDC case definition, were reported to CDC as of 12/29/86. New York, California, Florida, Texas, New Jersey, New York City (NY), San Francisco (CA), and Los Angeles

(CA) are eligible areas for priority funding. Awards to these States and cities may be approximately \$300,000.

The second funding priority will be given to approved applications from SEAs in States from which a cumulative total of 200 or more AIDS cases, as defined by the CDC case definition, were reported to CDC as of 12/29/86; and from LEAs in cities from which a cumulative total of 150 or more AIDS cases, as defined by the CDC case definition were reported to CDC as of 12/29/86. Illinois, Pennsylvania, Georgia, Massachusetts, District of Columbia, Maryland, Washington, Louisiana, Virginia, Connecticut, Puerto Rico, Colorado, Ohio, Michigan, Houston (TX), Miami (FL), Dallas (TX), Newark (NJ), Chicago (IL), Philadelphia (PA), Atlanta (GA), Boston (MA), Ft. Lauderdale (FL), Seattle (WA), San Diego (CA), New Orleans (LA), Denver (CO), Baltimore (MD), and Jersey City (NJ) are areas eligible for second funding priority. Awards to these States and cities may be approximately \$125,000.

2. In addition, approximately \$1,000,000 will be available to fund an optional Training/Demonstration activity in 2-3 LEAs and one SEA applying for the cooperative agreements described above.

It is expected that the initial cooperative agreements will be awarded on or about September 15, 1987, and will be funded for a 12 month budget period with a project period of 1 to 5 years. Funding estimates outlined above may vary and are subject to change.

C. Application Submission and Deadline Date

The original and two copies of the application must be submitted to Leo A. Sanders, Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305, on or before July 15, 1987.

(1) *Deadline.* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date, or

b. Sent on or before the deadline date and received in time for submission to the independent review group.

(Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing).

(2) *Late Applications.* Applications which do not meet the criteria in 1.a or

b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

D. Other Submission and Review Requirements

1. All applications will be subjected to an objective review by an ad hoc review committee.

2. Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Where to Obtain Additional Information

Information on application procedures, copies of application forms, Program Announcement, and other material may be obtained from Marsha Driggans, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305, or by calling (404) 262-6575 or FTS 236-6575. Technical assistance may be obtained from Jack Jones, Public Health Advisor, Division of Health Education, Center for Health Promotion and Education, Centers for Disease Control, Atlanta, Georgia 30333, Telephone (404) 329-3824 or FTS 236-3824.

Dated: April 15, 1987.

Robert L. Foster,

*Acting Director, Office of Program Support,
Centers for Disease Control.*

[FR Doc. 87-8852 Filed 4-20-87; 8:45 am]

BILLING CODE 4160-18-M

Project Grants for Sexually Transmitted Diseases Research, Demonstrations, and Public and Professional Education Program Announcement and Notice of Availability of Funds for Fiscal Year 1987; Correction

A notice announcing the availability of funds for Fiscal Year 1987 for project grants for Sexually Transmitted Diseases (STD) Research, Demonstrations, and Public Information and Education, and Professional Education, Training, and Clinical Skills Improvement Activities was published in the *Federal Register* on Friday, March 27, 1987 (52 FR 9944). The notice is corrected as follows:

1. On page 9944, third column, "AVAILABILITY OF FUNDS, A *New Applications*," line five, change "aware" to "award."

2. On page 9946, second column, "OTHER SUBMISSION AND REVIEW REQUIREMENTS," is corrected to read:

"Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Program."

All other information and requirements in the notice remain the same.

Dated: April 15, 1987.

Robert L. Foster,

*Acting Director, Office of Program Support,
Centers for Disease Control.*

[FR Doc. 87-8853 Filed 4-20-87; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 86D-0335]

Oral Contraceptive Drug Product Labeling

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revising the guideline texts of professional and patient labeling for estrogen-progestogen combination oral contraceptive drug products. This revision is being made to incorporate important new information about the benefits and risks of oral contraceptive drug product use.

EFFECTIVE DATES: *Professional labeling:* Effective April 21, 1987, a person may adopt the revised labeling guideline for estrogen-progestogen combination oral contraceptive drug products and rely on it to meet FDA's professional labeling requirements for prescription drugs. *Patient package insert:* Effective April 21, 1987, a person may rely on the revised guideline to meet the patient package insert requirement set forth in 21 CFR 310.501 for estrogen-progestogen combination oral contraceptive drug products.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Requests for a copy of either guideline to the Legislative, Consumer, and Professional Relations Branch (HFN-365), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8012.

FOR FURTHER INFORMATION CONTACT: Philip Corfman, Center for Drugs and Biologics (HFN-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3510.

SUPPLEMENTARY INFORMATION: Guidelines texts for professional and patient labeling for oral contraceptive

drug products were previously made available through a notice published in the *Federal Register* of December 7, 1976 (41 FR 53633), and amended in the *Federal Register* of May 27, 1977 (42 FR 27303) and in the *Federal Register* of January 31, 1978 (43 FR 4223).

FDA is charged with assuring that drugs are safe and effective for their intended uses and that their labeling provides adequate information for such uses and is not false or misleading. The full disclosure of information to health professionals and, where appropriate, to patients concerning warnings and contraindications is an important element in the discharge of that responsibility. The statutory scheme anticipates that new information concerning the safety and effectiveness of marketed drugs may require that FDA prescribe changes in their labeling to reveal limitations on use or to warn of previously unanticipated hazards.

FDA has revised the professional and patient labeling of estrogen-progestogen oral contraceptive products to incorporate important new information about oral contraceptives. This information includes evidence of a decreased incidence of benign breast disorders, functional ovarian cysts and pelvic inflammatory disease, as well as some evidence of protection against the development of ovarian and endometrial cancer. Additionally, oral contraceptive use has been reported to decrease the incidence of iron deficiency anemia and to decrease the incidence of dysmenorrhea.

The revisions are the result of the combined efforts of FDA scientists in the Center for Drugs and Biologics as well as members of FDA's Advisory Committee on Fertility and Maternal Health Drugs. FDA also considered the oral and written comments submitted by interested members of the public, including representatives of health professions, consumer organizations, and the pharmaceutical industry.

This notice, announcing the availability of revised guidelines, is issued under 21 CFR 10.90(b) of FDA's regulations which provides for the use of guidelines to establish procedures of general applicability that are not legal requirements, but are acceptable to the agency. A person who follows a guideline can be assured that his or her conduct is acceptable to the agency. FDA advises that the professional labeling guideline for estrogen-progestogen oral contraceptive drug products complies with the prescription drug labeling regulations in 21 CFR 201.56, 201.57, and 201.100, and that the patient package insert guideline for such

products complies with the requirements of 21 CFR 301.501. Under the provisions of 21 CFR 314.70(c), manufacturers are required to submit supplemental new drug applications advising the agency that the professional labeling or patient package inserts are being revised. However, under § 314.70(c)(2) the guideline labeling texts may be used before approval of a supplement covering adoption of the new labeling. A person may choose to use alternative labeling statements that are different from the guideline. If a person chooses to depart from the guideline, he or she may discuss the matter further with the agency to prevent an expenditure of money and effort for labeling that the agency may later determine to be unacceptable.

Effective April 21, 1987, a person may adopt the professional labeling guideline or patient package insert guideline for estrogen-progestational oral contraceptive drug products. Comments will be considered in determining whether future changes to the guidelines are necessary.

Interested persons may submit written comments on these guidelines to the Dockets Management Branch (address above). Two copies should be submitted except that individuals may submit single copies. Comments should be identified with the docket number found in brackets in the heading of this document. The guidelines and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 30, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-8849 Filed 4-20-87; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Medicaid Program; Notice of Hearing; Reconsideration of Disapproval of a Washington State Plan Amendment

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on June 3, 1987 in Seattle, Washington to reconsider our decision to disapprove Washington State Plan Amendment 86-8.

Closing Date: Request to participate in the hearing as a party must be received by the Docket Clerk by May 6, 1987.

FOR FURTHER INFORMATION CONTACT: Docket Clerk, Hearing Staff, Bureau of Eligibility, Reimbursement and Coverage, 300 East High Rise, 6325

Security Boulevard, Baltimore, Maryland 21207, Telephone: (301) 594-8261.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove a Washington State Plan Amendment.

Section 1116 of the Social Security Act and 45 CFR Parts 201 and 213 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. HCFA is required to publish a copy of the notice to a State Medicaid Agency that informs the agency of the time and place of the hearing and the issues to be considered. (If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.)

Any individual or group that wants to participate in the hearing as a party must petition the Hearing Officer within 15 days after publication of this notice, in accordance with the requirements contained in 45 CFR 213.15(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the Hearing Officer before the hearing begins in accordance with the requirements contained in 45 CFR 213.15(c)(1).

If the hearing is later rescheduled, the Hearing Officer will notify all participants.

The issue in this matter is whether Washington SPA 86-8 violates section 1902(a)(10)(C)(i)(III) of the Social Security Act.

Under SPA 86-8, Washington proposes to disregard the costs of health insurance premiums in determining an individual's countable income when determining Medicaid eligibility.

Under section 1902(a)(10)(C)(i)(III) of the Act, in determining eligibility under the Medicaid program, States must apply the same income and resource methodologies, including income and resource disregards, as are used in the related cash assistance programs (e.g., Aid to Families with Dependent Children (AFDC), and the Supplemental Security Income (SSI) programs). The cash assistance programs do not contain any income disregards for the costs of health insurance premiums. Therefore, HCFA has determined SPA 86-8 violates section 1902(a)(10)(C)(i)(III) of the Act.

Section 2373(c) of DEFRA permits States in certain circumstances to apply in their Medicaid programs less restrictive income and resource methodologies than are applied in the cash assistance programs. However, under HCFA's implementation of section

2373(c) only those less restrictive provisions which are already in a State's approved State plan may continue to be applied. The provisions of SPA 86-8 are not in Washington's currently approved State plan and are thus not permitted under section 2373(c) of DEFRA.

We would like to note that Washington has referred to the decision of the Ninth Circuit court of Appeals in *Cubanski v. Heckler* with respect to the State of California in support of Washington SPA 86-8. The mandate of the *Cubanski* decision only governs California amendment no. 83-14. We believe the Court of Appeals decision to be wrong and on February 23, 1987 the United States Supreme Court granted our petition for *certiorari* to review that decision. Thus, unless the Supreme court affirms the *Cubanski* holding, we will not apply the Court of Appeal's interpretation of section 1903(f) or the Deficit Reduction Act moratorium to any situation not covered by the mandate in the *Cubanski* case.

The notice to Washington announcing an administrative hearing to reconsider our disapproval of its State plan amendment reads as follows:

Mr. Ronald W. Kero,
Acting Director, Division of Medical Assistance Department of Social and Health Services MS HB-41 Olympia, Washington 98504.

Dear Mr. Kero: This is to advise you that your request for reconsideration of the decision to disapprove Washington State Plan Amendment No. 86-8 was received on March 17, 1987.

Washington SPA 86-8 proposes to disregard the costs of health insurance premiums in determining an individual's countable income when determining eligibility. You have requested a reconsideration of whether this plan amendment conforms to the requirements for approval under the Social Security Act and pertinent regulations. The issues to be considered at the hearing are: (1) Whether the plan amendment violates section 1902(a)(10)(C)(i)(III) of the Social Security Act which requires States in determining eligibility under the Medicaid program to apply the same income and disregards as are used in the related cash assistance programs, and (2) whether the disapproval of the amendment is precluded by the moratorium established by section 2373(c) of the Deficit Reduction Act of 1984.

I am scheduling a hearing on your request to be held on June 3, 1987 at 10:00 a.m. in Room 470-472, 2901 Third Avenue, Seattle, Washington. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties.

I am designating Mr. Lawrence Ageloff as the presiding officer. If these arrangements present any problems, please contact the Docket Clerk. In order to facilitate any communication which may be necessary

between the parties to the hearing, please notify the Docket Clerk of the names of the individuals who will represent the State at the hearing. The Docket Clerk can be reached at (301) 594-8261.

Sincerely,

William L. Roper, M.D.,

Administrator.

(Section 1116 of the Social Security Act (42 U.S.C. 1316))

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: April 13, 1987.

William L. Roper,

Administrator, Health Care Financing Administration.

[FR Doc. 87-8931 Filed 4-20-87; 8:45 am]

BILLING CODE 4120-03-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY-920-07-4111-15; W-80191]

Proposed Reinstatement of Terminated Oil and Gas Lease; Natrona County, WY

April 13, 1987.

Pursuant to the provisions of Pub. L. 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas lease W-80191 for lands in Natrona County, Wyoming, was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$10 per acre, or fraction thereof, per year and not less than 16% percent, respectively.

The lessee has paid the required \$500 administrative fee and \$106.25 to reimburse the Department for the cost of this Federal Register notice. The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease W-80191 effective July 1, 1986, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Andrew L. Tarshis,

Chief, Leasing Section.

[FR Doc. 87-8842 Filed 4-20-87; 8:45 am]

BILLING CODE 4310-22-M

[UT-942-07-4220-10; U-54908]

Utah; Proposed Withdrawal of Public Land; Opportunity for Public Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management proposes to withdraw 344,641.44 acres of public land for the protection of three sites currently being considered by the State of Utah for the Department of Energy's Superconducting Supercollider project, near Salt Lake City, Utah. This notice closes the land for up to 2 years from mining location. The land will remain open to surface entry and mineral leasing.

DATE: Comments and request for a public meeting should be received by July 20, 1987.

ADDRESS: Comments and meeting requests should be sent to: Utah State Director, Bureau of Land Management, 324 South State, Suite 301, Salt Lake City, Utah 84111-2303.

FOR FURTHER INFORMATION CONTACT: Lillie Hikida, BLM, Utah State Office, 801 524-3074.

On April 15, 1987, a petition was approved allowing the Bureau of Land Management to file an application to withdraw the following described public land from location under the mining laws, subject to valid existing rights:

Salt Lake Meridian, Utah

- T. 1 N., R. 9 W.,
 Sec. 1, Lots 1, 2, SW $\frac{1}{4}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$,
 NW $\frac{1}{4}$ SE $\frac{1}{4}$, S $\frac{1}{2}$ SE $\frac{1}{4}$;
 Sec. 3-15, 17, All;
 Sec. 18, Lots 1-4, NE $\frac{1}{4}$, E $\frac{1}{2}$ W $\frac{1}{2}$, NE $\frac{1}{4}$ SE $\frac{1}{4}$,
 S $\frac{1}{2}$ SE $\frac{1}{4}$;
 Sec. 19-31, 33-35, All.
 T. 1 S., R. 9 W.,
 Sec. 1, 3-15, 17-31, 33-35, All.
 T. 2 S., R. 9 W.,
 Sec. 1, 3-8, All;
 Sec. 7, Lots 1, 2, 4, E $\frac{1}{2}$, E $\frac{1}{2}$ NW $\frac{1}{4}$,
 NE $\frac{1}{4}$ SW $\frac{1}{4}$;
 Sec. 8-15, 17-31, 33-35, All.
 T. 3 S., R. 9 W.,
 Sec. 1, 3-7, All;
 Sec. 8, N $\frac{1}{2}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$;
 Sec. 9-15, All;
 Sec. 17, E $\frac{1}{2}$, S $\frac{1}{2}$ NW $\frac{1}{4}$, SE $\frac{1}{4}$;
 Sec. 18, All.
 T. 1 N., R. 10 W.,
 Sec. 1, 3-15, 17-22, All;
 Sec. 23, N $\frac{1}{2}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$;
 Sec. 24-31, All;
 Sec. 33, N $\frac{1}{2}$;
 Sec. 34, 35, All.
 T. 1 S., R. 10 W.,
 Sec. 1, 3, All;
 Sec. 4, S $\frac{1}{2}$ NE $\frac{1}{4}$, S $\frac{1}{2}$;
 Sec. 5, Lots 3, 4, S $\frac{1}{2}$ NW $\frac{1}{4}$, S $\frac{1}{2}$;
 Sec. 6-13, All;
 Sec. 14, All, except for patented portion;
 Sec. 15, 17-22, All;

Sec. 23, All, except for patented portion;
 Sec. 24-31, 33-35, All.

T. 2 S., R. 10 W.,

Sec. 1, 3-15, 17-31, 33-35, All.

T. 3 S., R. 10 W.,

Sec. 1, 3-7, All;

Sec. 8 N $\frac{1}{2}$, SW $\frac{1}{4}$, NE $\frac{1}{4}$ SE $\frac{1}{4}$, S $\frac{1}{2}$ SE $\frac{1}{4}$;

Sec. 9-15, 17, 18, All.

T. 1 N., R. 11 W.,

Sec. 1, 3-15, 17-31, 33-35, All.

T. 2 S., R. 11 W.,

Sec. 1, 3-15, 17-31, 33-35, All.

T. 1 S., R. 11 W.,

Sec. 1, 3-15, 17-31, 33-35, All.

T. 3 S., R. 11 W.,

Sec. 1, 3-15, 17, 18, All.

T. 1 N., R. 12 W.,

Sec. 1, 3-15, 17-21, All.

Sec. 22, All except patented por.;

Sec. 23-28, All;

Sec. 27, All except patented por.;

Sec. 28-31, All;

Sec. 33-34, All except patented por.;

Sec. 35, All.

T. 1 S., R. 12 W.,

Sec. 1, 3-15, 17-31, 33-35, All.

T. 2 S., R. 12 W.,

Sec. 1, 3-15, 17, 18, All.

T. 1 N., R. 13 W.,

Sec. 1, 3-15, 17-31, 33-35, All.

T. 1 S., R. 13 W.,

Sec. 1, 3-15, 17-31, 33-35, All.

T. 2 S., R. 13 W.,

Sec. 1, 3-15, 17, 18, All.

T. 1 N., R. 14 W.,

Sec. 1, 3, 10-15, 22-27, 34, 35, All.

T. 1 S., R. 14 W.,

Sec. 1, 3, 10-15, 22-27, 34, 35, All.

T. 2 S., R. 14 W., SLM, UT

Sec. 1, 3, 10-15, All.

The area described contains 344,641.44 acres in Tooele County, Utah. There are no lands to be excepted from those described above, except as noted above.

The purpose of the proposed withdrawal is protection of three sites currently being considered by the State of Utah for the Department of Energy's Superconducting Supercollider Project.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the Utah State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request of the Utah State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be

published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR Part 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the lands will be segregated as specified above unless the application is denied or cancelled or the withdrawal is approved prior to that date.

The temporary segregation of the lands in connection with a withdrawal application or proposal shall not affect administrative jurisdiction over the lands, and the segregation shall not have the effect of authorizing any use of the land by the Bureau of Land Management.

Dated: April 15, 1987.

Orval L. Hadley,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 87-8887 Filed 4-20-87; 8:45 am]

BILLING CODE 4310-DQ-M

[WY-930-07-5410-10 ZKKH; W-101124]

Conveyance of Federally-owned Mineral Interests Application; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of receipt of conveyance of Federally-owned mineral interests application.

SUMMARY: Notice is hereby given that pursuant to section 209 of the Act of October 21, 1976, 90 Stat. 2757, Leland Forrest Asa has applied to purchase the mineral interests in the following described land:

Sixth Principal Meridian, Nebraska

T. 23 N., R. 58 W.,

Sec. 1, lots 1 and 2.

The area described contains 80.20 acres.

Additional information concerning this application may be obtained from the Branch of Land Resources, Wyoming State Office, Bureau of Land Management, 2515 Warren Avenue, Cheyenne, Wyoming 82001.

Upon publication of this notice in the **Federal Register**, the mineral interests in the land described above will be segregated to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. The segregative effect of the application shall terminate either upon issuance of a patent or other document of conveyance of such mineral interests, upon final rejection of

the application, or 2 years from the date of filing of the application, June 2, 1986, whichever occurs first.

Melvin Schlager,

Acting Deputy State Director, Lands and Renewable Resources.

[FR Doc. 87-8841 Filed 4-20-87; 8:45 am]

BILLING CODE 4310-22-M

Minerals Management Service

Outer Continental Shelf; Development Operations Coordination Document; Chevron U.S.A. Inc.

AGENCY: Mineral Management Service Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Chevron U.S.A. Inc., Unit Operator of the Main Pass Block 299 Federal Unit agreement No. 14-08-0001-8850, has submitted a DOCD describing the activities it proposes to conduct on the Main Pass Block 299 Federal unit. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Venice, Louisiana.

DATE: The subject DOCD was deemed submitted on April 9, 1987.

ADDRESS: a copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 9: a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Dessauer: Minerals Management Service; Gulf of Mexico OCS Region; Production and Development; Development and Unitization Section; Unitization Unit; Telephone (504) 736-2660

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and

procedures are set out in revised §250.34 of Title 30 of the CFR.

Dated: April 14, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-8843 Filed 4-20-87; 8:45 am]

BILLING CODE 4310-MR-M

Outer Continental Shelf; Development Operations Coordination Document; Union Texas Petroleum

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Union Texas Petroleum has submitted a DOCD describing the activities it proposes to conduct on Leases OCS-G 3159 and 2329, Blocks 384 and 385, respectively, Eugene Island Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Fourchon, Louisiana.

DATE: The subject DOCD was deemed submitted on April 13, 1987.

ADDRESS: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2867.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised §250.34 of Title 30 of the CFR.

Dated: April 14, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS
Region.

[FR Doc. 87-8844 Filed 4-20-87; 8:45 am]

BILLING CODE 4310-MR-M

INTERSTATE COMMERCE COMMISSION

[Notice No. 40129]

The Atchison, Topeka & Santa Fe Railway Co. and Ulysses Irrigation Pipe Co.; Exemption To Waive Demurrage Charges

AGENCY: The Interstate Commerce
Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce
Commission grants The Atchison,
Topeka and Santa Fe Railway Company
an exemption under 49 U.S.C. 10505
from the civil and criminal forfeiture
penalties of 49 U.S.C. 10741, 10761,
11902, 11903, and 11904 in order to waive
collection of demurrage charges
assessed against certain shipments
received by Ulysses Irrigation Pipe
Company at Ulysses, KS.

DATE: This decision will be effective on
May 21, 1987.

ADDRESSES: Send pleadings referring to
No. 40129 to:

- (1) Office of the Secretary, Case Control
Branch, Interstate Commerce
Commission, Washington, DC 20423
- (2) Petitioner's representative: Michael
W. Blaszk, 80 East Jackson Blvd.,
Chicago, IL 60604.

FOR FURTHER INFORMATION CONTACT:
Joseph H. Dettmar, (202) 275-7245.

SUPPLEMENTARY INFORMATION:
Additional information is contained in
the Commission's decision. To purchase
a copy of the full decision, write to T.S.
InfoSystems, Inc., Room 2229, Interstate
Commerce Commission Building,
Washington, DC 20423, or call 289-4357
(D.C. Metropolitan Area).

Decided: April 13, 1987.

By the Commission, Chairman Gradison,
Vice Chairman Lamboley, Commissioners
Sterrett, Andre, and Simmons.

Noreta R. McGee,
Secretary.

[FR Doc. 87-8922 Filed 4-20-87; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Registration; Hoffmann La Roche, Inc.

By Notice dated January 20, 1987, and
published in the *Federal Register* on
February 3, 1987; (52 FR 3357), Hoffmann
La Roche, Inc., 340 Kingsland Street,
Nutley, New Jersey 07110, made
application to the Drug Enforcement
Administration to be registered as a
bulk manufacturer of the basic classes
of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I.
Alpharodine (9010)	II.
Levorphanol (9220)	II.

No comments or objections have been
received. Therefore, pursuant to section
303 of the Comprehensive Drug Abuse
Prevention and Control Act of 1970 and
Title 21, Code of Federal Regulations,
§ 1301.54(e), the Deputy Assistant
Administrator hereby orders that the
application submitted by the above firm
for registration as a bulk manufacturer
of the basic classes of controlled
substances listed above is granted.

Dated: April 14, 1987.

Gene R. Haislip,

Deputy Assistant Administrator, Office of
Diversion Control, Drug Enforcement
Administration.

[FR Doc. 87-8889 Filed 4-20-87; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Registration; Norac Co., Inc.

By Notice dated January 28, 1987, and
published in the *Federal Register* on
February 5, 1987; (52 FR 3719), Norac
Company, Inc., 405 South Motor Avenue,
Azusa, California 91702, made
application to the Drug Enforcement
Administration to be registered as a
bulk manufacturer of the basic classes
of controlled substances listed below:

Drug	Schedule
Ibogaïne (7260)	I.
Tetrahydrocannabinols (7370)	I.

No comments or objections have been
received. Therefore, pursuant to section
303 of the Comprehensive Drug Abuse
Prevention and Control Act of 1970 and
Title 21, Code of Federal Regulations,
§ 1301.54(e), the Deputy Assistant
Administrator hereby orders that the

application submitted by the above firm
for registration as a bulk manufacturer
of the basic classes of controlled
substances listed above is granted.

Dated: April 14, 1987.

Gene R. Haislip,

Deputy Assistant Administrator, Office of
Diversion Control, Drug Enforcement
Administration.

[FR Doc. 87-8888 Filed 4-20-87; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 86-6]

Revocation of Registration; Park and King Pharmacy

On December 11, 1985, the Deputy
Assistant Administrator, Office of
Diversion Control Drug Enforcement
Administration (DEA), issued an Order
to Show Cause to Leon Earl Waters, Jr.,
trading as Park and King Pharmacy, of
2665 King Street, Jacksonville, Florida
32204, proposing to revoke DEA
Certificate of Registration AP 1160453,
and deny any pending applications for
renewal of the registration as a retail
pharmacy, under 21 U.S.C. 823(f). The
statutory predicate for the proposed
revocation was that Leon Earl Waters,
Jr., president and registered pharmacist
of Park and King Pharmacy, unlawfully
dispensed controlled substances other
than pursuant to the lawful order of a
practitioner, and for further reason that
on May 10, 1985, in the Circuit Court for
Duval County, Florida, Mr. Waters
entered a plea of nolo contendere to the
felony offense of possession of a
controlled substance with intent to
deliver or sell. The withholding of
adjudication on these charges
constitutes a final judgment of the trial
court, subject to review, and is a
conviction within the meaning and
intent of 21 U.S.C. 824(a)(2). See *United
States v. Hartsfield*, 387 F. Supp. 16
(U.S.D.C., M.D. Florida 1975); *United
States v. Cook*, 10 M.J. 138 (U.S. Ct. Mil.
App. 1981); *Matter of Stephen Granet
Rosen*, D.D.S., DEA Docket No. 84-44, 50
FR 46844 (1985).

On January 10, 1986, Mr. Waters,
proceeding through counsel, requested a
hearing on the issues raised by the
Order to Show Cause. The Matter was
placed on the docket of Administrative
Law Judge Francis L. Young and was
subsequently heard in Jacksonville,
Florida on April 17, 1986. On July 15,
1986, the Administrative Law Judge
issued his Opinion and Recommended
Ruling, Findings of Fact, Conclusion of
Law and Decision. On August 15, 1986,
the Administrative Law Judge
transmitted the record to the

Administrator. On September 24, 1986, Judge Young requested that the Administrator return the record when counsel for both sides made known a desire that the record be supplemented by additional material. The Administrator complied with the request and, on November 14, 1986, the Administrative Law Judge issued his revised Opinion and Recommended Decision. Judge Young again transmitted the record to the Administrator on December 24, 1986. The Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues his final order in this matter based upon findings of fact and conclusions of law as hereinafter set forth.

The Administrative Law Judge found that Leon Earl Waters, Jr. is a licensed pharmacist in Florida and president and registered pharmacist of Park and King Pharmacy. In January 1985, the criminal activities of Leon Earl Waters came to the attention of the Jacksonville, Florida Sheriff's Office when the Vice Squad received information from a confidential source that a named individual was receiving considerable amounts of controlled substances from Park and King Pharmacy without a valid prescription. In the course of their investigation of Park and King Pharmacy, investigators obtained a computer printout of prescriptions dispensed to the said individual. The printout revealed that on 41 occasions in 1984, the woman had received 50 Tylenol #3 tablets, a Schedule III narcotic controlled substance. Although these prescriptions were listed as having been issued by a physician, the physician named had not seen the woman since 1982, nor had he written or called in any prescriptions for her in 1984. As the individual subsequently admitted, the 2050 Tylenol #3 tablets had been delivered to her by Leon Earl Waters without the authorization of a physician. The woman had been receiving controlled substances illegally from Mr. Waters since 1980, even after she was hospitalized for drug dependency, a fact known to Mr. Waters.

When the investigators confronted Mr. Waters with the evidence, he admitted that he knew the individual and that she was taking too many drugs but insisted that the physician had been calling in the refills. He then contacted the individual for the purpose of arranging a meeting at the pharmacy where they could "get their stories straight." The individual agreed to cooperate with the investigators and went to the pharmacy wearing a

concealed recording device. During the course of their conversation, Mr. Waters counselled the individual to tell the authorities that she'd called the doctor's office and asked them to call in the prescriptions to Park and King Pharmacy. He hypothesized that the doctor's office would deny having been called or having authorized the refills, thus making it their word against that of the doctor's office. Mr. Waters admonished the individual to stick to her story because he could get into a great deal of trouble and could lose his pharmacy.

The Administrative Law Judge concluded that there was a lawful basis for revocation of the subject registration and for the denial of any pending applications for its renewal. Judge Young also concluded that there was no basis for a lesser action and recommended that the Administrator revoke the registration and deny any pending applications for its renewal. After the Administrative Law Judge certified and transmitted the record, including his original Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision dated July 15, 1986, to the Administrator, counsel for both sides requested the opportunity to supplement the record with additional material. At Judge Young's request, the Administrator returned the record to him.

On October 7, 1986, in a joint post-hearing filing, it was stipulated that: (1) On June 1, 1986, Leon Earl Waters, Jr. sold and thereby divested himself of all rights, title of interest in King and Park Pharmacy, 2665 King Street, Jacksonville, Florida to a purchaser who was then operating a pharmacy at the same address. Mr. Waters has not been employed by said pharmacy since the sale; and (2) Since the sale of King and Park Pharmacy, Mr. Waters as a licensed pharmacist under the laws of the State of Florida, has been and is currently employed as a pharmacist with another drugstore.

Upon reviewing all of the new evidence, the Administrative Law Judge concluded that the issues under consideration in this matter had become moot and not appropriate for consideration because the registration with which this proceeding is concerned no longer exists. Judge Young based his position on the following facts: (1) The registration which is the subject of this proceeding states on its face that it "expires" on March 31, 1986. The record contains no application for its renewal; (2) Mr. Waters sold the pharmacy for which he held the subject registration and is presently employed in a

pharmacy owned by somebody else. Therefore, Judge Young contends Mr. Waters has discontinued the pharmacy operation for which he held the subject registration; and (3) 21 CFR 1301.62 provides that: "the registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business of professional practices."

In a memorandum dated October 17, 1986, counsel for DEA made several points in support of the revocation of Mr. Waters' registration: (1) If the registrant was a medical practitioner, there is no question but that the DEA would not permit him to surrender his registration or withdraw his application for registration during the 23rd hour of a proceeding to revoke the registration or deny the application; (2) The registrant's ability to direct the destiny of his registration or application terminated once the agency had issued an Order to Show Cause, seeking to revoke the registration or deny the application; (3) If a registrant or applicant were permitted to withdraw at any time, he could put the agency to the expense of a hearing, with a commitment of public resources which is not insubstantial, and then at the last minute duck the issue by mailing in his registration or, in the case of a pharmacy, by selling out. If this were to occur, the person could then avoid any or all of the collateral sanctions which accompany the revocation of a registration. He could reopen at a later time or in a different location, submitting a new application for registration and truthfully answering on such application that he had never had a registration revoked or denied. This would diminish the chances that the application would be noticed for further administrative proceedings; and (4) If there were no final order following the last minute withdrawal of a Respondent, another full hearing on the new application might be required. Such a measure would prevent the administrative processes of DEA from operating effectively.

After considering the Administrative Law Judge's revised opinion, together with the post-hearing papers filed by the parties, the Administrator concludes that this matter is not moot. The practice of the Drug Enforcement Administration, as well as its predecessor agency, since the implementation of the Controlled Substance Act has been to maintain registrations on a day-to-day basis pending resolution of administrative proceedings seeking to revoke such registrations. The Respondent in this matter possessed a viable DEA registration when he received the Order

to Show Cause which initiated the proceedings. That registration remained in effect, on a day-to-day basis, following its nominal expiration date on March 31, 1986. The same administrative "hold" that prevented the registration from expiring also prevented the Respondent from renewing the registration. Accordingly, the Administrator concludes that neither the nominal expiration date on the face of the Respondent's registration nor his inability to file a renewal application have any effect upon the matter pending before the Administrator.

The Administrative Law Judge also concluded that the Respondent's DEA registration terminated, pursuant to 21 CFR 1301.62, when Respondent Waters sold his pharmacy to new owners. That a new entity has been registered on the premises formerly occupied by Respondent Waters and his pharmacy is not disputed. The question is whether a registration which is the subject of an ongoing administrative proceeding can be terminated by the unilateral action of the registrant in declaring his decision to discontinue his business or professional practice. As agency counsel pointed out in his memorandum to the Administrative Law Judge, permitting a registrant to terminate his registration unilaterally, during the eleventh hour of a proceeding to revoke that registration, would permit the registrant to avoid any of the collateral effects of revocation and could require the Administration to grant the individual another full evidentiary hearing should he decide to re-establish his business or professional practice and apply for a new registration shortly thereafter. DEA's regulations permit an applicant for registration to modify or withdraw his application at any time prior to the issuance of an Order to Show Cause seeking to deny the application. That regulation, 21 CFR 1301.37(a), effectively precludes an applicant's abrupt and unilateral termination of proceedings by requiring the Administrator's permission for withdrawal of an application at any time after issuance of the Order to Show Cause. The "application," apart from the applicant who filed it, becomes the subject of the proceedings and cannot be withdrawn without the Administrator's permission. Similarly, the Administrator concludes that a "registration," apart from the registrant who possessed it, becomes the subject of a revocation hearing and likewise cannot be withdrawn without the Administrator's prior approval. Accordingly, the registration which was in the possession of Respondent Waters

and Park and King Pharmacy remains the subject of these proceedings.

In his first opinion in this matter, the Administrative Law Judge concluded that the registration of Leon Waters and Park and King Pharmacy was inconsistent with the public interest. Mr. Waters dispensed controlled substances, unlawfully, over a period of four years. He gave narcotic drugs to a young woman who he knew had a drug abuse problem and who he knew had been hospitalized for that condition. Judge Young concluded that the record in this matter established Mr. Waters' calculated and continued unwillingness to fulfill the responsibilities of a pharmacist and DEA registrant. Society entrusts professionals, such as pharmacists and physicians, with the responsibility for control over a force which, when properly used, has great benefit for mankind, but when abused is a force for evil and destruction. It follows that society cannot tolerate the presence of individuals within these professions who abdicate their professional responsibility and permit themselves to be a conduit by which controlled substances are diverted from legitimate medical use and become that force for evil and human destruction. The Administrator concludes, as did the Administrative Law Judge, that the registration of Mr. Waters, and Park and King Pharmacy, is inconsistent with the public interest and that such registration must be revoked.

Having considered the record of those proceedings in its entirety, including the initial and revised opinions of the Administrative Law Judge, the Administrator of the Drug Enforcement Administration, pursuant to the authority granted to the Attorney General in 21 U.S.C. 823 and 824 and delegated to the Administrator in 28 CFR 0.100(b), hereby orders that DEA Certificate of Registration AP1160453, previously issued to Leon Earl Waters, Jr., d.b.a. Park and King Pharmacy, be, and it hereby is, revoked, effective immediately. Any applications for renewal of such registration are hereby denied.

Should another pharmacy desire to seek waiver of the regulatory prohibition of 21 CFR 1316.76(a), so as to permit the supervised employment of Leon Waters as pharmacist, the Administrator will grant such a waiver.

Dated: April 16, 1987.

John C. Lawn,
Administrator.

[FR Doc. 87-8890 Filed 4-20-87; 8:45 am]

BILLING CODE 4410-09-M

Warrenville Drug, Co., Inc.; Denial of Application

On December 24, 1986, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Warrenville Drug, Co., Inc., Aiken Blvd., P.O. Box 155, Warrenville, South Carolina 29851, proposing to deny the application for a DEA Certification of Registration submitted by the pharmacy. The statutory predicate for the Order to Show Cause was that registration of the pharmacy would be inconsistent with the public interest as evidenced by the conviction of Andrew J. Chavous, officer, shareholder and pharmacist at Warrenville Drug Company, in the United States District Court for the District of South Carolina on April 30, 1986, of illegal distribution of controlled substances, a felony relating to controlled substances.

The Order to Show Cause was sent to Warrenville Drug Co., Inc. registered mail, return receipt requested. DEA received the receipt which indicated that the Order to Show Cause was received on January 2, 1987, by Mr. Chavous at the pharmacy. More than thirty days have elapsed since the Order to Show Cause was received, and the Drug Enforcement Administration has received no response. Pursuant to 21 CFR 1301.54(a) and (d), Warrenville Drug Co., Inc. is deemed to have waived its opportunity for a hearing. Accordingly, the Administrator now enters his final order in this matter without a hearing and based upon the investigative file. 21 CFR 1301.57.

The Administrator finds that an investigation of Andrew Chavous was initiated after DEA received information from a confidential source that Mr. Chavous was dispensing controlled substances without prescriptions from Warrenville Drug. In May, 1985, a DEA Special Agent accompanied the confidential source to Warrenville Drug in Warrenville, South Carolina, where she filled a prescription for morphine. The prescription which the source had was in a fictitious name, which Mr. Chavous, the dispensing pharmacist, knew was not the name of the confidential source. A few days later the DEA Agent and the confidential source returned to the pharmacy with another prescription for morphine with the same fictitious name. Mr. Chavous filled the prescription, and then discussed trading drugs for stereo equipment with the DEA Agent. On July 3, 1985, the DEA Agent met Mr. Chavous in the parking lot of a pharmacy in a neighboring

community and obtained a bottle containing 24 morphine tablets in exchange for \$360. The bottle bore the manufacturer's label. There was no prescription exchanged. On September 4, 1985, Mr. Chavous sold the DEA Agent a pint bottle of liquid morphine.

On September 24, 1985, the DEA Agent made arrangements to meet with Mr. Chavous in a local parking lot and to receive controlled substances to sell for him. After he delivered two bottles, one containing 100 Valium tablets, a Schedule IV controlled substance, and the other 100 Adipex tablets, a Schedule IV controlled substance, he was arrested. Mr. Chavous was indicted for three counts of illegal distribution of controlled substances in violation of 21 U.S.C. 841(a)(1). On November 21, 1985, Mr. Chavous pled guilty to one count of illegal distribution of Valium, a Schedule IV controlled substance. He was subsequently convicted and sentenced on April 30, 1986, to four years probation, 300 hours of community service, and a fine of \$1,500.

After Mr. Chavous' arrest, an audit was conducted at Warrentville Drug by DEA Investigators. The results of this accountability revealed substantial shortages of Valium and Adipex, as well as shortages of other controlled substances for the four-month audit period. The investigation also revealed numerous recordkeeping violations relating to the handling of controlled substances. On June 25, 1986, the South Carolina Board of Health and Environmental Control revoked the South Carolina controlled substance registration of Andrew Chavous. The pharmacy's registration was not revoked, and Mr. Chavous was permitted to maintain an ownership interest, but not to have access to, or to acquire, possess, or dispense any controlled substances.

As evidenced by the application for registration submitted in this matter, Mr. Chavous maintains an ownership interest in Warrentville Drug Co., Inc., the applicant for registration. There is no evidence that Mr. Chavous is not involved in the operation of the pharmacy and may exert control over matters which involve the dispensing of controlled substances. In addition, the applicant submitted no evidence in mitigation or explanation of the evidence found in the investigative file.

The Administrator concludes that Mr. Chavous' felony conviction relating to controlled substances constitutes sufficient grounds for denial of the application for registration of the pharmacy in which he has an ownership interest. The Administrator of DEA has consistently held that the registration of

a corporate registrant may be revoked or denied upon a finding that a natural person who is an owner, officer or key employee, has been convicted of a felony offense relating to controlled substances. This is especially significant when the felony relates to dispensing controlled substances from a registered pharmacy. See: *Taneytown Pharmacy*, Docket No. 86-56, 51 FR 45068 (1986); *Spoon's Pharmacy*, Docket No. 84-42, 50 FR 46520 (1985); and *K & B Successors, Inc.*, Docket No. 82-15, 49 FR 34588 (1984).

The Administrator concludes that, based upon the facts and circumstances involved in this matter, the application for registration submitted by Warrentville Drug Co., Inc. should be denied. In addition to Mr. Chavous' felony conviction, the previous pharmacy registrant has demonstrated a lack of compliance with the regulations involving the maintenance of records documenting the receipt and dispensing of controlled substances. The Administrator finds that registration of Warrentville Drug Co., Inc. would be inconsistent with the public interest.

Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) hereby orders that the application for a DEA Certificate of Registration submitted by Warrentville Drug Co., Inc. be, and it hereby is denied. This order is effective April 21, 1987.

Dated: April 16, 1987.

John C. Lawn,

Administrator.

[FR Doc. 87-8940 Filed 4-20-87; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Office of the Secretary

[Secretary of Labor's Order 1-87]

Delegation of Authority and Assignment of Responsibilities for Pension and Welfare Benefits Administration

April 13, 1987.

1. Purpose.

To delegate authority and assign responsibilities for the administration of the Department of Labor's responsibilities under the Employee Retirement Income Security Act (ERISA), Welfare and Pension Plans Disclosure Act (WPPDA) and the Federal Employees' Retirement System Act of 1986 (FERSA).

2. Background

ERISA places responsibility in the Department of Labor for the administration of a comprehensive program to protect the interests of participants and beneficiaries of private employee benefit plans. Secretary's Order 1-84 established the Office of Pension and Welfare Benefit Programs as a separate agency within the Department of Labor and delegated authority and assigned responsibility for ERISA and WPPDA activities to the Administrator. The authority placed in the Office of Pension and Welfare Benefit Programs was transferred by Secretary's Order 1-86 to a successor agency, the Pension and Welfare Benefits Administration (PWBA) which is headed by an Assistant Secretary for Pension and Welfare Benefits who reports to the Secretary of Labor.

FERSA requires the Department of Labor to, among other things administer and enforce the fiduciary responsibility, prohibited transaction, and bonding provisions of FERSA. These new responsibilities will also be handled by PWBA.

3. The Pension and Welfare Benefits Administration (PWBA)

The Pension and Welfare Benefits Administration, which is headed by an Assistant Secretary for Pension and Welfare Benefits who reports to the Secretary of Labor, continues as the successor agency to the Office of Pension and Welfare Benefit Programs in the Department of Labor.

4. Delegation of Authority and Assignment of Responsibilities

a. *The Assistant Secretary for Pension and Welfare Benefits* is delegated authority (including the authority to redelegate) and assigned responsibilities, except as hereinafter provided, for carrying out programs and activities to be performed by the Secretary of Labor under:

(1) The Employee Retirement Income Security Act of 1974, as amended, except for Subtitle C of Title III and Title IV;

(2) The Welfare and Pension Plans Disclosure Act of 1985 as amended; and

(3) The Federal Employees' Retirement System Act of 1986.

Included in the delegation under 4a.(1) is authority to request information the Internal Revenue Service (IRS) possesses to be used in connection with the administration of Title I of the ERISA of 1974.

b. *The Assistant Secretary for Administration and Management* is responsible for providing all administrative support services to

PWBA such as personnel, payroll, budget, accounting, contracting and grants and other such services deemed necessary in support of the PWBA mission.

c. *The Solicitor of Labor* is responsible for providing legal advice and assistance to all officials of the Department relating to the administration of the statutes listed in 4a. above and for bringing appropriate legal actions on behalf of the Secretary, and representing the Secretary in all civil proceedings. The Solicitor of Labor is also authorized to request information the IRS possesses to be used in connection with the administration of Title I of ERISA.

d. *The Inspector General* is authorized to request information the IRS possesses to be used in connection with the administration of Title I of ERISA.

5. Reservation of Authority

The submission of reports and recommendations to the President and the Congress concerning the administration of the statutes listed in 4a. above and responsibilities under Subtitle C of Title III of ERISA are reserved to the Secretary. Responsibilities under Title IV of ERISA are carried out by the Pension Benefit Guaranty Corporation.

6. Directives Affected

Secretary's Order 9-80 and 1-86 are canceled.

7. Effective Date

This Order is effective immediately.

William E. Brock,
Secretary of Labor.

[FR Doc. 87-8902 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-23-M

Labor Advisory Committee for Trade Negotiations and Trade Policy; Steering Subcommittee; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (P.L. 92-463 as amended), notice is hereby given of a meeting of the Steering Subcommittee of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

Date, time and place: May 12, 1987, 9:30 a.m., Rm S4215 A&B Frances Perkins, Department of Labor Building, 200 Constitution Avenue, NW., Washington, DC 20210.

Purpose: To discuss trade negotiations and trade policy of the United States.

This meeting will be closed under the authority of section 10(d) of the Federal

Advisory Committee Act. The Committee will hear and discuss sensitive and confidential matters concerning U.S. trade negotiations and trade policy.

For further information, contact: Fernand Lavallee, Executive Secretary, Labor Advisory Committee, Phone: (202) 523-8565.

Signed at Washington, DC, this 14th day of April 1987.

Robert W. Searby,

Deputy Under Secretary International Affairs.

[FR Doc. 87-8901 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-28-M

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

Background

The Department of Labor, in carrying out its responsibilities under the Paperwork Reduction Act (44 U.S.C. Chapter 35), considers comments on the reporting and recordkeeping requirements that will affect the public.

List of Recordkeeping/Reporting Requirements under Review

As necessary, the Department of Labor will publish a list of the Agency recordkeeping/reporting requirements under review by the Office of Management and Budget (OMB) since the last list was published. The list will have all entries grouped into new collections, revisions, extensions, or reinstatements. The Departmental Clearance Office will, upon request, be able to advise members of the public of the nature of the particular submission they are interested in. Each entry may contain the following information:

The Agency of the Department issuing this recordkeeping/reporting requirement.

The title of the recordkeeping/reporting requirement.

The OMB and Agency identification numbers, if applicable.

How often the recordkeeping/reporting requirement is needed.

Who will be required to or asked to report or keep records.

Whether small businesses or organizations are affected.

An estimate of the total number of hours needed to comply with the recordkeeping/reporting requirements.

The number of forms in the request for approval, if applicable.

An abstract describing the need for and uses of the information collection.

Comments and Questions

Copies of the recordkeeping/reporting requirements may be obtained by calling

the Departmental Clearance Officer, Paul E. Larson, telephone (202) 523-6331. Comments and questions about the items on this list should be directed to Mr. Larson, Office of Information Management, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-1301, Washington, DC 20210. Comments should also be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ESA/ETA/OLMS/MSHA/OSHA/PWBA/VETS), Office of Management and Budget, Room 3208, Washington, DC 20503 (Telephone (202) 395-6880).

Any member of the public who wants to comment on a recordkeeping/reporting requirement which has been submitted to OMB should advise Mr. Larson of this intent at the earliest possible date.

Extension

Employment Standards Administration
Payment of Compensation Without Award
1215-0022; LS-206

On occasion

Businesses or other for-profit
34,200 responses; 8,550 hours; 1 form
Used by insurance carriers and self
insurers to report the payment of
compensation benefits to injured
claimants.

Extension

Employment Standards Administration
Pre-Hearing Statement
1215-0085; LS-18

On occasion

Individuals or households; businesses or
other for-profit 6,800 responses; 1,088
hours; 1 form

Used to refer cases to the Office of
Administrative Law Judges for formal
hearing under the Longshore Act and
extensions.

Extension

Occupational Safety and Health
Administration
Grantee Quarterly Progress Report
1218-0100; OSHA 171

Quarterly

New Directions training and education
program grantees; labor organizations;
employer associations; educational
institutions; and other nonprofit
organization

200 responses; 2,400 hours

The OSHA 171 is used to collect
information concerning activities
conducted by grantees. The
information is used to monitor and
manage the program.

Reinstatement

Departmental Management
Women's Bureau Regional III Women
Veteran's Job Information Packet
Evaluation Form

1225-0035

Reporting on occasion
Individuals or households
1,360 responses; 326 hours

The information will be used to make decisions about the content of the Women's Bureau Region III Women Veteran's Job Information Packet, the cost effectiveness of a national distribution of the packet and the most effective dissemination strategy for the information.

Signed at Washington, DC this 16th day of April, 1987.

Paul E. Larson,

Departmental Clearance Officer.

[FR Doc. 87-8903 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-27-M

Employment and Training Administration**Investigations Regarding Certification of Eligibility To Apply for Worker Adjustment Assistance; AT&T Technologies et al.**

Petitions have been filed with the Secretary of Labor under section 221 (a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than May 1, 1987.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than May 1, 1987.

The petition filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street, NW., Washington, DC 20213.

Signed at Washington, DC, this 6th day of April 1987.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers/firm	Location	Date received	Date of petition	Petition No.	Articles produced
AT&T Technologies, (Workers)	Mesquite, TX	4/6/87	3/23/87	19,457	Communications Power Supplies.
Abex Corporation Waukesha, Division (Company)	Rochester, NY	4/6/87	3/22/87	19,458	Grey Metal Castings.
Amboy Terminaling (I.U.O.E.)	Perth Amboy, NJ	4/6/87	3/17/87	19,459	Product Packaging.
Amoco Production, Co (Workers)	Denver, CO	4/6/87	3/26/87	19,460	Oil & Natural Gas.
American Electric Co. (Workers)	Pittsfield, NH	4/6/87	3/20/87	19,461	Electrical Outlets.
American Motors Jeep Corp. (U.A.W.)	Toledo, OH	4/6/87	3/20/87	19,462	Jeep Vehicles.
Ansoco Answering Serv. (Workers)	Snyder, TX	4/6/87	3/25/87	19,463	Answering Service.
Arcticwear Manufacturing Co. (Workers)	Thief River Falls, MN	4/6/87	3/20/87	19,464	Snowmobile Clothing.
Armstrong Drilling (Company)	Wooster, OH	4/6/87	3/24/87	19,465	Oil & Gas Wells.
Automotive Proving Grounds (UAW)	Pecos, TX	4/6/87	3/25/87	19,466	Auto Tires.
Bandera Energy Co. (Company)	Midland, TX	4/6/87	3/11/87	19,467	Oil & Gas.
Bata Shoe Co., Inc. (Company)	Belcamp, MD	4/6/87	3/31/87	19,468	Athletic Footwear.
Beckley Lick Run, Co. (UMWA)	Beckley, WV	4/6/87	3/26/87	19,469	Coal.
Beicher & Windels, Inc. (Company)	Golden, CO	4/6/87	3/25/87	19,470	Oil & Gas.
Carbery Fabricatori Co. (Company)	Dallas, TX	4/6/87	3/26/87	19,471	Pressure Vessels.
Caterpillar Industrial Inc. (IAAMAW)	Odesa, TX	4/6/87	3/27/87	19,472	Industrial Forklift Trucks.
Certified Brakes (Lear Siegler) (USW)	Danville, KY	4/6/87	3/30/87	19,473	Drum & Disc Brakes.
Copperweld Corp. (Company)	Marietta, GA	4/6/87	3/27/87	19,474	Steel.
Colorado Electro-Optics Inc. (Company)	Boulder, CO	4/6/87	3/24/87	19,475	Security Systems.
Cricketeer Manufacturing Co. (ACTWU)	Harrodsburg, KY	4/6/87	3/27/87	19,476	Men's Coats.
Exxon, Western Division Production Department (Workers)	Thousand Oaks, CA	4/6/87	3/16/87	19,477	Crude Oil.
Ford Motor Co., Canton Forge Plant (UAW)	Canton, OH	4/6/87	3/26/87	19,478	Friged Auto Parts.
General Electric Ohio Lamp Plant (IUE, AFL, CIO)	Warren, OH	4/6/87	3/18/87	19,479	Incandescent Lamps.
Glassco Apparel, Co. (Workers)	Scranton, PA	4/6/87	3/30/87	19,480	Dresses.
High Plains Oil Corp. (Company)	Denver, CO	4/6/87	3/23/87	19,481	Oil & Natural Gas.
Jet Oilfield Equipment Rental & serv., Inc. (Workers)	Dickinson, ND	4/6/87	1/10/87	19,482	Oilfield Equipment.
Jewell Ridge Coal Corp. (Workers)	Jewell Ridge, VA	4/6/87	3/23/87	19,483	Coal.
Koch Exploration, Co. Div. of Koch Industries (Workers)	Denver, CO	4/6/87	3/30/87	19,484	Oil & Natural Gas.
LTV Steel, Co. (Workers)	Paramus, NJ	4/6/87	3/30/87	19,485	Steel.
Loftis Co. (Workers)	Midland, TX	4/6/87	2/4/87	19,486	Pipeline Protection.
3 M Company (USWA)	Newark, NJ	4/6/87	3/24/87	19,487	Bottle Cap Liner Seals.
Marathon International Oil Co. (Workers)	Houston, TX	4/6/87	3/24/87	19,488	Crude Oil.
Mineral Search, Inc. (Workers)	Houston, TX	4/6/87	3/19/87	19,489	Oil Exploration.
North American Systems (ILGWU)	Clifton, NJ	4/6/87	3/26/87	19,490	Coffee Filters.
Ogdon Allied Services Corp. (SGU)	Pittsburgh, PA	4/6/87	3/29/87	19,491	Steel.
Optex Technologies (Workers)	El Paso, TX	4/6/87	3/19/87	19,492	Computer Components.
Ortho Fertilizer Division, Chevron Chemical Co. (Workers)	FL Madison, IA	4/6/87	3/30/87	19,493	Fertilizers.
Oster Company (IBEW)	Wilwaukee, WI	4/6/87	3/19/87	19,494	Clipper Blades.
Paper Converting Machine, Co. (UAW)	Green Bay, WI	4/6/87	3/25/87	19,495	Paper Converting Machinery
Perspectives, Inc. (Company)	Blanchester, OH	4/6/87	3/30/87	19,496	Ice Buckets.
Primary Fuels, Incorp. (Workers)	Denver, CO	4/6/87	3/24/87	19,497	Oil & Natural Gas.
Primary Fuels, Incorp. (Workers)	Houston, TX	4/6/87	3/24/87	19,498	Oil & Natural Gas.
Primary Fuels, Incorp. (Workers)	Midland, TX	4/6/87	3/24/87	19,499	Oil & Natural Gas.
Ranchers Cotton Oil (ILWU)	Bakersfield, CA	4/6/87	3/27/87	19,500	Cottonseed Oil.
Ranchers Cotton Oil (ILWU)	Fresno, CA	4/6/87	3/27/87	19,501	Cottonseed Oil.
Scovill Apparel Fasteners, Inc. (UAW)	Watertown, CT	4/6/87	3/26/87	19,502	Snap Fasteners.
Sea B Mining Co., (Workers)	Jewell Ridge, VA	4/6/87	3/23/87	19,503	Coal.
Smart Styles Inc. (Workers)	Clarks Summit, PA	4/6/87	3/30/87	19,504	Dresses.
Spring Fever Limited (Workers)	Springvale, ME	4/6/87	3/24/87	19,505	Women's Apparel.
Square D. Company (IBEW)	Milwaukee, WI	4/6/87	3/23/87	19,506	Programmable Controllers.

APPENDIX—Continued

Petitioner: Union/workers/firm	Location	Date received	Date of petition	Petition No.	Articles produced
Toub Distributors (Workers)	Thorofare, NJ	4/6/87	3/26/87	19,507	School Supplies.
United Detector Technology Caribe, Inc. (Workers)	Juncos, PR	4/6/87	3/27/87	19,508	Photo Sensors.
Valero Producing (Workers)	San Antonio, TX	4/6/87	3/26/87	19,509	Oil & Gas.
Wilker Brothers, Co. (Workers)	McKenzie, TN	4/6/87	3/23/87	19,510	Pajamas, Robes.

[FR Doc. 87-8915 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-18,739 et al.]

Dismissals of Applications for Reconsideration; AT&T Technologies, Inc., et al.

Pursuant to 29 CFR 90.18 applications for administrative reconsideration were filed with the Director of the Office of Trade Adjustment Assistance for workers at the AT&T Technologies, Incorporated, AT&T Technology Systems, Reading, Pennsylvania; U.S. Steel Mining Company, Gary #50 Mine and Gary #51 Mine, Pineville, West Virginia. The reviews indicated that the applications contained no new substantial information which would bear importantly on the Department's determinations. Therefore, dismissals of the applications were issued.

TA-W-18,739; AT&T Technologies, Incorporated, AT&T Technology Systems, Reading, Pennsylvania; Hazleton, Pennsylvania (March 30, 1987)

TA-W-18,627; U.S. Steel Mining Company, Gary #50 Mine, Pineville, West Virginia (March 30, 1987)

TA-W-18,621; U.S. Steel Mining Company, Gary #51 Mine, Pineville, West Virginia (March 31, 1987)

Signed at Washington, DC, this 14th day of April 1987.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 87-8918 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-19,269 et al.]

Dismissals of Applications for Reconsideration; Cameron Iron Works, Inc., et al.

Pursuant to 29 CFR § 90.18 applications for administrative reconsideration were filed with the Director of the Office of Trade Adjustment Assistance for workers at the Cameron Iron Works, Incorporated, Houston, Texas; Lucas-Milhaupt, Cudahy, Wisconsin; Consolidation Coal Company, Amonate #31 Mine,

Amonate, Virginia. The reviews indicated that the applications contained no new substantial information which would bear importantly on the Department's determinations. Therefore dismissals of the applications were issued.

TA-W-19,269; Cameron Iron Works, Incorporated, Houston, Texas (April 8, 1987)

TA-W-18,664; Lucas-Milhaupt, Cudahy, Wisconsin (April 1, 1987)

TA-W-18,841; Consolidation Coal Company, Amonate #31 Mine, Amonate, Virginia (March 31, 1987)

Signed at Washington, DC, this 15th day of April 1987.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 87-8919 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-19,156 et al.]

Dismissals of Applications for Reconsideration; Express Services, Inc., et al.

Pursuant to 29 CFR § 90.18 applications for administrative reconsideration were filed with the Director of the Office of Trade Adjustment Assistance for Workers at the Express Services, Incorporated, Midland, Texas; International Titanium Incorporated of Washington, Moses Lake, Washington; Impala Drilling, Incorporated, College Station, Texas. Indicated that the applications contained no new substantial information which would bear importantly on the Department's determinations. Therefore dismissals of the applications were issued.

TA-W-19,156; Express Services, Incorporated, Midland Texas (April 8, 1987)

TA-W-19,036; International Titanium, Incorporated of Washington, Moses Lake, Washington (April 8, 1987)

TA-W-19,146; Impala Drilling,

Incorporated, College Station, Texas (April 8, 1987)

Signed at Washington, DC, this 14th day of April 1987.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 87-8920 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-18,724 et al.]

Dismissals of Applications for Reconsideration; Hazle Garment, Inc., et al.

Pursuant to 29 CFR § 90.18 applications for administrative reconsideration were filed with the Director of the Office of Trade Adjustment Assistance for workers at the Hazle Garment, Incorporated, Hazleton, Pennsylvania; Beckley Coal Mining Company, Glen Daniel, West Virginia; Consolidation Coal Company, Jenkinjones #4 Mine, Jenkinjones, West Virginia. The review indicated that the applications contained no new substantial information which would bear importantly on the Department's determinations. Therefore dismissals of the applications were issued.

TA-W-18,724; Hazle Garment, Incorporated, Hazleton, Pennsylvania (March 27, 1987)

TA-W-18,842; Beckley Coal Mining Company, Glen Daniel, West Virginia (March 30, 1987)

TA-W-18,841; Consolidation Coal Company, Jenkinjones #4 Mine, Jenkinjones, Virginia (March 31, 1987)

Signed at Washington, DC, this 15th day of April 1987.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 87-8917 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-19,170 et al.]

Dismissals of Applications of Reconsideration; Seismic Prospecting of Denver, Inc., et al.

Pursuant to 29 CFR 90.18 applications

of administrative reconsideration were filed with the Director of the Office of Trade Adjustment Assistance of workers at the Seismic Prospecting of Denver, Incorporated, Englewood, Colorado; Gerard Mills, Mazeltion, Pennsylvania; Ranger Fuel Corporation, Sabine (Beckley #2) Mine, Beckley, West Virginia indicated that the applications contained no new substantial information which would bear importantly on the Department's determinations. Therefore dismissals of the applications were issued.

TA-W-19,170; Seismic Prospecting of Denver, Incorporated, Englewood, Colorado (April 10, 1987)

TA-W-18,942 Gerard Mills, Hazeltion, Pennsylvania (April 9, 1987)

TA-W-18,844; Ranger Fuel Corporation, Sabine (Beckley #a2) Minem Beckley, West Virginia (April 3, 1987)

Signed at Washington, DC, this 14th day of April 1987.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 8916 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-18,616]

Smurfit Newsprint Corp. Clackamas Mill, Oregon City, OR; Negative Determination Regarding Application for Reconsideration

By an application dated March 8, 1987 the petitioners requested administrative reconsideration of the Department's negative determination on the subject petition for trade adjustment assistance filed on behalf of workers and former workers at Smurfit Newsprint Corporation, Clackamas Mill, Oregon City OR. The denial notice was signed on February 20, 1987 and published in the Federal Register on March 10, 1987 (52 FR 7330).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The petitioners request an explanation as to how the Department

can certify workers at another company facility (Molalla Mill) and not certify workers at the Clackamas Mill. Petitioners claim that both mills produced the same product, had the same customers and served the same market in the same time periods.

In order for a work group to become certified eligible to apply for adjustment assistance it must meet all three group eligibility criteria of the Group Eligibility Requirements of the Trade Act of 1974—significantly decreased employment; decreased sales or production and increased imports contributing importantly to worker separations. Investigative findings show that workers at the Molalla Mill petitioned the Department a year earlier (TA-W-16,728) and met all the criteria for certification. The investigative period covered was from 1983 to 1985.

The Clackamas investigation was instituted on November 17, 1986 and all workers were laid off on December 26, 1986. The investigative findings show that the decreased sales or production criterion of the Act was met for workers at the Clackamas Mill in 1985. Although workers at the Clackamas Mill met the decreased employment and sales or production criteria in 1986 they did not meet the "contributed importantly" test of the increased import criterion for 1986. This test is usually demonstrated through a survey of the firm's customers. The Department surveyed the major customers of Smurfit Corporation for the January to September 1985 and 1986 periods. The survey revealed that the respondents who imported were not important in the survey period. All the customers who imported either had remained the same during the survey period. One of the major customers commented that the sizes and grades purchased from Smurfit are not manufactured by foreign producers.

Conclusion

After review of the application and investigative findings, I conclude that there has been error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly the application is denied.

Signed at Washington, DC, this 10th day of April 1987.

Barbara Ann Farmer,

Acting Director, Office of Program Management, UIS.

[FR Doc. 8914 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-16,637]

Louisiana-Pacific Corp., Ashland, WI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 28, 1986 applicable to all workers of Louisiana-Pacific Corporation, Ashland, Wisconsin. The certification notice was published in the Federal Register on May 19, 1986 (51 FR 18367).

On the basis of additional information, the Office of Trade Adjustment Assistance, reviewed the certification. The additional information from the company revealed that some workers were retained beyond the April 15, 1986 termination date. In May, 1986 the Ashland firm recalled all workers and then shut the plant down permanently in July, 1986.

The intent of the certification is to cover all workers at the Ashland plant of Louisiana-Pacific who were affected by the decline in sales or production of lumber related to import competition. The notice, therefore, is amended by deleting the April 15, 1986 termination date and inserting a new termination date of September 1, 1986.

The amended notice applicable to TA-W-16,637 is hereby issued as follows:

All workers of Louisiana-Pacific Corporation, Ashland, Wisconsin who became totally or partially separated from employment on or after January 1, 1985 and before September 1, 1986 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 13th day of April 1987.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 87-8913 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-30-M

Mine Safety and Health Administration

[Docket No. M-87-79-C]

Bailey Brothers Coal Co.; Petition for Modification of Application of Mandatory Safety Standard

Bailey Brother Coal Co., P.O. Box 70, Vansant, Virginia 24656 has filed a petition to modify the application of 30 CFR 75.1701 (abandoned areas, adjacent mines; drilling of boreholes) to its No. 6

Mine (I.D. No. 44-05384) located in Buchanan County, Virginia. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. The petition concerns the requirement that whenever any working place approaches within 50 feet of abandoned areas in the mine as shown by surveys made and certified by a registered engineer or surveyor, or within 200 feet of any other abandoned areas of the mine which cannot be inspected and which may contain dangerous accumulations of water or gas, or within 200 feet of any working of an adjacent mine, a borehole or boreholes shall be drilled to a distance of at least 20 feet in advance of the working face of such working place and shall be continually maintained to a distance of at least 10 feet in advance of the advancing working face. When there is more than one borehole, they shall be drilled sufficiently close to each other to insure that the advancing working face will not accidentally hole through into abandoned areas or adjacent mines. Boreholes shall also be drilled not more than 8 feet apart in the rib of such working place to a distance of at least 20 feet and at an angle of 45 degrees.

2. Petitioner requests a modification of the standards to allow for a 20-foot cut to be taken in the face. In further support of this request, petitioner states that:

(a) The provision requiring 20-foot test holes to be drilled at a 45 degree angle at 8-foot intervals in the rib restricts the depth of a cut that can be extracted with a continuous miner;

(b) A continuous mining machine is designed to take a 20-foot cut without the controls of the mining machine passing the last row of roof supports;

(c) Petitioner proposes to drill five holes in the face of the entry, spaced at 5-foot intervals; one hole in each corner of the entry 20 feet deep and 3 holes in the face of the entry 30 feet deep. The holes drilled in the corner of the entry will be at 30 degree angles to the rib. The hole drilled 5 feet from the left rib would be on a 105 degree angle to the face. The hole in the middle of the entry will be a 90 degree angle to the face and the hole drilled 5 feet from the right rib will be a 75 degree angle to the face with a margin or error of ± 5 degrees. This pattern will provide a 10-foot barrier in all direction to the cut to be taken. This pattern will also prevent the cut being taken from intersecting with any entry driven in an unexplored old works 10 feet or greater in width; and

(d) It is more practical to drill a 30 degree angle as opposed to drilling a 45 degree angle due to the size of the drill

and the length of the drill steel, as well as the restricted area available to maneuver the drilling machine.

3. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987.

Copies of the petition are available for inspection at that address.

Dated: April 9, 1987.

Patricia W. Silvey,

Associate Assistant Secretary for Mine Safety and Health.

[FR Doc. 87-8904 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-87-C]

Chapperal Coal Corp.; Petition for Modification of Application of Mandatory Safety Standard

Chapperal Coal Corporation, 441 Marion Branch Road, Pikeville, Kentucky 41501 has filed a petition to modify the application of 30 CFR 75.1103-4(a) (automatic fire sensor and warning device systems; installation; minimum requirements) to its No. 3 Mine (I.D. No. 15-08257) located in Pike County, Kentucky. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that automatic fire sensor and warning device systems provide identification of fire within each belt flight.

2. As an alternate method, petitioner proposes to install a carbon monoxide system in lieu of a point-type system. In support of this request, petitioner states that:

(a) Carbon monoxide (CO) sensor will be installed at the beginning and end of each belt flight and at intervals not to exceed 2,000 feet along the belts. The CO sensors will be capable of giving early warning of a fire automatically. An audible and visual signal will be activated when the level is 10 parts per million (ppm) above ambient air. All persons will be withdrawn to a safe area. The signal will be activated at an

attended surface location where there is two-way communication. The CO system will be capable of identifying any activated sensor;

(b) If the CO system is affected by a power interruption or other malfunction, the belts will continue to operate and qualified persons will monitor the belt conveyor with suitable instruments;

(c) Each CO sensor will be visually examined weekly during production periods to ensure proper functioning. The monitoring system will be calibrated with known concentrations of CO and gas every six weeks; and

(d) The primary intake will be separated from the belt conveyor entry with permanent stoppings.

3. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987. Copies of the petition are available for inspection at that address.

Dated: April 13, 1987.

Patricia W. Silvey,

Associate Assistant Secretary for Mine Safety and Health.

[FR Doc. 87-8905 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-94-C]

J and B Mining Co.; Petition for Modification of Application of Mandatory Safety Standard

J & B Mining Company, 304 Crest Street, Barbourville, Kentucky 40906 has filed a petition to modify the application of 30 CFR 75.313 (methane monitor) to its No. 5 Mine (I.D. No. 15-15438) located in Knox County, Kentucky. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that a methane monitor be installed on any electric face cutting equipment, continuous miner, longwall face equipment and loading machine and shall be kept operative and properly maintained and frequently tested.

2. Petitioner states that no methane has been detected in the mine. The three wheel tractors are permissible DC powered machines, with no hydraulics. The bucket is a drag type, where approximately 30-40% of the coal is hand loaded. Approximately 35% of the time that the tractor is in use, it is used as a man trip and supply vehicle.

3. As an alternate method, petitioner proposes to use hand held continuous oxygen and methane monitors in lieu of continuous methane monitors on three wheel tractors. In further support of this request, petitioner states that:

(a) Each three wheel tractor will be equipped with a hand held continuous monitoring methane and oxygen detector and all persons will be trained in the use of the detector;

(b) A gas test will be performed, prior to allowing the coal loading tractor in the face area, to determine the methane concentration in the atmosphere. The air quality will be monitored continuously after each trip, provided the elapse time between trips does not exceed 20 minutes. This will provide continuous monitoring of the mine atmosphere for methane to assure any undetected methane buildup between trips;

(c) If one percent of methane is detected, the operator will manually deenergize his/her battery tractor immediately. Production will cease and will not resume until the methane level is lower than one percent;

(d) A spare continuous miner will be available to assure that all coal hauling tractors will be equipped with a continuous miner;

(e) Each monitor will be removed from the mine at the end of the shift, and will be inspected and charged by a qualified person. The monitor will also be calibrated monthly; and

(f) No alterations or modifications will be made in addition to the manufacturer's specifications.

4. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987. Copies of the petition are available for inspection at that address.

Dated: April 13, 1987.

Patricia W. Silvey,
Associate Assistant Secretary for Mine
Safety and Health.

[FR Doc. 87-8906 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-59-C]

McCoy Elkhorn Coal Corp.; Petition for Modification of Application of Mandatory Safety Standard

McCoy Elkhorn Coal Corporation, General Delivery, Kimber, Kentucky 41539 has filed a petition to modify the application of 30 CFR 75.305 (weekly examinations for hazardous conditions) to its No. 8-A Mine (I.D. No. 15-13439) located in Pike County, Kentucky. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that return aircourses be examined in their entirety on a weekly basis.

2. Petitioner states that due to deteriorating roof conditions and an overall seam height of twelve feet, certain areas of the return aircourse are unsafe to travel.

3. As an alternate method, petitioner proposes to establish two evaluation points where a qualified person can examine the quantity and quality of air used to ventilate the return aircourse. The examinations will be made daily and recorded in the Pre-Shift/On-Shift Examination Book.

4. In further support of this request, petitioner states:

(a) The return airway is not a part of the mine's escapeway system;

(b) Air passing through this area does not pass over any electrical power sources; and

(c) No methane has been detected in the face area or in the immediate return area with a hand-held detection device.

5. Petitioner states that the proposed alternate method will provide the same degree of safety for the mines affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mines Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987. Copies of the petition are available for inspection at that address.

Dated: April 13, 1987.

Patricia W. Silvey,
Associate Assistant Secretary for Mine
Safety and Health.

[FR Doc. 87-8907 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-86-234-C]

Pyro Mining Co.; Petition for Modification of Application of Mandatory Safety Standard

Pyro Mining Company, P.O. Box 267, Sturgis, Kentucky 42459 has filed an amendment to a petition for modification. On November 26, 1986, Pyro Mining Company submitted a petition to modify the application of 30 CFR 75.312 (air passing through abandoned, inaccessible, or robbed area) to its Pyro #9 Wheatcroft Mine (I.D. No. 15-13920) located in Webster County, Kentucky. On February 6, 1987, MSHA published notice of the petition in the Federal Register (52 FR 3891), allowing interested parties 30 days to submit comments. On March 23, 1987, petitioner submitted a request to amend the originally submitted petition for modification to designate 30 CFR 75.303 (preshift examination) as the standard to be affected. The amendment is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that within 3 hours immediately preceding the beginning of any shift, and before any miner in such shift enters the active workings of a coal mine, certified persons shall examine such workings and any other underground area of the mine. Each such examiner shall examine every working section in such workings and shall make tests in each working section for accumulations of methane.

2. Petitioner states that the northeast sub-mains serves as the intake aircourse for three operating sections. These submains have taken considerable weight from horizontal and vertical stresses. As a result of these stresses, the effective area has been reduced, causing a high pressure area for the fan to overcome.

3. As an alternate method, petitioner proposes to cut the southwest panel into the main aircourse (northeast sub-main) at the intake air shaft and to use the panel to ventilate number one and three units.

4. In further support of this request, petitioner states that:

(a) Continuous reading methane and carbon monoxide sensors will be placed

where intake air from the rooms dump into the 1st main southeast;

(b) The methane sensor will be set to alarm if the level reaches $\pm 0.25\%$;

(c) An audible alarm will sound on number three unit to alert miners if the limits are exceeded. The alarm will be fail-safe and activated by the computer;

(d) An immediate investigation will begin if an alarm sounds. Persons will be withdrawn to a safe place until the cause of the alarm is determined; and

(e) The intake aircourse will be examined weekly.

5. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this amendment to the petition for modification may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987. Copies of the amendment and the original petition for modification are available for inspection at that address.

Dated: April 9, 1986.

Patricia W. Silvey,

Associate Assistant Secretary for Mine Safety and Health.

[FR Doc. 87-8908 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-91-C]

Rhonda Coal Co.; Petition for Modification of Application of Mandatory Safety Standard

Rhonda Coal Company, P.O. Box 70, Vansant, Virginia 24656 has filed a petition to modify the application of 30 CFR 75.1701 (abandoned areas, adjacent mines; drilling of boreholes) to its No. 6 Mine (I.D. No. 44-06180) located in Buchanan County, Virginia. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that whenever any working place approaches within 50 feet of abandoned areas in the mine as shown by surveys made and certified by a registered engineer or surveyor, or within 200 feet of any other abandoned areas of the mine which cannot be inspected and which may contain dangerous accumulations of water or

gas, or within 200 feet of any workings of an adjacent mine, a borehole or boreholes shall be drilled to a distance of at least 20 feet in advance of the working face of such working place and shall be continually maintained to a distance of at least 10 feet in advance of the advancing working face. When there is more than one borehole, they shall be drilled sufficiently close to each other to insure that the advancing working face will not accidentally hole through into abandoned areas or adjacent mines. Boreholes shall also be drilled not more than 8 feet apart in the rib of such working place to a distance of least 20 feet and at an angle of 45 degrees.

2. Petitioner requests a modification of the standard to allow for a 20-foot cut to be taken in the face. In further support of this request, petitioner states that:

(a) The provision requiring 20-foot test holes to be drilled at a 45 degree angle at 8-foot intervals in the rib restricts the depth of a cut that can be extracted with a continuous miner;

(b) A continuous mining machine is designed to take a 20-foot cut without the controls of the mining machine passing the last row of roof supports;

(c) Petitioner proposes to drill five holes in the face of the entry, spaced at 5-foot intervals; one hole in each corner of the entry 20 feet deep and 3 holes in the face of the entry 30 feet deep. The holes drilled in the corner of the entry will be at 30 degree angles to the rib. The hole drilled 5 feet from the left rib would be on a 105 degree angle to the face. The hole in the middle of the entry will be a 90 degree angle to the face and the hole drilled 5 feet from the right rib will be a 75 degree angle to the face with a margin of error of ± 5 degrees. This pattern will provide a 10-foot barrier in all direction to the cut to be taken. This pattern will also prevent the cut being taken from intersecting with any entry driven in an unexplored old works 10 feet or greater in width; and

(d) It is more practical to drill a 30 degree angle as opposed to drilling a 45 degree angle due to the size of the drill and the length of the drill steel, as well as the restricted area available to maneuver the drilling machine.

3. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments

must be postmarked or received in that office on or before May 21, 1987. Copies of the petition are available for inspection at that address.

Dated: April 13, 1987.

Patricia W. Silvey,

Associate Assistant Secretary for Mine Safety and Health.

[FR Doc. 87-8909 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-90-C]

S.A.B. Coal Co. No. 4; Petition for Modification of Application of Mandatory Safety Standard

S.A.B. Coal Company No. 4, P.O. Box 70, Vansant, Virginia 24656 has filed a petition to modify the application of 30 CFR 75.1701 (abandoned areas, adjacent mines; drilling of boreholes) to its No. 1 Mine (I.D. No. 44-06051) located in Buchanan County, Virginia. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that whenever any working place approaches within 50 feet of abandoned areas in the mine as shown by surveys made and certified by a registered engineer or surveyor, or within 200 feet of any other abandoned areas of the mine which cannot be inspected and which may contain dangerous accumulations of water or gas, or within 200 feet of any workings of an adjacent mine, a borehole or boreholes shall be drilled to a distance of at least 20 feet in advance of the working face of such working place and shall be continually maintained to a distance of at least 10 feet in advance of the advancing working face. When there is more than one borehole, they shall be drilled sufficiently close to each other to insure that the advancing working face will not accidentally hole through into abandoned areas or adjacent mines. Boreholes shall also be drilled not more than 8 feet apart in the rib of such working place to a distance of at least 20 feet and at an angle of 45 degrees.

2. Petitioner requests a modification of the standard to allow for a 20-foot cut to be taken in the face. In further support of this request, petitioner states that:

(a) The provision requiring 20-foot test holes to be drilled at a 45 degree angle at 8-foot intervals in the rib restricts the depth of a cut that can be extracted with a continuous miner;

(b) A continuous mining machine is designed to take a 20-foot cut without

the controls of the mining machine passing the last row of roof supports;

(c) Petitioner proposes to drill five holes in the face of the entry, spaced at 5-foot intervals; one hole in each corner of the entry 20 feet deep and 3 holes in the face of the entry 30 feet deep. The holes drilled in the corner of the entry will be at 30 degree angles to the rib. The holes drilled 5 feet from the left rib would be on a 105 degree angle to the face. The hole in the middle of the entry will be a 90 degree angle to the face and the hole drilled 5 feet from the right rib will be a 75 degree angle to the face with a margin of error of ± 5 degrees. This pattern will provide a 10-foot barrier in all directions to the cut to be taken. This pattern will also prevent the cut being taken from intersecting with any entry driven in an unexplored old works 10 feet or greater in width; and

(d) It is more practical to drill a 30 degree angle as opposed to drilling a 45 degree angle due to the size of the drill and the length of the drill steel, as well as the restricted area available to maneuver the drilling machine.

3. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987. Copies of the petition are available for inspection at that address.

Dated: April 14, 1987.

Patricia W. Silvey,

Associate Assistant Secretary for Mine Safety and Health.

[FR Doc. 87-8910 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-60-C]

Scarab Energy Corp.; Petition for Modification of Application of Mandatory Safety Standard

Scarab Energy Corporation, P.O. Box 68, Petros, Tennessee 37845 has filed a petition to modify the application of 30 CFR 77.1605(k) (berms or guards) to its Mine No. 3R (I.D. No. 40-02939) located in Anderson County, Tennessee. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that berms or guards be provided on the outer banks of elevated roadways.

2. Petitioner states that application of the standard will result in a diminution of safety to the miners affected because berms confine water runoff to the road surface which washes away the surfacing materials, resulting in a dangerous road surface. The berms also hamper the removal of snow and ice with a motor grader.

3. As an alternate method, petitioner states that:

(a) Daily inspections of all coal-hauling vehicles will be made. Any defects will be corrected before the vehicle is put into service;

(b) A specific traffic system and rules will be developed for the roads. These rules will be posted throughout the mine area, on the bulletin board, and will become a part of the training and retraining programs;

(c) All haulage vehicles will have original manufacturers brakes and an emergency braking system;

(d) All equipment operators will be trained in the use of haulage equipment and the safety of vehicles on haulage roads;

(e) Where abrupt drop-offs occur along the outer banks, elevation will be provided to cause the vehicles to gravitate toward the highwall side of the road;

(f) Roadway surfaces will be kept free of debris, excessive water, snow, and ice; and

(g) The speed at which trucks will be operated will be consistent with conditions of roadway clearance, visibility and traffic. Trucks operating on any descending grade will be restricted to 10 miles per hour.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987. Copies of the petition are available for inspection at that address.

Dated: April 13, 1987.

Patricia W. Silvey,

Associate Assistant Secretary for Mine Safety and Health.

[FR Doc. 87-8911 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-87-93-C]

Shannon Coal Co., Inc.; Petition for Modification of Application of Mandatory Safety Standard

Shannon Coal Company, Inc., P.O. Box 70, Vansant, Virginia 24656 has filed a petition to modify the application of 30 CFR 75.1701 (abandoned areas, adjacent mines; drilling of boreholes) to its No. 2 Mine (I.D. No. 44-06177) located in Buchanan County, Virginia. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that whenever any working place approaches within 50 feet of abandoned areas in the mine as shown by surveys made and certified by a registered engineer or surveyor, or within 200 feet of any other abandoned areas of the mine which cannot be inspected and which may contain dangerous accumulations of water or gas, or within 200 feet of any workings of an adjacent mine, a borehole or boreholes shall be drilled to a distance of at least 20 feet in advance of the working face of such working place and shall be continually maintained to a distance of at least 10 feet in advance of the advancing working face. When there is more than one borehole, they shall be drilled sufficiently close to each other to insure that the advancing working face will not accidentally hole through into abandoned areas or adjacent mines. Boreholes shall also be drilled not more than 8 feet apart in the rib of such working place to a distance of at least 20 feet and at an angle of 45 degrees.

2. Petitioner requests a modification of the standard to allow for a 20-foot cut to be taken in the face. In further support of this request, petitioner states that:

(a) The provision requiring 20-foot test holes to be drilled at a 45 degree angle at 8-foot intervals in the rib restricts the depth of a cut that can be extracted with a continuous miner;

(b) A continuous mining machine is designed to take a 20-foot cut without the controls of the mining machine passing the last row of roof supports;

(c) Petitioner proposes to drill five holes in the face of the entry, spaced at 5-foot intervals; one hole in each corner of the entry 20 feet deep and 3 holes in the face of the entry 30 feet deep. The holes drilled in the corner of the entry will be at 30 degree angles to the rib. The hole drilled 5 feet from the left rib would be on a 105 degree angle to the face. The hole in the middle of the entry

will be a 90 degree angle to the face and the hole drilled 5 feet from the right rib will be a 75 degree angle to the face with a margin of error of ± 5 degrees. This pattern will provide a 10-foot barrier in all direction to the cut to be taken. This pattern will also prevent the cut being taken from intersecting with any entry driven in an unexplored old works 10 feet or greater in width; and

(d) It is more practical to drill a 30 degree angle as opposed to drilling a 45 degree angle due to the size of the drill and the length of the drill steel as well as the restricted area available to maneuver the drilling machine.

3. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before May 21, 1987. Copies of the petition are available for inspection at that address.

Dated: April 13, 1987.

Patricia W. Silvey,

Associate Assistant Secretary for Mine Safety and Health.

[FR Doc. 87-8912 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-04-M

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 87-36; Exemption Application No. D-6282 et al.]

Grant of Individual Exemptions; Phelps Time Lock Security Corp. et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1954 (the Code).

Notices were published in the *Federal Register* of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for

exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, DC. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of pendency were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following findings:

- (a) The exemptions are administratively feasible;
- (b) They are in the interests of the plans and their participants and beneficiaries; and
- (c) They are protective of the rights of the participants and beneficiaries of the plans.

Phelps Time Lock Security Corporation Employees Profit Sharing Plan (the Plan)

Located in Miami, Florida

[Prohibited Transaction Exemption 87-36; Exemption Application No. D-6282]

Exemption

The restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of

¹ The notice of proposed exemption published in the *Federal Register* on December 23, 1986 (51 FR 45982) stated that the real property (the Property) would be sold by the Plan to Phelps Time Lock Security Corporation (the Employer). Subsequent to the date of the publication of the proposed exemption in the *Federal Register*, the applicant requested that the Property be sold to Mr. Robert C. Gilbert, (Mr. Gilbert) the Plan trustee and sole

section 4975(c)(1) (A) through (E) of the Code, shall not apply to the sale of certain real property by the Plan to Robert C. Gilbert,¹ a party in interest with respect to the Plan, provided that the terms of the proposed sale are as favorable to the Plan as those obtainable in an arm's-length transaction with an unrelated party on the date of its consummation.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on December 23, 1986 at 41 FR 45962.

For Further Information Contact: Ms. Linda Hamilton of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

IBI, Inc. Profit Sharing Plan and Trust Agreement and IBI, Inc. and Top Home Center, Inc. Defined Benefit Pension and Trust (the Plans)

[Prohibited Transaction Exemption 87-37; Exemption Application Nos. D-6397 and D-6398]

Exemption

The restrictions of sections 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply, for a period of 5 years, to the proposed sales by IBI, Inc. (IBI) of contracts for deed (Contracts) to the Plans, nor to the guarantee of repayment by certain shareholders of IBI, provided that the terms and conditions of such sales are at least as favorable to the Plans as those which the Plans could receive in similar transactions with unrelated parties.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on February 3, 1987 at 52 FR 3361.

Temporary Nature of Exemption

This exemption is temporary and will expire 5 years after the date of grant. Subsequent to the expiration of this exemption, the Plans may continue to

shareholder of the Employer, rather than to the Plan. All interested persons were notified of the sale of the Property by the Plan to Mr. Gilbert rather than to the Employer and no comments and/or requests for a hearing have been received by the Department. All other representations made in the notice of proposed exemption concerning this transaction remain unchanged.

hold Contracts originated during this 5-year period until repaid. Should the applicant wish to continue selling Contracts to the Plans beyond the 5-year period, the applicant may submit another application for exemption.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Midwest Financial Group Employee Savings Plan and Trust (the Plan)

Located in Kankakee, Illinois

[Prohibited Transaction Exemption 87-38; Exemption Application No. D-6664]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash sale of a parcel of real property located at the Northwest corner of East Station and South Dearborn Streets, Kankakee, Illinois (the Property) by the Plan to First Trust and Savings Bank of Kankakee (the Employer) for \$99,000, provided that the terms of the transaction were not less favorable to the Plan than those obtainable in an arm's-length transaction with an unrelated party at the time the transaction was consummated.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on February 13, 1987 at 52 FR 4687.

Effective Date: This exemption is effective December 31, 1986.

Written Comments: The Department received one comment from the applicant with regard to the notice of proposed exemption. The applicant represented that in order to avoid the occurrence of additional excise tax penalties, the Plan sold the Property to the Employer for \$99,000 on December 31, 1986. The applicant represents that the sale was completed in accordance with the terms and conditions contained in the notice of proposed exemption. On the basis of the applicant's representations, the Department has decided to amend the final exemption to provide for an effective date of December 31, 1986.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

James S. Torchia, D.D.S. Inc. Profit Sharing Plan and James S. Torchia, D.D.S. Inc. Pension Plan (the Plans)

Located in Tulsa, Oklahoma

[Prohibited Transaction Exemption 87-39; Exemption Application Nos. D-6759 and D-6760]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale of an undivided interest in a parcel of real property located at 9405 South Yale, Tulsa, Oklahoma, by the Plans to Dr. James S. Torchia, a party in interest with respect to the Plans, provided that the terms of the transaction are not less favorable to the Plans than those obtainable in an arm's-length transaction with an unrelated person at the time the transaction is consummated.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on February 13, 1987 at 52 FR 4688.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Jamestown Clinic, Ltd. Employee Retirement Plan (the Plan)

Located in Jamestown, ND

[Prohibited Transaction Exemption 87-40; Exemption Application No. D-6936]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash sale by the Plan of certain improved real property to Medical Properties, Inc., a party in interest with respect to the Plan, provided that such sale is on terms no less favorable to the Plan than the Plan could obtain in an arm's-length transaction with an unrelated party.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on February 3, 1987 at 52 FR 3366.

For Further Information Contact: Ronald Willett of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

Donald S. Perkins Defined Benefit Plan and Trust (the Plan)

Located in Chicago, Illinois

[Prohibited Transaction Exemption 87-41; Exemption Application No. D-6984]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale of certain publicly traded securities to the Plan by Donald S. Perkins (Mr. Perkins), a disqualified person with respect to the Plan, provided that the terms of sale are no less favorable to the Plan than those obtainable in an arm's-length transaction with an unrelated party at the time the transaction is consummated.²

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on March 9, 1987 at 52 FR 7240.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or

² Since Mr. Perkins is the only participant in the Plan there is no jurisdiction under Title I of the Act pursuant to 29 CFR 2510.3-3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 14th day of April, 1987.

Elliot I. Daniel,

Associate Director for Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 87-8936 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-6900]

Proposed Exemption Involving Pennfield Precision Machining, Inc. Profit Sharing Plan (the Plan) Located in Sellersville, PA; Withdrawal

In the Federal Register dated December 23, 1986 (51 FR 45966), the Department of Labor published a notice of proposed exemption from the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 and from certain taxes imposed by the Internal Revenue Code of 1986. The notice of proposed exemption concerned the prospective cash sale by the Plan of certain unimproved real property to John F. Matczak and Carl F. Tate, parties in interest with respect to the Plan.

By letter dated February 25, 1987 the applicants have requested that the exemption application be withdrawn.

Accordingly, the notice of proposed exemption is hereby withdrawn.

Signed at Washington, DC, this 10th day of April, 1987.

Elliot I. Daniel,

Associate Director for Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 87-8937 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-6747 et al.]

Proposed Exemptions; Restated Arens Controls, Inc. et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1954 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Pendency, within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state the reasons for the writer's interest in the the pending exemption.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Regulations and Interpretations, Room N-5669, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. stated in each Notice of Pendency. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of pendency of the exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue

exemptions of the type requested to the Secretary of Labor. Therefore, these notices of pendency are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for complete statement of the fact and representations.

Restated Arens Controls, Inc. Salaried Employees' Retirement Plan (the Plan)

Located in Evanston, IL

[Application No. D-6747]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(A) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to a proposed loan (the Loan) by the Plan, not exceeding 25 percent of the assets of the Plan, to Arens Controls, Inc. (the Employer), provided the terms and conditions of the Loan are not less favorable to the Plan than those obtainable in an arm's length transaction with an unrelated party.

Summary of Facts and Representations

1. The Plan is a defined benefit plan with 42 participants and net assets having a fair market value of \$2,106,188 as of February 26, 1986. The trustee of the Plan (the Trustee) is State National Bank of Evanston, Illinois. The trustee makes investment decisions for the Plan. The Employer, which maintains its principal place of business in Evanston, Illinois, is engaged in the manufacture and sale of mechanical remote control devices.

2. The Employer requests an exemption to borrow an amount of not more than 25 percent of the Plan's assets. The Loan proceeds will be used by the Employer to purchase certain land and an industrial building (the Property) located at 2017 Greenleaf Street, Evanston, Illinois. The Property is presently leased by the Employer from the estate of Calhoun Norton, a deceased officer and shareholder. It is used by the Employer as its business premises. The lease expires the earlier

of July 1, 1987 or at such time as the parties execute a purchase and sale agreement on the Property.

3. The Loan, which will be evidenced by a promissory note, will have a duration of 15 years. It will be an adjustable rate loan bearing a fixed rate of interest of 9% percent per annum for the first three years. At the end of the initial three year period the Loan is in effect, the interest rate will be adjusted by the Trustee according to the rate of interest the Trustee is charging at that time for a comparable loan. The Trustee will serve as the independent fiduciary for the Plan with respect to the proposed Loan.

4. The Loan will be secured by a duly recorded first mortgage on the Property. The Property will be insured against casualty loss in favor of the Plan to the extent of the amount of Loan. The Property was initially appraised at \$850,000 on April 4, 1983 by Mr. John H. Marling, M.A.I., and independent appraiser affiliated with the Marling Group, Limited of Northfield, Illinois. In an updated appraisal of February 17, 1986, Messrs. Jules H. Marling, Jr., M.A.I., C.R.E.; James Passalino, J.D.; and Stephen E. Fennell, M.A.I. Candidate, independent appraisers (the Appraisers) affiliated with Sudler Marling, Inc. of Chicago, Illinois, successor firm, again placed the fair market value of the Property at \$850,000. The Appraisers stated that they had personally reinspected the Property and performed a thorough investigation and analysis of existing market conditions. In a July 29, 1986 addendum to their earlier report, the Appraisers concluded that there was no change in their valuation estimate for the Property.

At all times the value of the Property will exceed 150 percent of the outstanding balance of the Loan. If the value of the Property ever falls below this level, the Trustee will require that the Employer pledge additional collateral.

5. As stated above, the Trustee has been designated as the independent fiduciary for the Loan. No principals of the Employer sit on the Board of Directors of the Trustee or vice versa. The sole commercial relationship existing between the Trustee and the Employer are two checking accounts maintained by the Trustee on behalf of the Employer and its parent corporation, Arens, Industries, Inc. (AII). These accounts represent less than one-tenth of one percent of the total deposits held by the Trustee in interest-bearing and non-interest bearing accounts.

In addition, the Trustee represents that its Trust Department has been engaged in the administration of

qualified retirement trusts for approximately 25 years and that it currently has 90 plans under administration. In administering these plans, including the one under consideration, the Trustee states that it understands its responsibilities, liabilities and duties as a fiduciary under the Act.

The Trustee also represents that the Loan is in the best interests of the Plan and protective of the Plan's participants and beneficiaries. The Trustee states that the terms of the Loan are reasonable and the interest rate is appropriate in the current climate for debt securities. The Trustee also represents that it would make a similar loan to the Employer on the same terms and conditions as the proposed Loan. Additionally, the Trustee states that it has examined the overall investment objectives of the Plan as they relate to the Plan's investment portfolio and it explains that it has considered the Plan's liquidity needs and the diversification of the Plan's assets. Based on these factors, the Trustee believes the Loan complies with Plan's investment objectives and it feels the Loan and other Plan assets satisfy the cash flow needs of the Plan at present as well as in the future.

As the independent fiduciary, the Trustee will monitor the terms and conditions of the Loan including the fair market value of the collateral. In addition, the Trustee will take all actions that are necessary and proper to enforce and protect the interests of the Plan and its participants and beneficiaries.

6. In summary, it is represented that the proposed transaction satisfy the criteria for an exemption under section 408(a) of the Act because: (a) The Loan will not represent more than 25 percent of the Plan's assets; (b) the Loan will be secured by a first mortgage on the Property which has a fair market value of approximately 160 percent of the Loan amount; (c) the Trustee, which will serve as the independent fiduciary for the Plan in monitoring the terms and conditions of the Loan, believes the Loan is in the best interests of the Plan and its participants and beneficiaries; and (d) the value of the Property plus any other collateral pledged will at all times exceed 150 percent of the outstanding balance of the Loan.

For Further Information Contact: Ms. Jan D. Broady of the Department, telephone (202) 523-8196. (This is not a toll-free number.)

Dental Associates, P.C. Money Purchase Plan (the Money Purchase Plan) and Profit Sharing Plan (the Profit Sharing Plan, Collectively, the Plans)

Located in Northford, CT

[Application Nos. D-6886 and D-6869]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedures 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed cash sale of an interest (the Interest) in a certain parcel of unimproved real property (the Property) by the Plans to Dr. Joseph Connolly (Dr. Connolly), the sole shareholder of the Plan sponsor, provided that the sale price is not less than the fair market value of the Interest as of the date of the sale plus the increase in the cost of living as reflected by the Consumer Price Index from May, 1986, to the date of closing.

Summary of Facts and Representations

1. The Profit Sharing Plan and the Money Purchase Plan are defined contribution plans with the same three participants and assets of \$96,418.65 and \$106,151.38, respectively, as of September 30, 1985. The assets of the Plans are held in a common trust. Dr. Connolly and his wife are the trustees of the Plans.

2. The interest is one-half interest in Northford Triangle Associates (Northford), a Connecticut general partnership. The Plans acquires the Interest from Donald and Dorothy McCluskey of Northford, CT, the other parties in Northford, in the spring of 1985 for \$45,000. The applicant represents that the McCluskeys are unrelated to the Plan, Dr. Connolly or the Plan's sponsor. The Property is the sole asset of Northford.

3. The applicant represents that, to economic conditions in North Branford, CT, the location of the Property, now is an appropriate time to subdivide and improve the Property. However, if the Plans were to participate in the subdivision and improvement of the Property, they might be liable for unrelated business income tax. Therefore, the applicant wishes to sell its Interest to Dr. Connolly for cash for

its appraised fair market value to enable the Plan to realize the appreciation on the Property.

4. The Property was appraised on April 15, 1986 by Susan Haller, G.R.I., of Beazly Company Realtors, who is represented to be independent of Dr. Connolly and the Plan's sponsor. Ms. Haller estimated the Property's fair market value as \$95,000. The Plan's Interest is therefore worth \$47,500. Ms. Haller represents that the Property's value is held down by the fact that the Property's highest and best use would be commercial, but that it is zoned for residential use, for which the Property has minimal appeal.

5. Dr. Connolly will pay the appraised fair market value for the Interest, \$47,500, plus the increase in the cost of living, as reflected in the Consumer Price Index, from May, 1986, the first month after the appraisal, to the date of closing, as well as all costs associated with the transaction. The applicant represents that the Plans have borne no expenses associated with holding the Interest. The Plans will bear no costs with respect to the transaction.¹

6. In summary, the applicant represents that the proposed transaction satisfies the criteria of section 408(a) of the Act because: (a) The Plans will receive no less than the appraised fair market value for the Interest; (b) the transaction will be for cash; and (c) the Plans will not bear any costs with respect to the transaction.

The Department of the Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer (or affiliate thereof) results in the Plan either paying less than or receiving more than fair market value such excess may be considered to be a contribution by the sponsoring employer to the plan and therefore must be examined under applicable provisions of the Internal Revenue Code, including sections 401(a)(4), 404 and 405.

For Further Information Contact: Mr. David Lurie of the Department, telephone (202) 523-8194. (This is not a toll-free number).

Sterling-Rock Falls Clinic Self-Employed Retirement Trust (the Plan)

Located in Sterling, Illinois

[Application No. D-6878]

Proposed Exemption

The Department is considering granting an exemption under the

authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed sale for cash by the Plan of an undivided three-fourths interest in certain real property (the Three-Fourths Interest) from the individual account of John R. Erickson, M.D. (Dr. Erickson), a party in interest with respect to the Plan, to Dr. Erickson, provided that the price paid is no less than the greater of the fair market value of the Three-Fourths Interest on the date of sale or the total expenses to the Plan in connection with the acquisition and holding of the Three-Fourths Interest.

Summary of Facts and Representations

1. The Plan is a defined contribution H.R. 10 (Keogh) plan under which individual accounts are maintained for each participant to which all contributions, forfeitures, investment income, gains or losses and expenses are credited or deducted. The Plan currently has 23 participants. The Plan sponsor is Sterling-Rock Falls Clinic, a partnership engaged in the practice of medicine. The Plan's trustee is the Central National Bank of Sterling (the Trustee) of Sterling, Illinois.

2. On April 30, 1980, the Trustee purchased on behalf of Dr. Erickson's individual account in the Plan an undivided three-fourths interest in a condominium residential unit in Bayway Isles-Point Brittany Six (the Condominium), in St. Petersburg, Florida. At the same time Dr. Erickson's wife, Mrs. Marion Erickson, (Mrs. Erickson) purchased an undivided one fourth interest in the Condominium as tenant in common.² The Condominium was purchased from unrelated third parties for \$98,000. Accordingly, the amount representing the original purchase price for the Three-Fourths Interest was approximately \$66,000. The applicant represents that as of March 4, 1987, the Plan has expended \$83,367.36 in connection with the acquisition and retention of the Three-Fourths Interest, including the original purchase price, legal expenses, real estate taxes,

personal property taxes, utilities, maintenance, and condominium fees.

3. The applicant represents that at the time the Plan bought the Three-Fourths Interest Florida real estate was at a peak in terms of appreciation of value and rental income. Although the Plan purchased the Three-Fourths Interest in the expectation that reasonable rental income and continuing appreciation in value would be realized, neither has been forthcoming. Since its purchase, the Condominium has been rented to third parties only during the four months of the winter season. Moreover, little if any appreciation has taken place. Accordingly, the applicant concludes that the Three-Fourths Interest has not been a good investment for the Plan.

4. The applicant represents that the Condominium was offered for sale in January, 1985 through the Florida Real Estate Center, Inc., of St. Petersburg, Florida for \$90,500. The applicant states that there have been no offers to purchase at that price or any other.

5. Carolyn A. Melley, S.R.E.A., of McKeon & Stroud, Inc., real estate appraisers and consultants doing business in St. Petersburg, Florida, stated that the fair market value of the Condominium was \$80,000 as of August 18, 1986.

6. The applicant acknowledges that Dr. Erickson made use of and paid nominal rent for the Condominium from time to time during the off season in the years 1980-1986. The applicant further represents that he will prepare Form 5330 (Return of Initial Excise Tax) with respect to this use, and will file this return with the Internal Revenue Service and pay all applicable excise taxes within 60 days from the date of the grant of this exemption.

7. Accordingly, the applicant proposes that the Plan sell the Three-Fourths Interest in the Condominium to Dr. Erickson for the greater of the fair market value of the Three-Fourths Interest on the date of sale or the total expenditure of the Plan in connection with the acquisition and retention of the Three-Fourths Interest, including, but not limited to the purchase price, legal expenses, property taxes, insurance, maintenance and condominium fees.

8. In summary, the applicant represents that the proposed transaction will satisfy the terms and conditions of section 408(a) of the Act because: (a) The Three-Fourths Interest will be sold for the greater of its fair market value on the date of sale as determined by an independent appraiser or for the total expenses to the Plan in connection with the acquisition and holding of the Three-Fourths Interest; (b) the sale represents

¹ The applicant represents that the proposed transaction will not cause the contribution limitations imposed by section 415 of the Code to be exceeded for either Plan.

² In this proposed exemption the Department expresses no opinion as to whether the purchase of the Condominium by Dr. Erickson's individual account in the Plan and by Mrs. Erickson as tenants in common violated any of the provisions of Part 4 of Title I of the Act.

a one-time transaction for cash which can be easily verified; (c) the sale will not require the payment of any commissions, fees, or taxes by the Plan; (d) the Plan will not suffer any loss with respect to its outlay in connection with its purchase and holding of the Three-Fourths Interest; and (e) Dr. Erickson, the participant whose individual account in the Plan is affected by this proposed exemption, has determined that the proposed transaction would be in the interest of his individual account in the Plan, in his interest and in that of his beneficiaries.

For Further Information Contact: Joseph L. Roberts III of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Plumbers & Steamfitters Local 60 Pension Fund (the Plan)

Located in Metairie, LA

[Application No. D-6935]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted: (1) The restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply, effective April 10, 1987, to the cash purchase by the Plan of a parcel of improved real property (the Property) located in Metairie, Louisiana, from the Plumbers & Steamfitters Local 60 Home Association, Inc. (the Association), a party in interest with respect to the Plan; (2) the restrictions of section 406(b)(2) of the Act shall not apply, effective April 10, 1987, to the lease of space in the Property to the Plumbers & Steamfitters Local 60 Education Trust (the Trust); and (3) the restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (D) of the Code, shall not apply, effective April 10, 1987, to the lease of space in the Property to Gardner, Robein & Healey (Gardner), a party in interest with respect to the Plan, provided that the terms of the transactions are at least as favorable to the Plan and the Trust as arms length transactions between unrelated parties would be.

Summary of Facts and Representations

1. The Plan is a multiemployer pension plan established and maintained in accordance with section 302(c)(5) of the Labor Management Relations Act of 1947 (the LMRA). The Plan has approximately 1000 participants and more than \$61,000,000 in assets. Participants in the Plan are employees of employers who are signatory to or bound by collective bargaining agreements executed with Local Union No. 60, United Association of Journeymen & Apprentices of the Plumbing and Pipefitting Industry of the United States and Canada, AFL-CIO (the Union). The Union covers employees in the New Orleans area. The Plan is administered by a Board of Trustees (the Trustees) composed of three Union and three employer members. The Union Trustees are also officers of the Union.

2. The Association is a realty corporation owned by the paid-up, current members of the Union. The applicant represents that the Association may be considered as the Union. The officers and directors of the Association serve as such only while they are officers of the Union. The sale or purchase of any immovable property must be approved by a two-thirds vote of a properly constituted meeting of Union members. The applicant represents that such a vote and approval has been acquired with respect to the Plan's proposed purchase of the Property. Gardner serves as legal counsel for the Union and the Plan and therefore is a party in interest with respect to the Plan under section 3(14)(C) of the Act.

3. The Property is located at 2540 Severn Avenue, Metairie, Louisiana. It consists of the land and a four story office building. Currently the Trust, also administered under the LMRA, is and will remain, a tenant in the Property.³ Gardner is also a tenant in the Building. If this proposed exemption is granted, the Plan and the Plumbers & Steamfitters Local 60 Welfare Fund (the Welfare Fund) will move from their current offices into the Property.⁴

³ The applicant represents that this lease is exempt from the prohibitions of section 406 of the Act by reason of Prohibited Transaction Exemption 78-6 (PTE 78-6, 43 FR 23024). The Department offers no opinion herein as to whether the condition of PTE 78-6 have been met.

⁴ The applicant represents that the lease to the Welfare Fund will be covered by Prohibited Transaction Exemptions 78-1, Part C and 77-10 (PTE 78-1, C, 41 FR 12,740, PTE 77-10 (42 FR 33918)). The Department offers no opinion herein as to whether the conditions of PTE's 78-1, C and 77-10 will be met.

4. The Property was appraised on May 21, 1986 by W. John Tessier, I.F.A.S. and C.J. Tessier, Jr. of W.J. Tessier, Inc., independent realtors and appraisers located in New Orleans. The Tessiers appraised the fair market value of the Property as \$6,500,000.

5. The Plan's Board of Trustees offered the Association \$6,400,000 for the Property, which was accepted by the Association on January 2, 1987. The applicant represents that the Plan will purchase the Property on April 10, 1987 in order to prevent the Property from being foreclosed upon.

6. Waters, Parkerson & Co., Inc., Registered Investment Counsel serves as the Plan's independent investment advisor (the Advisor). The Advisor has reviewed the proposed purchase of the Property by the Plan and the leases of space to the Trust and Gardner. With respect to the Plan's purchase of the Property, the Advisor examined the appraisal by the Tessiers, a detailed analysis of projected cash flows and rates of return prepared by Thomas L. Axelrad, an independent real estate consultant in New Orleans, and the current leases (including the leases to the Trust and Gardner), consulted with third parties familiar with the commercial real estate market in the greater New Orleans area, and analyzed the diversification of the Plan's assets. Mr. Axelrad's analysis found that the yields from the Property are favorable as compared to other real estate investments of similar risk and quality; that many of the tenants are committed to the buildings, and/or have made a significant financial investment, thereby reducing turnover; the Property has a superior location and a low likelihood of significant new competition, and the Property has the potential for growth in value as a hedge against inflation. The Advisor concluded that the Property should produce very favorable results over the long term and that it compares favorably with the investment goals of the Plan.

7. With respect to the lease to the Trust, the Advisor found, based on consultation with an independent leasing consultant, that the lease to the Trust is fair and reasonable, and that: (a) The Trust is the first and primary tenant in the Property; (b) the Trust provides its own janitorial service; and (c) the majority of the Trust's space is painted concrete block interior, rather than finished office space, which required far less construction expense for the owner.

8. With respect to the lease of office space to Gardner, the Advisor found, based on consultation with the

independent leasing consultant that the lease's rate appears to be slightly above the prevailing rates in the Property's building category and that the lease terms are normal. The Advisor concluded that the lease to Gardner is beneficial to the owner of the Property.

9. In summary, the applicant represents that the proposed transactions meet the criteria of section 408(a) because: (a) The Plan will acquire the Property for no more than the Property's appraised fair market value; (b) the Plan's Advisor has concluded that the acquisition of the Property will be a beneficial long term investment for the Plan; and (c) the leases to the Trust and to Gardner are at fair market rent and at standard terms.

For Further Information Contact: David Lurie of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Dr. Phillips, Inc., Employee Trust Profit Sharing Plan (the Plan)

Located in Orlando, Florida

[Application No. D-6962]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the proposed sale by the Plan of five parcels of improved real property (the Parcels) and a tract of unimproved land (the Tract) for the total cash consideration of \$1,235,000, to Dr. Phillips, Inc. (the Employer), a party in interest with respect to the Plan, provided the total amount paid for the Parcels and the Tract is not less than fair market value at the time the transaction is consummated.

Summary of Facts and Representations

1. The Plan is a defined contribution plan with 47 participants and total assets having a fair market value of approximately \$2,386,563 as of August 31, 1986. The trustee of the Plan (the Trustee) is Freedom Savings and Loan Association of Tampa, Florida. Investment decisions for the Plan are made by the Trustee subject to the direction of a five-member Plan committee comprised of officers, directors and employees of the

Employer. The Employer, which maintains its principal place of business in Orlando, Florida, is the owner of commercial and industrial real estate located in the Orlando, Florida area. The Employer develops such real estate for rental purposes.

2. Among the assets of the Plan are the Parcels and the Tract. These properties were transferred to the Plan during 1986 by Lockwood Associates, Inc. (Lockwood), a Delaware corporation that was wholly owned by the Plan and engaged in real estate brokerage and leasing prior to its dissolution on November 26, 1986. The Parcels and the Tract are located on or near North Orange Blossom Trail, one of the major north-south routes leading through Orlando, Florida and also designated as U.S. Highway 441. The Parcels and the Tract are also located in commercial/industrial areas and is adjacent to other properties that are owned and leased by the Employer. With one limited exception (see paragraphs 2.e and 3 below), none of the land comprising the Parcels and the Tract is leased to a party in interest. In addition, none of the land comprising the Parcels and the Tract is encumbered by a mortgage. The Parcels and the Tract presently produce annual rental income to the Plan of \$116,935.

Following is descriptive information about the Parcels and the Tract.

a. *Parcel One (Parcel One) 1224 West Amelia Street.* Parcel One, which is located at the corner of West Amelia Street and Hames Avenue, is approximately one block off North Orange Blossom Trail. It was acquired by Lockwood on July 2, 1954 from the Ozark Corporation (Ozark), a predecessor of the Employer. The purchase price for Parcel One was \$3,214. Following the purchase, Lockwood constructed a building on Parcel One. The building was completed about September 1, 1954 at an initial cost of \$17,691. Since that time, Lockwood made improvements to the building at a total additional cost of \$24,908. Until June 30, 1985, Parcel One was leased to Mr. Jack Morrison, Jr. and it was used as a furniture frame and upholstery shop. Parcel One remains vacant at this time.

b. *Parcel Two (Parcel Two) 2120 North Orange Blossom Trail.* Parcel Two, together with a building situated thereon, was acquired by Lockwood from the Employer on August 6, 1957 at a total price of \$72,406. Subsequent to the acquisition, Lockwood placed equipment on Parcel Two at a cost of \$2,042. Lockwood also had Parcel Two paved and made other land improvements to this property between

1957-1967 at a total cost of \$11,639. On August 31, 1979, additional buildings and improvements were placed upon Parcel Two by Lockwood at a cost of \$40,632. Parcel Two is presently leased as a rental lot for used automobiles to H and S Equipment Rental Company at a monthly rental of \$1,753 or an annual rental of \$21,046.

c. *Parcel Three (Parcel Three) 2550 North Orange Blossom Trail.* Parcel Three was acquired by Lockwood on May 2, 1952 from Ozark at a cost of \$36,860. Lockwood subsequently made numerous improvements to Parcel Three for a total cost of \$106,626. At present, Parcel Three is leased to Black and Todd, Inc. for an annual rental of \$26,558. It is used as a restaurant by the lessee.

d. *Parcel Four (Parcel Four) 1861-31 Traylor Boulevard.* Parcel Four was acquired by Lockwood from Ozark on May 2, 1952 at a cost of \$4,168. Lockwood constructed improvements on Parcel Four. The improvements were completed about September 1, 1953 at a total cost of \$21,689. Subsequent to the construction of the improvements, Lockwood spent \$53,630 on improvements to the building comprising Parcel Four plus \$9,325 on paving and land improvements. Parcel Four is presently leased to Continental Baking Company (Continental) where it is used as a warehouse and distribution center for the retail sale of bread and an associated truck repair facility for Continental's delivery trucks. The monthly rental paid by Continental for its use of Parcel Four is \$2,487 or a total annual rental of \$29,851.

e. *Parcel Five (Parcel Five) 2200 North Orange Blossom Trail.* Parcel Five and the improvements situated thereon were acquired by Lockwood from the Employer on August 6, 1957 at a total cost of \$55,783. Subsequent to the purchase, Lockwood expended a total of \$36,120 on building improvements, \$5,905 on equipment purchases and \$9,393 on land improvements and paving. Most of Parcel Five is currently leased to James and Carol Trunk at a monthly rental of \$3,000 or \$36,000 annually and it is used as a dealership for payloaders (small motorized loading trucks). A small portion of Parcel Five is leased to the Trustee (see paragraph 3 below).

In addition to the Parcels, the Plan owns the Tract which is vacant land behind Parcels Two and Five. The Tract was acquired by Lockwood for \$7,342 from the Employer on February 2, 1970 in order to round out Lockwood's ownership of the portion of the block in which the Tract is located. Portions of

the Tract are leased to the lessees of Parcels Two and Five. The rental for those properties includes the right to use the Tract.

Aside from the costs expended during its ownership of the Parcels and the Tract, Lockwood has paid real estate taxes on the subject properties. Although such information is not readily available for prior years, the Employer has represented that for the years 1984, 1985 and 1986, Lockwood paid real estate taxes of \$10,673, \$13,385 and \$9,178, respectively.

3. In mid-1985, the State of Florida initiated a road widening project. The Trustee owned and occupied property adjacent to Parcel Five on which it constructed a branch banking facility. As a result of the road widening project, the Trustee realized that it would lose street access to its drive-in teller facilities. Accordingly, at the Trustee's request, Lockwood commenced leasing the north 20 feet of Parcel Five to the Trustee on July 1, 1985 under the terms of a written net lease (the Lease). The Lease is for a duration of approximately 29 years. The rental rate for the initial two years of the Lease is \$290 per month or \$3,480 annually. During the remaining years the Lease is in effect, the rental will be increased in accordance with the Consumer Price Index.⁵ To the Employer's best knowledge, all rental payments under the Lease have been timely paid. Because the Lease constitutes a prohibited transaction in violation of the Act, the Employer represents that the Trustee will pay the Internal Revenue Service (the Service) all excise taxes that may be due by reason of the Trustee's past and continued leasing of a portion of Parcel Five from the Plan as well as the Trustee's use of the Tract, within 90 days of the date of the publication in the Federal Register of the grant of the notice of proposed exemption.

4. Because the Employer proposes to use the Parcels and the Tract in an overall development program, it requests an administrative exemption in order to acquire the properties from the Plan. Accordingly, the Employer will purchase the Parcels and the Tract for a cash price reflecting the fair market value of the Parcels and Tract as determined by an independent appraiser. The Plan will not be required to pay any real estate fees or commissions in connection with the proposed sale.

5. The Parcels and the Tract were initially appraised by Mr. Thomas W. Bledsoe, M.A.I., S.R.P.A. Associate, an

independent appraiser affiliated with Consortium Appraisal and Consulting Services of Winter Park, Florida. In appraisal reports prepared by Mr. Bledsoe in April 1985, he determined the fair market values of the Parcels inclusive of the Tract were as follows as of January 3 and 4, 1985: Parcel One, \$125,000; Parcel Two, \$325,000; Parcel Three, \$285,000; Parcel Four, \$170,000; and Parcel Five, \$330,000.

In updated appraisal reports prepared by Mr. Bledsoe on May 20, 1986, he represented that he had reinspected the properties as of May 8, 1986 but found no material change in their value. Mr. Bledsoe also stated that he took into consideration the possibility of having the Employer pay a higher market value for the properties by reason of their proximity to the Employer's business premises. However, he said he found no support that would indicate that the Employer should be required to pay a premium price. In Mr. Bledsoe's opinion, the fair market value of the Parcels and the Tract, in relation to the adjoining properties owned by the Employer, would be no different than it would to other potential buyers in the market place. Thus, the aggregate sales price for the Parcels and to Tract will be \$1,235,000.

In addition to determining the fair market value of the properties, Mr. Bledsoe completed an analysis of the Lease with the objective of determining whether the Trustee had been paying the Plan the fair market rental value of the subject real estate. Mr. Bledsoe explained that for the type of property involved (which consists primarily of land) the portion of Parcel Five leased to the Trustee had a fair market value of \$34,560 as of May 7, 1985 and an annual fair market rental value of \$3,456 based upon a 10 percent rate of return and incremental adjustments to the Lease. Although the contract rental in the Lease was \$3,480 annually (or \$290 monthly), Mr. Bledsoe submitted that this was less than a one percent differential. Accordingly, it was his opinion that the contract rental of \$3,480 should be considered the market rental for the portion of Parcel Five that is leased to the Trustee.

6. In summary, it is represented that the proposed transaction satisfies the statutory criteria for an exemption under section 408(a) of the Act because: (a) The sale will be a one-time transaction for cash; (b) the sales price for each Parcel inclusive of the Tract is based on their fair market values as determined by an independent appraiser; (c) the Plan will not be required to pay any real estate fees or commissions in

connection therewith; (d) the sale will permit the Plan to diversify its investment and to maintain a greater percentage of its assets in more liquid investments; and (d) within 90 days of the publication in the Federal Register of the grant of the notice of proposed exemption, the Trustee will pay all applicable excise taxes that may be assessed by the Service by reason of its past and continued leasing of a portion of Parcel Five as well as the Trustee's use of the Tract.

For Further Information Contact: Ms. Jan D. Broady of the Department, telephone (202) 523-8196. (This is not a toll-free number.)

Duggins Construction, Inc. Defined Benefit Pension Plan (the Plan)

Located in El Centro, California

[Application No. D-7001]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed cash sale by the Plan of certain improved real property (the Property) to Triple D Investments (Triple D), a party in interest with respect to the Plan, provided that the Plan receives not less than the fair market value of the Property as of the date of sale.

Summary of Facts and Representations

1. The Plan is a defined benefit plan with eleven participants and assets of \$1,176,644.00 as of October 31, 1986. The trustees of the Plan are Ray Duggins and James Duggins, each of whom is a shareholder and officer of Duggins Construction Inc. (the Employer). Ray Duggins, James Duggins and the Employer each holds a 1/3 partnership interest in Triple D. The Employer is engaged in the construction industry.

2. The Property is located at 902 South Second Street in El Centro, California. The Plan purchased the Property on January 2, 1985 from Tiffany Investment Corp., an unrelated party, for \$115,000. Since acquisition of the Property, the Plan has expended \$8,524.00 for capital improvements and \$9,121.00 for operating expenses. The Plan currently leases the Property to an unrelated party on a month-to-month basis at a rent of

⁵ The Department is not, herein, proposing any exemptive relief for the Lease.

\$1,930.00 per month. However, for the period from August 15, 1986 to January 15, 1987, the Employer leased a portion of the subject property. In this regard, the applicant states that Form 5330, Return of Initial Excise Taxes Relating to Pension and Profit Sharing Plans, will be filed with the Internal Revenue Service and that all appropriate excise taxes for the leasing transaction will be paid by the Employer within 60 days of a grant of an exemption for the sale of the Property.

3. The applicant requests an exemption that will permit the Plan to sell the Property to Triple D for cash at a price greater than its fair market value in order to improve the Plan's liquidity. The applicant represents that the additional liquidity will (a) permit future benefit payments without restricting investments to low-yielding money market funds; and (b) facilitate capital improvements on a second parcel of real estate located at 1150 McCallum Street, El Centro, California (McCallum property).⁶ The improvements to the McCallum property, which is currently leased to an unrelated party, will enable the Plan to charge a higher rent thereby increasing Plan income.

4. The Property was appraised by William S. Smith, A.R.A., an independent real estate appraiser in El Centro, California, as of October 22, 1986. Mr. Smith appraised the fair market value of the Property as \$145,000. The applicant proposes to purchase the Property from the Plan for cash in the amount of \$150,000, a price greater than the Property's appraised fair market value. The applicant represents that the Plan will not incur any expenses or commissions concerning the Plan's sale of the Property.

5. In summary, the applicant represents that the proposed transaction meets the statutory criteria of section 408(a) because:

- (1) This will be a one-time cash transaction;
- (2) The Plan will receive greater than fair market value for the Property; and
- (3) The Plan will pay no fees or commissions in connection with the proposed transaction.

For Further Information Contact: Betsy Scott of the Department, telephone (202) 523-8196. (This is not a toll-free number.)

A. Raimondo, Inc. Defined Contribution Pension Plan and Trust (the Plan)

Located in Greensburg, Pennsylvania

[Application No. D-7013]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to: (1) The proposed cash purchase of certain improved real property (the Property) by the Plan from A. Raimondo, Inc. (the Employer), a party in interest with respect to the Plan; and (2) the proposed lease (the Lease) of the Property by the Plan to the Employer, provided that the terms and conditions of the transactions are at least as favorable to the Plan as those between unrelated parties.

Summary of Facts and Representations

1. The Plan is a money purchase pension plan with two participants and assets of \$596,410.72 as of April 30, 1986. The Employer is in the masonry reconstruction and restoration business in the greater Pittsburgh, Pennsylvania area.

2. The applicant is seeking an exemption to permit the Plan to acquire the Property and lease it to the Employer. The Property consists of an office and warehouse building containing 8,050 square feet located on 6.679 acres in Hempfield Township, Westmoreland County, Pennsylvania. The Property serves as the Employer's place of business. The Property was appraised as of February 24, 1987, by H. Kenneth Gehr, an independent real estate appraiser in Jeannette, Pennsylvania. The applicant represents that Mr. Gehr is unrelated to the parties in interest in this transaction. As of the appraisal date, the Property's fair market value was \$148,500. The applicant proposes to sell the Property to the Plan for a sales price of \$125,000.⁷

⁷ The applicant represents that the Plan would not be in violation of section 415 of the Code if the difference between the sales price and the fair market value of the Property were to be treated as a contribution to the Plan.

This amount falls below the appraised fair market value and represents approximately 21% of the Plan's assets.

3. An independent fiduciary, Halliwell & Associates, Inc., employee benefits consultants in Pittsburgh, Pennsylvania, has agreed to monitor the lease throughout its term. The applicant represents that substantially less than 1% of the independent fiduciary's fees are derived from services rendered of the Employer.

4. The Lease will be for ten years with an additional five-year renewal period. The applicant represents that renewal of the Lease will be finalized only with the approval of the independent fiduciary. The rent will be triple net and will require the Employer-lessee to pay taxes, maintenance and utilities expenses. The applicant represents that the independent fiduciary will select a qualified independent appraiser to re-appraise the Property at least every three years to determine the appropriate fair market rental value. Mr. Gehr appraised the fair market rental value, as of February 24, 1987, as \$2,500.00 per month. The rent will be adjusted annually to reflect changes in the Consumer Price Index, but will at no time be adjusted below \$2,500.00 per month.

5. The independent fiduciary has examined the proposed transactions within the context of the Plan's investment portfolio and funding policy. The independent fiduciary concluded that:

a. The overall value of the investment will represent only 21% of the total value of the Plan's assets and thus will significantly contribute to the diversification of the investments of the Plan in line with the stated funding policy;

b. The Employer is a profitable building restoration enterprise in an area demonstrating a growing need for its services. The independent fiduciary projects the Employer's business to continue at existing or even higher levels for the next few years. Because of the Employer's financial condition, the independent fiduciary deems there to be very small overall risk of loss by the Plan on the proposed transactions;

c. The projected return to the Plan is above average and will provide a favorable level of income for the foreseeable future, especially when compared to the returns currently available from alternative investments;

d. The proposed rent compares favorably with others and is appropriate and at fair market value; and

e. Under the provisions of the Lease, the independent fiduciary will be

⁶ The Department is expressing no opinion as to whether the use of Plan assets for the improvement of the McCallum property violates any provisions of Part 4 of Title I of the Act.

empowered to enforce all of the terms of the Lease. The independent fiduciary will verify the collection of rent and will ensure that the Property is adequately insured and maintained. The independent fiduciary will monitor the transactions to safeguard the interests of the Plan and its participants and beneficiaries.

6. In summary, the applicant represents that the proposed transactions satisfy the criteria of section 408(a) of the Act because:

(a) The Plan will pay below fair market value for the Property;

(b) The Employer will pay at least the Property's fair rental value under the Lease;

(c) The rent will be adjusted annually to reflect changes in the Consumer Price Index and will be re-appraised at least every three years by a qualified independent appraiser to determine the appropriate fair market rental value; and

(d) An independent fiduciary has reviewed the transactions and has concluded that they are in and best interests of the protective of the Plan and its participants and beneficiaries.

Tax Consequences of Transaction: The Department of the Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer (or affiliate thereof) results in the plan's either paying less than or receiving more than fair market value, such excess may be considered to be a contribution by the sponsoring employer to the plan and therefore must be examined under applicable provisions of the Internal Revenue Code, including sections 401(a)(4), 404 and 415.

For Further Information Contact: Betsy Scott of the Department, telephone (202) 523-8196. (This is not a toll-free number.)

Weight Watchers of Arizona, Inc. Defined Contribution Pension Plan (the Plan)

Located in Phoenix, Arizona

[Application No. D-7065]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed

cash sale for \$125,000 of an unimproved parcel of real property (the Property) from the Plan to Robert Machiz, Iris Machiz, Gerald Appell, and Isabelle Appell (the Applicants), parties in interest with respect to the Plan; provided that the sales price is not less than the fair market value of the Property as of the date of sale.

Summary of Facts and Representations

1. The Plan is a defined contribution plan with 26 participants as of February 1987 and net assets with a value of approximately \$632,738 as of September 1986. The Applicants are the only shareholders, members of the Board of Directors, and the officers of the Weight Watchers of Arizona, Inc. (the Employer), located at 1608 E. Earll Drive, Phoenix, Arizona. The Applicants also serve as the trustees of the Plan and have discretionary authority over the investment decisions of the Plan.

2. The Property is located 125 feet north of the northeast corner of 16th Street and Earll Drive, Phoenix, Arizona and is adjacent to and south of two parcels of real property owned by the Applicants. The Property is a level, street grade, rectangular vacant parcel totalling 10,061 square feet with a 60.9 frontage along 16th Street, a one mile north/south arterial roadway. Prior to the passage of the Act, the Property was acquired by a predecessor defined benefit plan (the Benefit Plan) on December 10, 1973, as an Employer contribution with a fair market value of \$24,322. At that time, the Employer contemplated leasing the Property for expansion of the corporate headquarters but was precluded from doing so after the passage of the Act. It is represented that the Employer and the Applicants have not used the Property nor has the Property generated income.

In 1976 the Benefit Plan was converted to the current Plan which since that time has held the Property as an investment vehicle which has appreciated in value. It is represented that the real estate taxes paid since the Plan acquired the Property total \$4,500. These taxes on the Property were paid by the Employer and treated as a Plan expense paid in addition to the annual contribution required under the Plan.

The Applicants represent that the current fair market value of the Property constitutes approximately 20% of the Plan's assets in 1986.

3. The Property was appraised at \$125,000 on January 19, 1987, by Donald C. Duncan, A.S.A. (Mr. Duncan) and Thomas Raynak (Mr. Raynak) of Iver C. Johnson and Company, Ltd., (Iver) located in Phoenix, Arizona. Mr. Duncan is a member of the American Society of

Appraisers and the vice president of and chief appraiser with Iver. Mr. Raynak is a staff appraiser with Iver. Both Mr. Duncan and Mr. Raynak represent that they are independent and have no present or contemplated interest in the Property nor has their compensation or employment been contingent on their appraised value of the Property. Mr. Duncan and Mr. Raynak indicated that due to the proximity of the Property to the land owned by the Applicants that the value to them would be five to ten percent above market value and that the appraised value of \$125,000 includes that premium.

4. It is represented that the Applicants intend to go forward on the commercial development on the two parcels which they own and which are adjacent to the subject Property. The Applicants propose to purchase the Property from the Plan for \$125,000 in cash in order to consolidate it with such development. The Plan will incur no costs of commissions or finder's fees in connection with the sale. It is represented that the proceeds of the sale of the Property will be used to diversify the Plan's portfolio of investments.

5. In summary, the Applicants represent that the proposed transaction satisfies the criteria of section 408(a) because:

(a) This will be a one-time transaction for cash;

(b) The Plan will be able to invest the proceeds from the sale of the Property in income producing assets; and

(c) The sale price is the fair market value of the Property as determined by independent appraisers and includes a premium due to the proximity of the Property to other real estate owned by the Applicants.

For Further Information Contact: Angelena Le Blanc of the Department, telephone (202) 523-8196. (This is not a toll-free number.)

Richard F. Pawlowski, M.D., P.C. Defined Benefit Pension Plan (the Plan)

Located in Carmichael, California

[Application No. D-7086]

Proposed Exemption

The Department is considering granting an exemption under the authority of 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed cash sale (the Sale) by

the Plan of a certain parcel of unimproved real property (the Property) to Dr. and Mrs. Richard F. Pawlowski (the Pawlowskis), disqualified persons with respect to the Plan, provided that the consideration paid for the Property is not less than the greater of its fair market value on the date of the Sale or the price originally paid by the Plan plus its holding costs.

Summary of Facts and Representations

1. The Plan is a defined benefit plan with total assets of \$670,778.29 as of September 30, 1986. The Pawlowskis are the sole participants and fiduciaries of the Plan. Dr. Pawlowski is the sole owner of the Plan sponsor, a medical corporation (the Employer).⁹

2. The Property is located at Powers Drive, Lot 226, Ridgeview Village #4 in El Dorado Hills, California. The Plan purchased the Property in July, 1983 from an unrelated party for \$57,520.45. Since the acquisition of the Property, the Plan has expended \$3,157.06 for property taxes. The applicants represent that the Property has been undeveloped throughout the holding period and that it has not been used for any purpose.

3. The applicant request an exemption that will permit the Plan to sell the Property to the Pawlowskis for cash in order to improve the Plan's liquidity and to divest the Plan of an asset which has not appreciated substantially in value. The Pawlowskis desire to construct their primary residence on the Property. The applicants represent that no attempts have been made to sell the Property to an unrelated party.

4. The Property was appraised by Sheri L. Donaldson, an Independent real estate appraiser in Shingle Springs California, as of December 20, 1986. The applicants represent that Ms. Donaldson is unrelated to the Pawlowskis. Ms. Donaldson appraised the fair market value of the Property as \$59,000. The applicants propose to purchase the Property from the Plan for cash in the amount of \$60,677.51, which represents the total of the Plan's expenditures connected with the acquisition and holding of the Property and which is in excess of the Property's appraised fair market value. The applicants represent that the Plan will not incur any expenses or commissions in connection with the Sale.

5. In summary, the applicants represent that the proposed transaction

meets the statutory criteria of section 408(a) because:

- (1) This will be a one-time cash transaction;
- (2) The Plan will receive greater than fair market value for the Property; and
- (3) The Plan will pay no commissions or expenses in connection with the proposed transaction.

Notice to Interested Persons: Because The Pawlowskis are the sole Plan participants, the Department has determined that there is no need to distribute the notice of pendency of the proposed exemption to interested persons. Comments and requests for hearing must be received by the Department within 30 days of the date of publication of this notice of proposed exemption.

For Further Information Contact: Mrs. Betsy Scott of the Department, telephone (202) 523-8196. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether

the transaction is in fact a prohibited transaction.

(4) The proposed exemptions, if granted, will be subject to the express condition that that material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 14th day of April, 1987.

Elliot I. Daniel,

Associate Director for Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor.
[FR Doc. 87-8938 Filed 4-20-87; 8:45 am]

BILLING CODE 4510-29-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-245]

Northeast Nuclear Energy Co.; Integrated Safety Assessment Program; Availability of the Draft Integrated Safety Assessment Report for the Millstone Nuclear Power Station, Unit No. 1

The Nuclear Regulatory Commission's (NRC) Office of Nuclear Reactor Regulation has published its Draft Integrated Safety Assessment Report (ISAR) (NUREG-1184) related to the Northeast Nuclear Energy Company's (licensee) Millstone Nuclear Power Station, Unit No. 1, located in New London County, Connecticut.

The Integrated Safety Assessment Program (ISAP) was initiated by the NRC to conduct integrated assessments for operating reactors to establish integrated implementation schedules. This report documents the review of Millstone Unit No. 1, which is one of two plants being reviewed under the pilot program for ISAP. This report indicates how 85 topics selected for review were addressed and presents the staff's recommendations regarding the corrective actions to resolve the 85 topics and other actions to enhance plant safety. The report is being issued in draft form to obtain comments from the licensee, nuclear safety experts, and the Advisory Committee for Reactor Safeguards. Once those comments have been resolved, the staff will present its positions, along with a long-term implementation schedule from the licensee, in the final version of this report.

The draft ISAR is being made available at the NRC's Public Document

⁹ Since the Pawlowskis are the sole Plan participants and Dr. Pawlowski is the sole owner of the Plan sponsor, there is no jurisdiction under Title I of the Act pursuant to 29 CFR 2510.3-3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

Room, 1717 H Street, NW., Washington, DC 20555 and at Waterford Public Library, Rope Ferry Road, Route 156, Waterford, Connecticut 06385 for inspection and copying. A free single copy of draft NUREG-1184, to the extent of supply, may be obtained by writing to the Distribution Section, Document Control Branch, Division of Information Support Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A copy is also available for inspection and/or copying for a fee in the NRC Public Document Room, 1717 H Street, NW., Washington, DC 20555.

Dated at Bethesda, Maryland, this 15th day of April, 1987.

For the Nuclear Regulatory Commission.
Cecil O. Thomas,

Director, Integrated Safety Assessment
Project Directorate, Division of PWR
Licensing-B, Office of Nuclear Reactor
Regulation.

[FR Doc. 87-8933 Filed 4-20-87; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-24345; File No. SR-CBOE-87-09]

Self-Regulatory Organizations; Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to Terms of Options Contracts

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on March 16, 1987, the Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Text of the Proposed Rule Change

Additions are italicized; deletions are bracketed.

Terms of Option Contracts

Rule 24.9. No change.

. . . Interpretations and Policies:

.01 The procedures for adding and deleting strike prices for index options are provided in Rule 5.5 and Interpretations and Policies related thereto, as otherwise generally provided by Rule 24.9, and include the following:

a. Regardless of the price of an index, the interval between strike prices will be no less than \$5.00.

b. New series of index option contracts may be added up to the fifth business day prior to expiration.

c. When a new series of index option contracts with a new expiration cycle are opened for trading, two strike prices above and two strike prices below the current index price may be added.

d. When the value of the index underlying a class of index options reaches a strike price, the Exchange may add one or more additional strike prices such that there are up to [two] *three* strike prices above and [two] *three* strike prices below the strike price which has been reached.

e. In unusual market conditions, the Exchange may add additional series of index option contracts up to [three] *four* strike prices above and [three] *four* strike prices below the current index price.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The proposed rule change will provide necessary flexibility for the Exchange to add series of index option contracts at sufficient price intervals away from the existing index value to allow appropriate trading strategies to be effectuated.

In recent days, the index value in the S&P 100 Index Options ("OEX") has, on an intra-day basis, moved as many as 13 points. This volatile price movement results in two particularly acute problems in trading. First, the volatility dramatically increases the price of the existing options, thereby limiting the ability to hedge with lower priced options. Second, the process for introduction of new strikes requires some degree of lead time and consequently relief cannot be offered to the marketplace rapidly enough to deal with this circumstance.

The Exchange has previously secured some relief in this area. See SR-CBOE-84-22, as amended. As approved by the Commission, the referenced proposed rule change allows for the maintenance

of two out-of-the-money strike prices in index options, and a third can be added in unusual market conditions. This relief, however, has been inadequate to deal with the increasing circumstances wherein index options trade through a substantial number of strike prices on a very short-term basis. The Exchange believes that the addition of an additional out-of-the-money strike price interval in unusual market conditions is an appropriate step.

The Exchange believes that the proposed rule change is consistent with the Securities Exchange Act of 1934 and in particular the requirements of section 6 of the Act and the Rules and Regulations thereunder in that the proposed rule change will accommodate market participants' investment needs and objectives, increase market depth and liquidity and improve the market efficiency. It should also be noted that the Exchange does not believe that the increased number of strike prices will impair market efficiency by dispersing trading activity. To the contrary, the Exchange believes that market participants are enabled, by hedging activity in the additional strike prices, to assume greater positions in the preexisting option series.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that this proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (1) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV Solicitation of Comments

Interested persons are invited to submit written data, views and

arguments concerning the foregoing. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies so such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by May 12, 1987.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: April 15, 1987.

Shirley E. Hollis,

Assistant Secretary.

[FR Docs. 87-8926 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-24347; File No. SR-CBOE-87-12]

**Self-Regulatory Organizations;
Chicago Board Options Exchange,
Inc.; Order Granting Accelerated
Approval to Proposed Rule Change**

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s (b)(1), notice is hereby given that on March 20, 1987, the Chicago Board Options Exchange, Incorporated ("CBOE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's
Statement of the Terms of Substance of
the Proposed Rule Change**

The proposed rule change would enable the Exchange to add two-and-a-half cent exercise prices in British pound option contracts, either singly or at the

same time as the next exercise price is added.

**II. Self-Regulatory Organization's
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections (A), (B), and (C) below.

**(A) Self-Regulatory Organization's
Statement of the Purpose of, and the
Statutory Basis for, the Proposed Rule
Change**

The Purpose of this proposed rule change is to allow the listing of additional exercise prices in British pound option contracts to enable the Exchange to compete with the Chicago Mercantile Exchange and the Philadelphia Stock Exchange, Inc. ("Phlx") both of which currently have \$.025 strike price intervals on British pound option contracts. The statutory basis for the proposed rule change is section 6(b)(5) of the Act, in that it is designed to facilitate transactions in British pound option contracts.

**(B) Self-Regulatory Organization's
Statement on Burden on Competition**

The Exchange does not believe that the proposed rule change imposes a burden on competition.

**(C) Self-Regulatory Organization's
Statement on Comments on the
Proposed Rule Change Received from
Members, Participants or Others**

Comments were neither solicited nor received.

**III. Date of Effectiveness of the
Proposed Rule Change and Timing for
Commission Action**

The Exchange requests that the proposed rule change be given accelerated effectiveness pursuant to section 19(b)(2) of the 1934 Act because the rule change is substantively identical to a proposed rule change previously filed by the Phlx and approved by the Commission.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, the requirements of section 6 and the rules

and regulations thereunder. This rule change will provide investors in a non-volatile currency with more choices as to their participation in this market. The flexibility of switching from a \$.05 to \$.025 intervals will enable the Exchange to be competitive with the Chicago Mercantile Exchange and the Phlx which currently have \$.025 intervals on British Pound option Contracts.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof because the proposed rule change is substantively identical to a rule proposal previously filed by the Phlx and approved by the Commission.¹ The strike price revision also is similar to others the Commission has approved in non-volatile currencies.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by May 12, 1987.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

Dated: April 15, 1987.

[FR Doc. 87-8927 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

¹ See Securities Exchange Act Release No. 24103, February 13, 1987.

[Rel. No. 34-24330; File No. SR-MCC-87-2]

**Self-Regulatory Organizations;
Midwest Clearing Corp.; 1987 Trade
Recording Fee Schedule; Filing and
Immediate Effectiveness of Proposed
Rule Change**

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on April 2, 1987, the Midwest Clearing Corporation filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, with Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's
Statement of the Terms of Substance of
the Proposed Rule Change**

Attached as Exhibit A is the 1987 Trade Recording Fee Schedule.

**II. Self-Regulatory Organization's
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of such statements.

**(A) Self-Regulatory Organization's
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change**

The Midwest Clearing Corporation has implemented a revised schedule of charges for trade recording for trades recorded on or after March 2, 1987. The MCC fee changes will result in lower trade recording costs for most firms.

Each year MCC analyzes the cost of providing trade recording and clearing services to its participants in order to determine how well the fee structure matches the cost of providing these services. The study includes an analysis of MCC services as they compare with services and fees in other market places and to determine how well MCC has addressed the broader needs of the financial community. The analysis indicated that MCC could improve the cost effectiveness of trade recording services for all participants by lowering costs for trades in the 1-1000 share

category and eliminating the trade per day discount calculations previously offered to high volume participants. To encourage large firms to use MCC services, a discount for high volume users who record 10,000 or more trades per month will still be in effect but will apply to that category of trades in the 1000 share size and above where a slight increase in fees would have an impact. The new structure effectively lowers costs for most participants while assuring MCC that the cost of providing trade recording services is covered.

The proposed rule change is consistent with section 17A(b)(3)(D) in that it provides for the equitable allocation of reasonable dues, fees, and other charges among MCC's Participants.

**(B) Self-Regulatory Organization's
Statement on Burden on Competition**

The Midwest Clearing Corporation does not believe that the proposed fee schedule will impose any burdens on competition.

**(C) Self-Regulatory Organization's
Statement on Comments on the
Proposed Rule Change Received from
Members, Participants or Others**

Comments have neither been solicited nor received.

**III. Date of Effectiveness of the
Proposed Rule Change and Timing for
Commission Action**

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b-4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission

and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-referenced self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by May 12, 1987.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: April 13, 1987.

Shirley E. Hollis,
Assistant Secretary.

Exhibit A—1987 Trade Recording Fees

Effective March 2, 1987, MCC Trade Recording fees will be changed to the following schedule:

Trade size in shares	Price/trade side
1-99	\$0.20
100-199	0.20
200-299	0.23
300-399	0.26
400-499	0.29
500-599	0.32
600-699	0.35
700-799	0.38
800-899	0.41
900-999	0.44
1000-1499	0.47
1500-1999	0.64
2000-2499	0.81
2500-2999	0.98
3000-3499	1.15
3500-3999	1.32
4000-4499	1.49
4500-4999	1.66
5000 and up	1.83

The monthly MCC/MSTC billing statement will continue to reflect the total number of trades by type (round/mix lot, odd lot, etc.). The associated fees will continue to be provided in an additional statement titled "Trade Recording Fees" which will be provided each month. This statement will reflect the above schedule, categorized by share size with the appropriate fee applied.

In addition, a discount of \$0.15 per trade side recorded will be applied to the trade recording fees for trades of 1000 shares and larger when a participant exceeds 10,000 recorded trade sides each month.

Discount Schedule

Total trades recorded exceeds 10,000 trades in any given month.

Total size in shares	Discount	Effective price/trade side
1000-1499	\$0.15	\$0.32
1500-1999	0.15	0.49
2000-2499	0.15	0.68
2500-2999	0.15	0.83
3000-3499	0.15	1.00
3500-3999	0.15	1.17
4000-4499	0.15	1.34
4500-4999	0.15	1.51
5000 and up	0.15	1.68

For participants whose volume qualifies them for the discount, the "Trade Recording Fees" statement will reflect the cost for trades in the 1000 share and above category less the \$0.15 per trade side discount. The statement will show a total trade recording fee for the month including non-discounted trades.

This fee will continue to be charged through the MST System as a cash adjustment separate from the MCC/MSTC monthly billing. Both fees will be processed on the sixth business day of the month via a "BLCLND" entry on the daily activity report.

[FR Doc. 87-8878 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-24342; File No. SR-MSTC-87-4]

Self-Regulatory Organizations; Midwest Securities Trust Co.; MSTC Revised Policy on Liability for Lost Use of Funds Due to the Late Processing of Call/Put/Maturity Redemptions

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on March 5, 1987, the Midwest Securities Trust Company filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Attached as Exhibit A is a Bulletin and Procedures describing Midwest Securities Trust Company's ("MSTC") revised policy on liability for lost use of

funds due to the late processing of call/put/maturity redemptions.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

MSTC has historically adhered to a policy, approved by its Board of Directors, of not assuming liability or honoring claims for the lost use of funds caused by the delay in crediting payments to the accounts of MSTC Participants. The rationale for this policy was based principally on MSTC's limited profit objective and the nature of MSTC's capacity as an agent in the maintenance and safekeeping of securities on behalf of its Participants. However, recent events in call/put/maturity redemptions have occasioned a re-review of this policy, both from the point of view of the MSTC Depository and MSTC Participants. Declines in interest rates occurring primarily in the last half of 1986 resulted in a significant increase in the number of full and partial redemptions of public and private debt securities, particularly municipal bonds. The increased redemption volume caused considerable burdens on the operations staffs of financial intermediaries, securities depositories and their participants, which sometimes resulted in delayed redemption processing and payments to the ultimate beneficial holders of such securities.

In some instances, delays in processing and crediting to MSTC Participants of collected funds has allowed MSTC to invest collected funds which would otherwise be made available and distributed to its participants. Based on the foregoing, as well as independent analysis by MSTC management, MSTC's Board of Directors has approved a change in MSTC's current liability policy in recognition of MSTC's responsibility to act

expeditiously for its Participants and promptly distribute income funds. As described more fully in the attached Exhibit, and subject to the conditions contained therein, for called bonds with a payable date on May 1, 1987 or thereafter, MSTC will assume liability for lost use of funds for the period of time beginning on the seventh (7) business day after such payable date, and ending on the actual payment date. MSTC will compute and pay interest due Participants automatically upon the crediting of the redemption proceeds. MSTC will not, however, pay interest or honor claims where such interest is \$500.00 per cusip or less. Furthermore, MSTC will not assume liability for interest payments when the (i) cause of delay in payment is wholly or substantially due to acts or failure to act on the part of a third party (such as an issuer, trustee or agent), or (ii) the third party is not in substantial compliance with the industry standards set forth in Securities Exchange Act Release No. 34-23856 (December 3, 1986, the substance of which has been previously distributed to MSTC Participants).

Finally, the attached Bulletin describes MSTC's plan to distribute accrued interest income to Participants. On or about July 15, 1987, MSTC will prorate and refund such income in proportion to each Participants dollar volume of call collection activity (amounts collected and disbursed to participants) during the time periods described in the Bulletin.

The purpose of the interest refund policy is to refund invested collected funds which would otherwise be available to Participants, as well as alleviate the costly and time consuming process to both MSTC and Participants in the preparation, research and resolution of individual call/put/maturity claims for payment dates prior to May 1, 1987.

The proposed rule change is consistent with the Securities Exchange Act of 1934 in that it facilitates the prompt and accurate clearance and settlement of securities transactions. The proposed rule change also clarifies certain MSTC responsibilities and obligations regarding the safekeeping of securities and funds which are in its custody or control.

(B) Self-Regulatory Organization's Statement on Burden on Competition

MSTC does not believe that any burdens will be placed on competition as a result of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

While MSTC has not generally solicited or received comments, members of MSTC's Operations Committee and Board of Directors have reviewed and approved the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b-4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of MSTC. All submission should refer to File No. SR-MSTC-87-4 and should be submitted by May 12, 1987.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: April 14, 1987.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 87-8880 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-24344; File No. SR-NASD-87-12]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change

The National Association of Securities Dealers, Inc. ("NASD") submitted on February 20, 1987, copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder to amend its By-Laws and Code of Procedure to provide Extended Hearing Committees for certain disciplinary actions.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by the issuance of a Commission release (Securities Exchange Act Release No. 24184, March 5, 1987) and by publication in the Federal Register (52 FR 7717, March 12, 1987). No comments were received with respect to the proposed rule change.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of section 15A, and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Dated: April 15, 1987.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 87-8879 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34- 24341; File No. SR-NYSE-87-11]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Opening Price Settlement of Expiring NYSE Composite and Beta Index Options

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on April 6, 1987, the New York Stock Exchange, Inc. filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

On March 13, 1987 the Exchange filed a proposed rule change to change the settlement pricing of expiring stock index options to the opening prices on expiration Friday.¹ That rule filing only was effective with respect to index options contracts expiring in June. In particular, the Exchange modified the definition of "Current Index Group Value" in Rule 700(b)(17) to permit the Exchange to specify that the value upon exercise of options on the NYSE Composite Index and the NYSE Beta Index on expiration Friday is to be calculated from the opening prices for the constituent stocks on that day. The Exchange made conforming changes to the contract specifications for options on both indexes to make clear that trading ceases on the Thursday before expiration Friday. The Exchange now proposes to make permanent the rule changes proposed in that filing.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) *Purpose.* The purpose of the proposed rule change is to ameliorate the impact of the concurrent expiration of index options and futures on the markets for individual stocks and on the stock market as a whole. The Exchange believes that settling index futures and options based upon the opening prices of the constituent stocks, and thereby permitting use of the Exchange's opening procedures in handling the accompanying stock volume, is the best strategy for addressing widely-held concerns about the actual and potential

¹ See SR-NYSE-87-06, and 3/16/87 Letter to Sharon M. Lawson, Branch Chief, SEC, from Daniel P. Odell, Assistant Secretary, NYSE. This rule filing was approved in Securities Exchange Act Release No. 24276.

impact of the derivative products on the pricing mechanism and integrity of the stock market.

(b) **Statutory Basis.** The basis under the Act for the proposed rule change is section 6(b)(5), which requires that the rules of the Exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments regarding the proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in

accordance with the provisions of 5 U.S.C. 552 will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the abovementioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by May 12, 1987.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: April 14, 1987.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-8881 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-15687; 812-6474]

CitiCMO, Inc.; Collateralized Mortgage Obligations

April 15, 1987.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act")

Applicant: CitiCMO, Inc.
Relevant 1940 Act Sections:

Exemption requested under section 6(c) from all provisions of the 1940 Act.

Summary of Application: Applicant seeks an order conditionally exempting Applicant and certain trusts that it may form from all provisions of the 1940 Act in connection with the proposed issuance of collateralized mortgage obligations and sale of beneficial ownership interests in such trust.

Filing Date: The application was filed on November 13, 1986 and amended on February 26, and April 3, 1987.

Hearing or Notification of Hearing: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m., on May 8, 1987. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicant with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549.

CitiCMO, Inc., 55 Water Street, New York, NY 10043.

FOR FURTHER INFORMATION CONTACT: Denis R. Molleur, Staff Attorney at (202) 272-2363 or Brion R. Thompson, Special Counsel at (202) 272-3016 (Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION:

Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

(1) Applicant is an indirect, wholly-owned subsidiary of Citicorp, a Delaware corporation. Applicant, a newly-formed Delaware Corporation, was incorporated to facilitate the financing of mortgage loans through the establishment of one or more trusts ("Trusts") for the limited purpose of issuing one or more series ("Series") of bonds ("Bonds") and investing in certain Mortgage Certificates¹ which will be used to collateralize such Bonds. No Trust will engage in any other unrelated business or investment activity.

(2) Applicant will establish one or more Trusts pursuant to separate trust agreements (each a "Trust Agreement") between Applicant, as settlor, depositor and sole beneficial owner, and Wilmington Trust Company or another independent bank, trust company or fiduciary acting as owner trustee (the "Owner Trustee").

(3) Under the terms of each Trust Agreement, Applicant will convey trust property to the related Trust in return for certificates or other instruments evidencing beneficial ownership of the Trust created under such Trust Agreement ("Trust Certificates"). Each Trust, acting through the Owner Trustee, will issue on or more Series of Bonds and, simultaneously with the sale of

¹ "Mortgage Certificates" will be limited to mortgage pass-through certificates and certain other certificates which are fully guaranteed as to principal and interest by the Government National Mortgage Association ("GNMA Certificates"), Mortgage Participation Certificates and certain other certificates issued by the Federal Home Loan Mortgage Corporation ("FHLMC Certificates") and Guaranteed Mortgage Pass-Through Certificates and Stripped Mortgage-Backed Securities issued by the Federal National Mortgage Association ("FNMA Certificates") (collectively, "Mortgage Certificates"). Mortgage Certificates included in the Collateral may or may not be Whole Pool Collateral. In addition to the Mortgage Certificates directly securing the Bonds, a Series may have additional collateral which may include cash, a letter of credit, certain collection accounts, debt service reserve funds and other reserve funds, the reinvestment income on such distributions and deposits, and/or payments under any minimum principal payment agreement.

such Series, purchase the Mortgage Certificates that will secure such Series of Bonds. Each Trust will pledge the collateral ("Collateral") for a particular Series of Bonds, including the Mortgage Certificates and certain other collateral, which may include on or more reserve funds, to the independent trustee (the "Bond Trustee") under an indenture (the "Indenture") between the Trust and the Bond Trustee, as supplemented by a series supplement ("Series Supplement") relating to such Series and will be subject to the lien of the related Indenture. The Bond Trustee will hold such Collateral as security only for that Series of Bonds, and the holders of Bonds of such Series (the "Bondholders") will be entitled to the equal and proportionate benefits of such security as if the same had been granted by a corporate issuer.

(4) In the case of each Series of Bonds: (a) Each Trust will hold no substantial assets other than the Mortgage Certificates; (b) the Bonds will be secured by Mortgage Certificates having a collateral value determined under the Indenture, at the time of issuance and following each payment date, equal to or greater than the outstanding principal balance of the Bonds; (c) distributions of principal and interest received on the Mortgage Certificates securing the Bonds and any applicable reserve funds, plus reinvestment income thereon, will be sufficient to pay all interest on the Bonds and to retire each class of Bonds by its stated maturity; and (d) the Mortgage Certificates will be assigned by the Owner Trustee to the Bond Trustee and will be subject to the lien of the related Indenture.

(5) Each Series of Bonds to be issued may contain one or more classes of variable or floating rate Bonds which will have a fixed maximum rate of interest ("interest rate cap") that will be payable on the Bonds (or the minimum rate of interest, in the case of an inverse-floating rate Bond). Any Series of Bonds containing one or more classes of variable or floating interest rate Bonds will be structured with reference to the interest rate caps for that particular Series, insuring that the scheduled distributions on the Mortgage Certificates together with the other Collateral pledged to secure the Bonds will be sufficient to make all payments on principal and interest on the Bonds, even if the interest rate on any class of variable or floating interest rate Bonds climbed to the interest rate cap in the first interest period and remained constant throughout the life of the Bonds.

(6) Applicant further intends to sell Trust Certificates representing the beneficial ownership in each Trust to not more than one hundred investors in transactions not involving a public offering within the meaning of section 4(2) of the Securities Act of 1933 ("1933 Act"). Such investors will be those who traditionally engage in investing in mortgages or mortgage related instruments, or such other investors who would qualify as "accredited investors" as such term is defined in Regulation D to the 1933 Act ("Owners"). The subsequent transfer of Trust Certificates will be also limited to private placements to these types of investors. Each investor will represent that it is purchasing such Trust Certificates for investment purposes. The Trust Agreement relating to each Trust will prohibit the transfer of Trust Certificates for such beneficial interests if there would be more than one hundred Owners of such certificates at any time.

(7) Neither the holders of the beneficial interests of any of the Trusts, the Owner Trustee nor the Trustee will be able to impair the security afforded by the Mortgage Certificates to the holders of the Bonds. That is, without the consent of each Bondholder to be affected, neither the Owners of the Trust, the Owner Trustee nor the Bond Trustee will be able to: (1) Change the stated maturity on any Bonds; (2) reduce the principal amount or the rate of interest on any Bonds; (3) change the priority of payment on any class of any Series of Bonds; (4) impair or adversely affect the Mortgage Certificates securing a Series of Bonds; (5) change the provisions in the Indenture in such a manner as to affect the calculation of the debt service requirement for any Bond or the rights of the holder of any Bond to the provisions for mandatory redemption of Bonds; (6) permit the creation of a lien ranking prior to or on a parity with the lien of the related Indenture with respect to the Mortgage Certificates; (7) terminate the lien of the Indenture on any Collateral at any time subject thereto (except in certain limited circumstances expressly permitted in the Indenture); or (8) otherwise deprive the Bondholders of the security afforded by the lien of the related Indenture.

(8) The ability of the Applicant to sell Trust Certificates in each Trust will not alter the payment of cash flows under the Indenture, including the amounts to be deposited in the collection account, debt service reserve fund or Reserve Fund created pursuant to the Indenture to support payments of principal and interest on the Bonds.

(9) No Owner of a controlling interest in a Trust (as the term "control" is defined in Rule 405 under the 1933 Act), will be affiliated with either (a) any custodian which may hold the Collateral on behalf of the Bond Trustee or (b) any nationally recognized statistical rating agency rating the Series of Bonds. Moreover, none of the Owners of the Trust Certificates of a particular Trust will be affiliates of the Bond Trustee under the Indenture relating to the Bonds issued by such Trust.

(10) The interest of the Bondholders will not be compromised or impaired by the ability of the Applicant to sell beneficial interests in each Trust, and there will not be a conflict of interest between the Bondholders and the Owners of the Trust Certificates because: (a) The Mortgage Certificates which initially will be deposited into each Trust will not be speculative in nature since they will consist solely of the Mortgage Certificates, which are guaranteed as to timely payment of interest and timely or ultimate payment of principal by each respective agency; (b) each Series of Bonds will only be issued provided an independent nationally recognized statistical rating agency has rated such Bonds in one of the two highest rating categories; (c) the Indenture under which a Series of Bonds will be issued subjects the Collateral pledged to secure the Bonds of such Series, all income distributions thereon and all proceeds from a conversion, voluntary or involuntary, of any of such Collateral to a first priority perfected security interest in the name of the Bond Trustee on behalf of the Bondholders;² and (d) the Owners of the Trust Certificates are entitled to receive current distributions representing the residual payments on the Collateral from each Trust in accordance with the terms of the applicable Trust Agreement, which distributions are analogous to dividends payable to a

² The Indenture further specifically provides that no amounts may be released from the lien of the Indenture to be remitted to the issuing Trust (and any Owner of Trust Certificates thereof) until (i) the Bond Trustee has made the scheduled payment of principal and interest on the Bonds, (ii) the Bond Trustee has received all fees currently owed to it, (iii) the firm of independent accountants have received all fees owed to it for services rendered under the Indenture, and (iv) to the extent required by any Series Supplement executed in connection with the issuance of a Series of Bonds, deposits have been made to certain Reserve Funds which will ultimately be used to make payments of principal and interest on the Bonds. Once amounts have been released from the lien of the Indenture, the Trust Agreement for each Trust provides that the Owner Trustee under the Trust Agreement has a lien superior to that of the Owners of the Trust Certificates of the Trust to the remaining cash flow.

shareholder of a corporate issuer of collateralized mortgage obligations. Furthermore, unless the Trust elects to be treated as a "real estate mortgage investment conduit" ("REMIC") pursuant to the Internal Revenue Code of 1986, the Owners will be liable for the expenses, taxes and other liabilities of the Trust (other than the principal and interest on the Bonds) to the extent not previously paid from the Trust estate. The choice of the form of issuer for the Bonds and the identity of the owners of the equity interests in such issuer, however, will not alter in any respect the payments made to the holders of such Bonds, which will be payments governed by an indenture meeting the requirements of the Trust Indenture Act of 1939.

(11) The election by any Trust to be treated as a REMIC will have no effect on the level of the expenses that would be incurred by any such Trust. Any Trust that elects to be treated as a REMIC will provide for the payment of administrative fees and expenses by any of four methods which are set forth in the application. Each Trust will insure that the anticipated level of fees and expenses will be more than adequately provided for regardless of which or all of the methods are selected by such Trust.

(12) The aggregated interests of the Owners of the Trust Certificates in the Collateral and the expected payments to be made to the Owners of the Trust Certificates will be far less than the payments made to Bondholders. In addition, Applicant does not intend to deposit in any Trust, Mortgage Certificates with a collateral value which exceeds 120 percent of the aggregate original principal amount of such Bonds at the time of issuance.

(13) Except to the extent permitted by the limited right to substitute mortgage collateral, it will not be possible for the Owners of the Trust Certificates to alter the mortgage collateral initially deposited into Trust, and in no event will such right to substitute mortgage collateral result in a diminution in the value or quality of such mortgage collateral. Although it is possible that any mortgage collateral substituted for the mortgage collateral initially deposited into a Trust may have a different prepayment experience than the substituted mortgage collateral, the interests of the Bondholders will not be impaired because: (a) The prepayment experience of any mortgage collateral will be determined by market conditions beyond the control of the Owners of the Trust Certificates, which market conditions are likely to affect all

mortgage collateral of similar payment terms and maturities in a similar fashion; (b) the interests of the Owners of the Trust Certificates are not likely to be greatly different from those of the Bondholders with respect to mortgage collateral prepayment experience; and (c) to the extent that it may be possible for the Owners of the Trust Certificates to cause the substitution of mortgage collateral which has a different prepayment experience than the original mortgage collateral, this situation is no different for the Bondholders than the traditional structure for collateralized mortgage obligations where the Bonds are issued by an entity which is a wholly-owned subsidiary. Further, due to the fact that there will be more than one Owner of each Trust, it appears less likely that such Owners will be able to agree on any desired substitution of mortgage collateral than if there were a single Owner which could unilaterally decide on the timing and execution of the substitution.

(14) The requested order is necessary and appropriate in the public interest because: (a) The acquisition of the Mortgage Certificates and issuance of Bonds by the Trusts are not the types of activities intended to be regulated by the Act; (b) the disclosure to Owners of a Trust and the restriction of such potential Owners to a limited number of sophisticated investors provide safeguards adequate to assure that such potential Owners do not require the protection of the Act; (c) the activities of the Trusts will promote the public interest by expanding the market for mortgage securities, thereby increasing the pool of funds available for mortgage loans and increasing the capacity of mortgage lenders to meet the housing finance needs of the nation; and (d) the exemption sought is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicant's Conditions

Supplicant agrees that if an order is granted it will be expressly conditioned on the following:

(1) Each Series of Bonds will be registered under the Securities Act, unless offered in a transaction exempt from registration pursuant to section 4(2) of the 1933 Act.

(2) The Bonds will be "mortgage related securities" within the meaning of section 3(a)(41) of the Securities Exchange Act of 1934, as amended. The mortgage collateral directly securing the Bonds will be limited to Mortgage Certificates.

(3) If new mortgage collateral is substituted, the substitute mortgage

collateral must: (i) Be of equal or better quality than the mortgage collateral replaced; (ii) have similar payment terms and cash flow as the mortgage collateral replaced; (iii) be insured or guaranteed to the same extent as the mortgage collateral replaced; and (iv) meet the conditions set forth in paragraphs (2) and (4). In addition, new mortgage collateral may not be substituted for more than 40% of the aggregate face amount of the Mortgage Certificates initially pledged as mortgage collateral. In no event may any new mortgage collateral be substituted for any substitute mortgage collateral.

(4) All Collateral securing a Series of Bonds will be held by the Bond Trustee or on behalf of the Bond Trustee by an independent custodian. The custodian may not be an affiliate (as the term "affiliate" is defined in 1933 Act Rule 405, 17 CFR 230.405) of the Applicant. The Bond Trustee will be provided with a first priority perfected security or lien interest in and to all Collateral for the Bonds.

(5) Each Series of Bonds will be rated in one of the two highest bond rating categories by at least one nationally recognized statistical rating agency that is not affiliated with Applicant or any of the Trusts. The Bonds will not be considered redeemable securities within the meaning of section 2(a)(32) of the 1940 Act.

(6) No less often than annually, an independent public accountant will audit the books and records of the Trust and will report on whether the anticipated payments of principal and interest on the mortgage collateral continue to be adequate to pay the principal and interest on the Bonds in accordance with their terms. Upon completion, copies of the auditor's report(s) will be provided to the Bond Trustee.

(7) The Trust Certificates will be offered and sold only to (i) institutional or (ii) non-institutions which are "accredited investors" as defined in Rule 501(a) of the 1933 Act. Institutional investors will have such knowledge and experience in financial and business matters as to be capable to evaluate the risks of purchasing Trust Certificates and understand the volatility of interest rate fluctuations as they affect the value of mortgages, mortgage-related securities and residual interest therein. Non-institutional accredited investors will be limited to not more than 15, will pay a purchase price of at least \$200,000 for such Trust Certificates and will have a net worth at the time of purchase that exceeds \$1,000,000 (exclusive of their

primary residence). Further, non-institutional accredited investors will have such knowledge and experience financial and business matters, specifically in the field of mortgage-related securities, as to be able to evaluate the risk of purchasing a Trust Certificate and will have direct, personal and significant experience in making investments in mortgage-related securities and because of such knowledge and experience, understands the volatility of interest rate fluctuations as they affect the value of mortgage-related securities and residual interests therein. Owners will be limited to mortgage lenders, thrift institutions, commercial and investment banks, savings and loan associations, pension funds, employee benefit plans, insurance companies, mutual funds, real estate investment trusts or other institutional or non-institutional investors as described above which customarily engage in the purchase of mortgages and mortgage-related securities.

(8) In addition, the above representations regarding the equity interests in the Trusts, the payment of Trust expenses upon the election of REMIC status and the issuance of floating rate Bonds (as more fully described in the application) will be express conditions to the requested order.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-8928 Filed 4-20-87; 45 am]

BILLING CODE 8015-01-M

[Release No. IC-15685; 812-6614]

Franklin Tax-Advantaged High Yield Securities Fund (A California Limited Partnership) et al.; Application

April 15, 1987

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 ("1940 Act")

Applicants: Franklin Tax-Advantaged High Yield Securities Fund (A California Limited Partnership) and Franklin Tax-Advantaged U.S. Government Securities Fund (A California Limited Partnership) ("Applicants" or "Partnerships").

Summary of Application: Applicants seek an order exempting Applicants' independent Managing General Partners from section 2(a)(19) to the extent that they are deemed "interested persons"

solely because they are general partners in the Partnerships.

Relevant 1940 Act Sections: Exemption requested under sections 6(c) from section 2(a)(19).

Filing Dates: The application was filed on February 4, 1987, and amended on April 10, 1987.

Hearing or Notification of Hearing: If not hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any request must be received by the SEC by 5:30 p.m., on May 8, 1987. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, Washington, DC 20549. Applicants, c/o Murray L. Simpson, Gaston Snow & Ely Bartlett, 101 California Street, Suite 3000, San Francisco, California 94111.

FOR FURTHER INFORMATION CONTACT: Staff Attorney Carson G. Frailey (202) 272-3015, or Special Counsel Karen L. Skidmore, (202) 272-3023, Office of Investment Company Regulation.

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person, or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

1. Each Applicant filed a registration statement under the Securities Act of 1933 ("1933 Act") and the 1940 Act (File Nos. 33-11963 and 33-11962), on February 13, 1987 which have not yet been declared effective. Each Applicant will be registered under the 1940 Act as a diversified, open-end management investment company. Each Applicant is also organized as a limited partnership in the State of California and has been designed as a specialized investment vehicle to preserve certain tax benefits for investors that would not be available if Applicants were organized in a corporate or trust form; shares of The Franklin Tax-Advantaged High Yield Securities Fund (A California Limited Partnership), which will invest in fixed income debt securities, will be offered exclusively to foreign investors seeking interest income or capital gains that are

not subject to federal income tax (or federal tax-withholding requirements) when received by such foreign investors; shares of the Franklin Tax-Advantaged U.S. Government Securities Fund (A California Limited Partnership), which will invest in United States Government Securities, will be offered to both foreign and domestic investors seeking income that is not subject to federal income tax (or to federal withholding) for qualifying foreign investors and which also may not be subject to state and local income tax. Each Partnership will offer a single class of shares, in the form of Partnership interests, and purchasers will be required to become limited partners of that Partnership.

2. The general partners of each Partnership will consist of one corporate general partner (the "Non-Managing General Partner"), which will not play any role in management (except temporarily, in extraordinary circumstances), and a number of individual general partners (the "Managing General Partners"), who establish the investment policies of each Partnership and supervise and review its operations. Only natural persons may serve as Managing General Partners. A majority of the Managing General Partners will be Independent Managing General Partners (defined to be individuals who are not "interested persons" of the Partnership within the meaning of section 2(a)(19) of the 1940 Act); and/or any person who may become a successor or additional Independent General Partner as provided in the Partnership Agreement; five of the eight current Managing General Partners are Independent Managing General Partners.

3. The primary obligation of the corporate Non-Managing General Partner is to maintain a minimum one percent (1%) investment in each Partnership to assure that each Partnership will be treated as a partnership under the Internal Revenue Code of 1986. The Managing Partners are expressly charged with the responsibility of managing each Partnership. The Managing General Partners will perform the same functions as directors of a corporation, act only by majority vote, and will assume all the responsibilities and obligations imposed by the 1940 Act upon directors of an incorporated investment company.

4. The Managing General Partners have been appointed for indefinite terms. The Partnership Agreement provides that if at any time the number of Managing General Partners is reduced to less than three, the remaining

Managing General Partners shall, within 120 days, call a meeting of shareholders for the purpose of electing one or more successors so as to restore the number to at least three. The Partnership Agreement provides that each new general partner must be approved by at least a majority of the outstanding shares of each Partnership and, upon such approval, will serve for an indefinite period. However, shareholders representing 10% or more of the outstanding shares of each Partnership may also call a meeting to remove any or all of the general partners.

5. Consistent with the California Revised Limited Partnership Act, each Partnership's Limited Partners have no right to control or otherwise participate in the management of the Partnership's business, but may exercise certain rights and powers under the Partnership Agreement, including voting rights and giving consents and approvals and other rights required under the 1940 Act. Applicants represent that they will obtain an opinion of California counsel for each Partnership that the existence or exercise of these voting rights does not subject the Limited Partners to liability as general partners under California law.

6. Each Partnership intends to include in its contracts a provision limiting the claims of creditors to the Applicant's assets. The Partnership Agreement of each Applicant provides for indemnification out of the Partnership's property for any Limited Partner held personally liable, and provides for the Partnership to assure the defense of any claim made against any Limited Partner, for any act or obligation of the Partnership, and satisfaction of any judgment. Each Partnership may carry insurance in such amounts as the Managing General Partners consider reasonable to cover potential liabilities of the Partnership and Managing General Partners will periodically review the question of the appropriateness of obtaining errors and omissions insurance for each Partnership.

7. Franklin Partners, Inc. ("FPI"), a California corporation, is the corporate Non-Managing General Partner of each Partnership. FPI is a wholly-owned subsidiary of Franklin Resources, Inc., ("FRI") which also owns 100% of the stock of Franklin Advisers, Inc., ("FAI"), the investment manager for each Partnership, and of Franklin Distributors, Inc., ("FDI") the distributor and principal underwriter for the shares of each Partnership. The principal shareholders of FRI include Charles B.

Johnson (approximately 20%) and Rupert H. Johnson (approximately 17%), each of whom is also a Managing General Partner of each Partnership. Messrs. Charles Johnson and Rupert Johnson are also directors and executive officers of each Partnership, FRI, FAI, FDI and FPI.

8. All of the Managing General Partners may be deemed to be "interested persons" of each Partnership and its investment manager and principal underwriter, as defined in section 2(a)(19) of the 1940 Act, by virtue of being partners of each Partnership and co-partners of FPI. However, Messrs. Charles Johnson and Rupert Johnson, will remain "interested persons" of each Partnership and its investment adviser and principal underwriter, notwithstanding the issuance of the requested exemption, because of their separate and direct affiliations as officers and directors and because of their stock ownership, as set forth in Paragraph 7. In addition to the Johnsons, Mr. Jamieson, a third Managing General Partner, will also remain an "interested person" of each Partnership notwithstanding the issuance of the requested exemption, because he is an officer of each Partnership and an affiliate of a registered broker-dealer.

9. The Independent Managing General Partners are "interested persons" of each Partnership within the meaning of section 2(a)(19) of the 1940 Act by virtue of being partners of the Partnership, which makes them "affiliated persons" of the Partnership within the meaning of section 2(a)(3) of the 1940 Act.

10. Applicants request that the Partnerships and their Independent Managing General Partner (and any person who may become a successor or additional Independent Managing General Partner as provided in the Partnership Agreement) be exempted from the provisions of section 2(a)(19) to the extent that the Independent Managing General Partners would be deemed to be "interested persons" of the Partnerships solely because such Independent Managing General Partners are general partners of the Partnerships and co-partners of FPI, the corporate Non-Managing General Partner. Each Partnership has been structured so that the Independent Managing Partners are the functional equivalents of the disinterested directors of an incorporated registered investment company. Section 2(a)(19) excludes from the definition of "interested persons" of an investment company those individuals who would be "interested persons" solely because they are directors of the investment company;

there is no equivalent exception for partners or co-partners of an investment company. Therefore, granting the requested exemption is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies of the 1940 Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Shirely E. Hollis,
Assistant Secretary.

[FR Doc. 87-8882 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-15686; 812-6640]

Hal Roach Studios, Inc.; Application

DATE: April 15, 1987.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act")
Applicant: Hal Roach Studios, Inc. (the "Applicant").

Relevant 1940 Act Sections: Order requested under section 3(b)(2) or, alternatively under section 6(c).

Summary of Application: Applicant seeks an order declaring it to be primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, or, alternatively, granting it an exemption from all provisions of the Act and the rules and regulations thereunder.

Filing Date: The application was filed on February 27, 1987 and amended on April 13, 1987.

Hearing or Notification of Hearing: If no hearing is ordered, the Application will be granted. Any interested person may request a hearing on this Application, or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m. on May 11, 1987. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicant with the request either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, Washington, DC 20549. Thomas C. Emma, Hal Roach Studios, Inc., 1600 North Fairfax Avenue, Los Angeles, California 90046.

FOR FURTHER INFORMATION CONTACT: Denis R. Molleur, Staff Attorney (202) 272-2363 or H.R. Hallock, Jr., Special Counsel (202) 272-3030 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the Application; the complete Application is available for a fee from either the Commission's Public Reference Branch in person, or the Commission's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representatives

(1) Applicant is engaged primarily in the distribution of motion pictures. It distributes motion pictures in the broadcast syndication, pay/cable television, home video, and non-theatrical markets. Applicant also manufactures prerecorded videocassettes for home use, produces the television program "Kids, Incorporated," and distributes its sound system products and associated audiocassettes.

(2) With the exceptions of the acquisition of distribution rights to motion pictures, and the exploitation of these rights in the cable television, non-theatrical and foreign markets, all of Applicant's business is conducted by its wholly-owned subsidiaries. In addition to its wholly-owned subsidiaries, Applicant owns less than a majority of the common stock of Robert Halmi, Inc. ("Halmi"), a leading producer of television and feature films, and Colorization, Inc. ("Colorization"), which has developed a computerized process for converting black and white film into color videotape. Further, Applicant owns convertible debt securities of Halmi and H R Broadcasting Corporation ("HRBC"), which owns two television stations, WTOO-Birmingham and WCGV-Milwaukee. Applicant's investments in Halmi, HRBC, and Colorization at the end of the nine months ended December 31, 1986, accounted for approximately 28.6%, 12.6%, and 4.8%, respectively, or 45.9% of Applicant's assets on an unconsolidated basis. Additionally, Applicant is negotiating for the sale of a majority interest of its wholly-owned subsidiary, The Singing Machine Company, to a group comprised of the management of The Singing Machine Company, for cash and notes.

(3) More than 40% of Applicant's assets currently are investment securities, thus, Applicant technically is an investment company, as defined in section 3(a)(3) of the 1940 Act. Applicant's percentage of investment

securities exceeded the 40% threshold on June 9, 1986, when Applicant acquired common stock and Convertible Subordinated Debentures issued by Halmi. At present, Applicant is relying upon the transient investment company exemption provided by Rule 3a-2, pursuant to resolution of Applicant's Board of Directors on April 23, 1986. For purposes of determining the percentage of Applicant's assets represented by investment securities its film library is valued at cost less amortization. If the value of the film library was trebled from the value stated on the balance sheet, and Applicant believes that the value of the library is substantially in excess of three times the book value, then Applicant's investment securities would be less than 40% of total assets.

(4) Since its inception in 1971, Applicant has been engaged primarily in the business of distribution of home videocassettes, the production of a television series, and the distribution of home videocassettes, the production of a television series, and the distribution of sound products. All of Applicant's investments are in the entertainment area, and compliment Applicant's operations. The investments in Halmi was a key transaction for Applicant, giving it access to Halmi's films through a Production and Distribution Agreement. Without the investment in Halmi by Applicant, Halmi would not have agreed to enter into the Production and Distribution Agreement. Applicant's purchase of convertible notes from HRBC comports with Applicant's expansion plans within the entertainment industry. HRBC, and its two wholly-owned television stations, represents an important new business for Applicant, and may also serve as an additional avenue for Applicant to distribute its motion pictures. If favorable opportunities are present, Applicant intends to acquire additional interests in United States television stations to expand its television broadcast business. Applicant's investment in Colorization represents an important business for Applicant. Because the vast majority of the Hal Roach Film Library consists of black and white films, the ability to convert these motion pictures into color videotape will generate new public interest and increased sales for films that have a limited market potential in the black and white version. Because of Applicant's ownership interest in Colorization, Applicant has been able to negotiate an agreement to receive priority access to Colorization's coloring process, as well as a favorable price.

(5) Applicant's annual and other reports have included detailed discussions of its endeavors in these areas, and its has never professed a policy of being engaged in the business of investing or trading in securities. At the time it acquired its investment securities, Applicant did not, nor does it presently, intend to become or hold itself out as an investment company.

(6) Applicant's officers and directors are personnel with substantial experience in the entertainment industry, primarily in the distribution of motion pictures. They devote their full time to the management of Applicant's motion picture distribution operations, and the operation of Applicant's subsidiaries. None of them have experience as investment advisors, and none are employed by Applicant to offer investment advice or monitor financial investments. In addition, of the approximately 55 employees of Applicant other than its executive officers, no one is employed to research or monitor investments for Applicant.

(7) In the nine months ended December 31, 1986, Applicant's investment securities accounted for approximately 56.2% of its net income. It should be noted that over half of Applicant's income from investment securities for this period was from an increase of equity in the income of Halmi, an adjustment required by accounting procedures. Applicant has not received any dividend distribution from its investment securities, nor has it recognized gains from sales of investment securities. With the exception of the Halmi common stock, there is no established market for any of Applicant's investment securities. Although the shares of Halmi are traded on the American Stock Exchange, the shares owned by Applicant are unregistered, and Applicant has agreed to contractual provisions that limit the ability of Applicant to sell or otherwise dispose of the shares. Furthermore, Applicant's operating income for the nine months ended December 31, 1986, was three times its income from investment securities.

Applicant's Conditions

If the requested order is granted, the Applicant agrees to the following conditions:

1. Applicant will not engage in the short term trading of investment securities for speculative purposes so as to bring Applicant's activities within those intended to be regulated by the Act.

2. Applicant intends to continue to be primarily engaged in non-investment company businesses.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,
Assistant Secretary.

[FR Doc. 87-8929 Filed 4-20-87; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF THE TREASURY

Form 990 Advisory Committee; Termination

This notice cancels the Form 990 Advisory Committee established by the Commissioner of Internal Revenue.

The Form 990 Advisory Committee was established to encourage active participation by states in the design of Tax Form 990. It has been determined by the Commissioner of Internal Revenue that the important and worthwhile purposes and functions of the Committee can now better be continued on an ad hoc basis and that its charter be terminated.

Jill E. Kent,

Acting Assistant Secretary of the Treasury
(Management).

[FR Doc. 87-8925 Filed 4-20-87; 8:45 am]

BILLING CODE 4810-25-M

Public Information Collection Requirements Submitted to OMB for Review

Dated: April 15, 1987.

The Department of Treasury has made revisions and resubmitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau

Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Room 2224, Main Treasury Building, 15th and Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545-0678

Form Number: IRS Form 637A

Type of Review: Resubmission

Title: Registration for Tax-Free Sales and Purchases of Fuel Used in Aircraft

Description: Certain sellers and purchasers are exempt from the Internal Revenue Code section 4041(c) excise tax on aviation fuel if they use this form to register for tax-free transactions. The data collected is used to determine if the applicants qualify for exemption from excise taxes.

Respondents: Individuals, Farms, Businesses

Estimated Burden: 2,829 hours

Clearance Officer: Garrick Shear (202)

566-6150, Room 5571, 1111 Constitution Avenue, NW, Washington, DC 20224

OMB Reviewer: Milo Sunderhauf, (202)

395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503

Dale A. Morgan,

Departmental Reports Management Office.

[FR Doc. 87-8877 Filed 4-20-87; 8:45 am]

BILLING CODE 4810-25-M

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition; Determination

Notice is hereby given of the following determination: Pursuant to the authority

vested in me by the act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85-5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, "Son of Heaven: Imperial Arts of China" (see list)¹ imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. These objects are imported pursuant to loan agreements with the foreign lenders. I also determine that the temporary exhibition or display of the listed exhibit objects at the Flag Pavillion/Art Pavillion, Seattle center, Seattle, Washington, Beginning on or about February 1, 1988, to on or about June 1, 1988; at the Convention Center or Pan Am Plaza, Indianapolis, Indiana, beginning on or about June 19, 1988, to on or about September 7, 1988, and at the Louisiana Science Center, New Orleans, Louisiana, beginning on or about October 2, 1988, to on or about January 31, 1989, is in the national interest.

Public notice of this determination is ordered to be published in the **Federal Register**.

Dated: April 3, 1987.

C. Normand Poirier

Acting General Counsel and Congressional Liaison.

[FR Doc. 87-8845 Filed 4-20-87; 8:45 am]

BILLING CODE 8230-01-M

¹ A copy of this list may be obtained by contacting Mr. John Lindburg of the Office of the General Counsel of USIA. The telephone number is 202-485-7976, and the address is Room 700, U.S. Information Agency, 301 4th Street, SW., Washington, DC 20547.

Sunshine Act Meetings

Federal Register

Vol. 52, No. 76

Tuesday, April 21, 1987

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL COMMUNICATIONS COMMISSION

April 10, 1987.

The Federal Commission has rescheduled the following items for consideration at the April 16, 1987, Open Meeting.

Agenda, Item No., and Subject

Common Carrier—1—Title: Report and Order regarding implementation of subscriber line charges, Docket Nos. 78-72 and 80-286. **Summary:** The Commission will consider a Recommended Decision and Order of the Federal/State Joint Board in CC Docket Nos. 78-72 and 80-286 regarding subscriber line charges, federal lifeline and high cost assistance and modifications to the interstate common line pooling mechanisms.

Common Carrier—2—Title: MTS and WATS Market Structure, Amendment of Part 67 (New Part 36) of the Commission's Rules and Establishment of a Joint Board, CC Docket Nos. 78-72, 80-286 and 86-297. **Summary:** The Commission will consider recommendations of two Joint Boards regarding the separations procedures applicable to Central Office Equipment; the procedures applicable to the Revenue Accounting Expenses in Account 662; and the procedures necessary to conform the Separations Manual (Part 67) to the new accounting rules in the Uniform System of Accounts.

Common Carrier—3—Title: In the Matter of Amendment of Part 69 of the Commission's Rules and Regulations, Access Charges, to conform it with Part 36, Jurisdictional Separations Procedures. **Summary:** The FCC will consider whether to adopt a Notice of Proposed Rulemaking to conform its Part 69 Access Charge Rules to the new Part 36 Separations Procedures.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-8972 Filed 4-17-87; 10:44 am]

BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Monday, April 27, 1987.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Street, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 17, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-9035 Filed 4-17-87; 3:34 pm]

BILLING CODE 6210-01-M

INTERNATIONAL TRADE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 52 FR 11416—dated April 8, 1987.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 2:30 p.m., Monday, April 13, 1987.

CHANGE IN TIME OF THE MEETING: 3:00 P.M., Monday, April 13, 1987.

In conformity with 19 CFR 201.37(b), Commissioners Liebler, Brunsdale, Eckes, and Rohr determined that Commission business required the change in time of the meeting on April 13, 1987, and affirmed that no earlier announcement of the change to the time was possible, and directed the issuance of this notice at the earliest practicable time. Commissioner Lodwick disapproved.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth R. Mason, Secretary (202) 523-0161.

Kenneth R. Mason,

Secretary.

April 13, 1987.

[FR Doc. 87-9016 Filed 4-17-87; 2:53 pm]

BILLING CODE 7020-02-M

POSTAL SERVICE BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 52 FR 12111, April 14, 1987.

PREVIOUSLY ANNOUNCED DATE OF MEETING: May 4, 1987.

CHANGE: Addition of the following agenda item:

Capital Investment: Beverly Hills (CA) Post Office

Authority: By telephone vote on April 15, 1987, the Board determined that pursuant to

section 552b(c)(9)(B) of Title 5, United States Code, and § 7.3(i) of Title 39, Code of Federal Regulations, discussion of this matter is exempt from the open meeting requirements of the Government in the Sunshine Act because it is likely to disclose information, the premature disclosure of which would likely significantly frustrate implementation of a proposed action of the Board.

In accordance with section 552b(f)(1) of Title 5, United States Code and § 7.6(a) of Title 39, Code of Federal Regulations, the General Counsel has certified that in his opinion the additional agenda item of the meeting may properly be closed to the public for the reason cited above.

CONTACT PERSON FOR MORE INFORMATION:

David F. Harris, (202) 268-4800.

David F. Harris,

Secretary.

[FR Doc. 87-8975 Filed 4-17-87; 11:13 am]

BILLING CODE 7710-12-M

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of April 20, 1987:

An open meeting will be held on Tuesday, April 21, 1987, at 2:00 p.m., followed by a closed meeting.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Peters, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the open meeting scheduled for Tuesday, April 21, 1987, at 2:00 p.m., will be:

1. Consideration of whether to reverse the no-action position taken by the Division of Corporation Finance with respect to the exclusion of a shareholder proposal submitted by the California Public Employees' Retirement System from the proxy material for the 1987 annual meeting of

Union Camp Corporation. For further information, please contact Cecilia D. Blye at (202) 272-2573.

2. Consideration of whether to reverse the noaction position taken by the Division of Corporation Finance with respect to the exclusion of a shareholder proposal submitted by the California Public Employees' Retirement System from the proxy material for the 1987 annual meeting of Aluminum Company of America.

The subject matter of the closed meeting scheduled for Tuesday, April 21,

1987, following the 2:00 p.m. open meeting will be:

Settlement of injunctive actions.
Institution of administrative proceedings of an enforcement nature.
Settlement of administrative proceeding of an enforcement nature.
Institution of injunctive actions.
Litigation matter.
Formal orders of investigation.
Opinion.

At times changes in Commission priorities require alterations in the

scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Judith Axe at, (202) 272-2092.

Jonathan G. Katz,
Secretary.

April 17, 1987.

[FR Doc. 87-9051 Filed 4-17-87; 4:02 pm]

BILLING CODE 8010-01-M

Corrections

Federal Register

Vol. 52, No. 76

Tuesday, April 21, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-51668; FRL-3176-6]

Certain Chemicals Premanufacture Notices

Correction

In notice document 87-6714 beginning on page 9932 in the issue of Friday, March 27, 1987, make the following correction:

On page 9933, in the first column, under P 87-816, in the seventh line, "owy" should read "oxy".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 1F2439, 4F3054/R878; FRL 3180-1]

Pesticide Tolerances for Clopyralid

Correction

In rule document 87-7260 beginning on page 10565 in the issue of Thursday,

April 2, 1987, make the following corrections:

1. On page 10566, in the table, in entry "Mbyy", the second and third columns should read "0.05" and "0.1" respectively.

2. Also on page 10566, in the table, in entry "Kidney", the text in the second and third columns should be removed.

BILLING CODE 1505-01-D

GENERAL SERVICES ADMINISTRATION

41 CFR Part 201-32

[FIRMR Amendment 8]

GSA Board of Contract Appeals ADP Protests

Correction

In rule document 87-7110 beginning on page 10379 in the issue of Wednesday, April 1, 1987, make the following corrections:

1. On page 10379, in the first column, the FIRMR Amendment No. in the heading should read as set forth above.

§ 201-32.402-5 [Corrected]

2. On page 10380, in the first column, in § 201-32.402-5(a), in the sixth line, "Rules 29-48" should read "Rule 29-48".

§ 201-32.403-3 [Corrected]

3. On the same page, in the third column, in § 201-32.403-3(a)(1), in the second line, "(if already made)" should read "(if not already made)".

BILLING CODE 1505-01-D

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-443-OL, 50-444-OL, (ASLBP No. 82-471-02-OL) (Offsite Emergency Planning)]

Public Service Co. of New Hampshire et al. (Seabrook Station, Units 1 and 2); Hearing

Correction

In notice document 87-7785 appearing on page 11388 in the issue of Wednesday, April 8, 1987, make the following correction:

In the second column, in the first line, the dates should read "July 20-24, 1987".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 86-AWA-40]

Establishment of Airport Radar Service Areas

Correction

In rule document 87-7772 beginning on page 11178 in the issue of Tuesday, April 7, 1987, make the following corrections:

1. On page 11178, in the first column, the Airspace Docket No. in the heading should read as set forth above.

2. On the same page, in the third column, in the first complete paragraph, in the 17th line, "TRSA" should read "ARSA"; and in the 19th line "ARSA" should read "TRSA".

BILLING CODE 1505-01-D

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federal register

Tuesday
April 21, 1987

Part II

Department of Health and Human Services

Health Care Financing Administration

**Medicare Program; List of Covered
Surgical Procedures for Ambulatory
Surgical Centers; Final Notice**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration
[BERC-274-FN]

Medicare Program; List of Covered Surgical Procedures for Ambulatory Surgical Centers

AGENCY: Health Care Financing Administration (HCFA), HHS.
ACTION: Final notice.

SUMMARY: This final notice announces additions and revisions to the current list of surgical procedures for which facility services are covered when the procedures are performed in an ambulatory surgical center. Our current list of covered ASC procedures was published in the *Federal Register* on August 5, 1982 (47 FR 34099). The changes contained in this final notice result from our consideration of the public comments received in response to a proposed notice published on February 16, 1984 (49 FR 6023), which requested additions or revisions to the current list of ASC procedures and charge schedules for the new procedures, and subsequent consultation which medical organizations.

EFFECTIVE DATE: For ambulatory surgical center procedures that are being removed from the current list, the effective date will be July 20, 1987. The effective date for procedures being added to the list is May 21, 1987.

FOR FURTHER INFORMATION CONTACT:
Rita McGrath, (301) 594-6719, for issues related to these additions to and revisions of the ASC list.
Vivian Braxton, (301) 594-8452, for issues related to ASC reimbursement group levels.

SUPPLEMENTARY INFORMATION:

I. Background

Section 934 of Pub. L. 96-499, the Omnibus Reconciliation Act of 1980, amended Title XVIII of the Social Security Act (the Act) to authorize Medicare Part B coverage for facility services furnished in connection with certain surgical procedures performed in an ambulatory surgical center (ASC), (42 CFR 416.60 and 416.61). In addition, for those procedures performed in the ambulatory surgical facility or on an outpatient basis in a hospital, 100 percent of the physician's reasonable charge will be paid if the physician accepts assignment. (Under the usual procedures, Medicare reimburses 80 percent of the physician's reasonable charge and the beneficiary is

responsible for the remainder (42 CFR 405.240).)

With respect to the surgical procedures covered under this provision, section 1833(i)(1) of the Act requires the Secretary to specify, in consultation with appropriate medical organizations, surgical procedures that, although appropriately performed in an inpatient hospital setting, may also be performed safely in certain ambulatory settings. The report accompanying the legislation (Report of the Committee on the Budget to Accompany H.R. 7765, H.R. No. 96-1167, 96th Cong., 2d Sess. 390 (1980)) explained that Congress intended that procedures currently performed on an ambulatory basis, especially in physicians' offices, that do not generally require the more elaborate facilities of an ASC, should not be included in the list of covered procedures.

In line with this Congressional intent, our current regulations specify the following four requirements regarding the range of covered services:

1. Procedures on the list are to be those commonly performed on an inpatient basis but which also may, consistent with accepted medical practice, be safely performed in an ambulatory surgical facility (42 CFR 416.65(a)(1)).
2. The list is to exclude procedures that are commonly performed, or that may be safely performed, in physicians' offices (42 CFR 416.65(a)(2)).
3. Procedures should be limited to those requiring a dedicated operating room and not requiring an overnight stay (42 CFR 416.65(a)(3)).
4. The list should not contain procedures excluded from Medicare coverage (42 CFR 416.65(a)(4)).

We recognize that for individuals with certain medical conditions, a procedure on the list may be safely performed only on an inpatient basis. The choice of operating site remains a matter for the professional judgement of the patient's physician.

The current list of covered ASC procedures was published as a final notice on August 5, 1982 (47 FR 34099). ASC covered procedures are classified according to a four group payment classification system, as follows:

- Group 1—\$231
- Group 2—\$275
- Group 3—\$296
- Group 4—\$336

The ASC facility payment for all procedures in each group is at a single rate adjusted for geographic variation. This prospectively determined facility group rate does not include physicians' fees and other medical items and services (for example, prosthetic

devices) for which separate payment is authorized under other provisions of the Medicare program. Rather, the rate is a standard overhead amount which covers the cost of services such as nursing, supplies, equipment and use of the facility. (A detailed explanation of the reimbursement methodology can be found in the March 23, 1982, issue of the *Federal Register* (47 FR 12579).)

Further, section 9343 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509) provides that by July 1, 1987, and annually thereafter, the Secretary must review and update ASC payment rates; in addition, the list of procedures must be reviewed and updated by April 21, 1987 and every 2 years thereafter.

II. Provisions of the Proposed Notice

Advances in medical science make additions or revisions to the list of covered ASC procedures necessary to keep pace with changing practices. On February 16, 1984, we issued a proposed notice (49 FR 6023) seeking suggestions for possible additions or revisions to the current list of ASC procedures. We asked that respondents, in proposing additions, specifically consider the four requirements contained in 42 CFR 416.65(a). We also requested that suggestions for additional procedures or changes in existing procedures refer to each surgical procedure according to the HCFA Common Procedure Coding System (HCPCS) or the American Medical Association (AMA) *Physicians' Current Procedural Terminology, Fourth Edition (CPT-4)* terminology and coding. (The AMA's CPT-4 terminology and coding is included, with permission, in the HCPCS system. For the surgical procedures under consideration, the codes would be the same.)

We also included a list of suggested additions to the current list of covered ASC procedures in the proposed notice. Those suggestions were taken from comments received after publication of our initial list of covered procedures, and did not represent an initial finding by HCFA that they should be covered. That list of procedures was set out by body system and the general term for procedures, and included reference to applicable HCPCS and CPT-4 codes, but did not list each procedure code separately. The list suggested 54 types of procedures for coverage as ASC procedures, 17 of which were ophthalmologic procedures. If each procedure code had been listed, it would have appeared that we were proposing a much larger expansion of ASC coverage. For example, the 17 ophthalmologic procedures in the list of suggestions would have included 44 separate

procedure codes. (See section V.C., below, for further discussion of the distinction between procedure codes and general types of procedures.)

We also requested charge schedules from ASCs, especially for proposed new procedures, so that we could ensure that any new procedures would be accurately assigned to payment groups.

III. Discussion of Public Comments on the Proposed Notice

We received 60 pieces of correspondence concerning suggestions for possible additions or revisions to the current list of ASC procedures covered under Medicare. We received comments from the American Academy of Orthopaedic Surgeons, the American Academy of Ophthalmology, and the Freestanding Ambulatory Surgical Association. The remainder of the comments were from individual practitioners. Most of the comments we received were in the form of lists. Some commenters suggested adding extensive portions or the entire surgical section of CPT-4 to the list of approved ASC procedures. Virtually every CPT-4 code in the surgery section of the manual was commented upon at least once. While the proposed notice specifically requested that suggested surgical procedures be accompanied by HCPCS or CPT-4 terminology and coding, some commenters listed their own descriptions of procedures without any code. In most instances, such descriptions could be correlated with an existing CPT-4 code.

1. *Comment:* Three commenters stated that the current ASC reimbursement levels are inadequate; they believe that HCFA should expedite the process of increasing facility rates and allege that local hospitals are marking up charges, while ASC reimbursement rates remain meager. One commenter specifically recommended adding a fifth reimbursement group, and included extensive recommendations as to how procedures should be grouped.

Response: We are in the process of updating the current ASC facility payment rates as required under section 9343 of the Omnibus Budget Reconciliation Act of 1986, Pub. L. 99-509. We expect to publish shortly a separate notice in the *Federal Register* proposing revised rates. With respect to the comment concerning adding the fifth payment group, sufficient data were not available in a timely manner to evaluate the appropriateness of revising our current classification system. In our February 16, 1984 notice (49 FR 6023), we specifically asked for charge schedules for new procedures from ASCs. We also stated that based on the data in our files

and the charging information received as a result of the notice, we would classify each procedure that we added to the list of covered surgical procedures to one of the four payment groups. We did not receive any charge schedules, even from the commenter who suggested a revised five group system. However, we recently completed a survey of over 500 Medicare participating ASCs from which we collected facility cost and charge data. If analysis of these new data warrant changes to our four group classification system, such revisions will be published in the *Federal Register* in the 1988 updating of the ASC facility payment rates.

2. *Comment:* One commenter stated that procedures and settings should not be mandated by regulation but rather that the physician and patient should make these decisions. In a related vein, three other commenters suggested that there be no restrictive list of procedures or that all procedures in the CPT-4 be covered.

Response: The statute does not mandate the setting in which procedures should be performed; the physician and patient are free to make these decisions. However, the amount of payment does depend on the procedure and setting. Section 1833(i)(1) of the Act specifically requires that the Secretary, after consultation with appropriate medical organizations, develop a list of surgical procedures that can be performed appropriately and safely on an ambulatory basis instead of in a hospital on an inpatient basis.

3. *Comment:* One commenter requested that the portion of section 934 of Pub. L. 96-499 pertaining to surgical procedures performed in a physician's office be implemented.

Response: In addition to payment for surgical procedures performed on an ambulatory basis in an ASC or hospital outpatient department, section 934 of Pub. L. 96-499 provides for payment for certain costs associated with specific surgical procedures (as determined by the Secretary) performed in a physician's office under certain conditions. While we have published ASC regulations, no regulations have been issued dealing with that portion of the law providing for physician office surgery. Although we support the objective of moving surgery from the inpatient to outpatient setting (when safe and appropriate), we have not been able to overcome the administrative problems (including the role of Peer Review Organizations) involved in covering and determining appropriate payment for ambulatory surgery in a physician's office.

4. *Comment:* Many commenters recommended covering CPT-4 codes that are miscellaneous, catch-all unlisted procedures (that is, with codes ending in "99" digits).

Response: We have not included any unlisted procedures, since the reimbursement of unlisted procedures would thwart the very purpose of an approved ASC list.

5. *Comment:* Three commenters proposed added or deleted wording from certain CPT-4 procedure descriptions to fit verbatim a procedure they felt should be covered.

Response: We have an agreement with the AMA to use CPT-4 as part of the HCPCS coding system (Agreement on the use of CPT-4; Schweiker and Sammons; February 1, 1983). Under the terms of that agreement, we may not tamper with the AMA copyright.

6. *Comment:* One commenter expressed the opinion that sequestrectomy is no longer considered an effective procedure and that it should be deleted from the list as outdated.

Response: We are taking this comment under consideration, although we are not deleting the relevant procedure codes from the list now. We are consulting the Public Health Service (PHS) through our normal process. Once PHS makes a recommendation as to the safety and efficacy of sequestrectomy, we will then make a decision regarding coverage of these procedures. If it is determined that we should no longer cover these procedures, we will issue an appropriate manual change in our usual manner. We will also publish in the *Federal Register* a revised list of covered surgical procedures and revisions as appropriate.

7. *Comment:* The majority of commenters proposed the addition of a number of ophthalmologic procedures. Typical comments recommended including:

- (1) Any eye surgery requiring admission to a hospital;
- (2) All eye procedures listed in the proposed notice;
- (3) All eye procedures listed in CPT-4; or
- (4) All eye procedures that can be done in 90 minutes under local anesthesia.

Response: We are required to publish a list of covered procedures, and we have decided to do so using CPT-4 procedure codes. We do not believe it would be medically appropriate to cover all CPT-4 ophthalmologic procedure codes if furnished in an ASC. Nonetheless, almost all of the 44 ophthalmologic procedures in the February 16, 1984 notice, are included in

the new list. (Four of the five procedure codes included under Iridectomy (CPT-4 codes 66600-66635) were already covered and were erroneously listed as suggested in that notice.) In response to comments, the majority of all CPT-4 eye procedures will now be covered when performed in an ASC.

We reviewed each procedure code that was omitted, and each code was omitted for specific reasons, such as:

- It is an unlisted code (that is, a code ending in "99", specifying the anatomical site but not the procedure);
- HCFA accepted the specific recommendation of the American Academy of Ophthalmology that it not be covered;
- It is a procedure commonly done in a doctor's office; or
- It is a procedure best done in a hospital.

IV. Provisions of the Final Notice

A. Procedures Added to the New ASC List

As noted above, nearly all commenters recommended substantial expansion of the list of covered ASC procedures, including expansion substantially beyond the suggested procedures included in the proposed notice. We compiled the suggestions in a single list by CPT-4 codes. The great majority of all the surgical codes included in CPT-4 were recommended at least once. Our medical staff reviewed the recommended additions, consulting with other specialist physicians and medical organizations as appropriate, and made the determination, in each case, as to whether a particular code or series of codes should be covered if performed in an ASC. When we arrayed the proposed covered ASC services by site of service, we found that our program data showed that many of them were not commonly furnished on an inpatient basis or were furnished in physicians' offices a majority of the time. Based on these data, it would be contrary to our regulations (42 CFR 416.65(a)) and program objectives to continue to cover them. We decided that if data indicate that a procedure is performed on an inpatient basis 20 percent of the time or less or in the physicians' office 50 percent of the time or more, it should not be covered in an ASC. Based on our analysis of available claims payment data, we believe these levels best reflect the legislative objectives of (1) moving procedures from the more expensive hospital setting to the less expensive ASC setting and (2) preventing the migration of procedures from the less expensive physicians' office setting to

the ASC. (We also applied these tests to the current list of over 400 individual CPT-4 codes, and we intend to delete codes that did not meet them in a proposed notice that will be published in the *Federal Register* at a later date.)

In applying the principles set forth in § 416.65, we have also recognized that many procedures that generally are performed on an inpatient basis may be performed in an ASC in some cases, particularly if a patient is generally healthy and capable. As a result, after consideration of recommendations from commenters and medical organizations that were consulted, we determined that many proposed procedure codes could reasonably be performed in an ASC, in at least a significant number of cases. It was recognized that a number of these procedures should generally be performed on an inpatient basis. Nonetheless, when such a procedure may safely be performed in an ASC, it is reasonable for Medicare to pay for it in that setting, rather than require it to be performed, unnecessarily, in a more expensive setting.

This final notice lists only additions to and deletions from the current list of ambulatory surgical center procedures that result from our consideration of the public comments received in response to the proposed notice. As noted above, we intend to publish a proposed notice in the *Federal Register* at a later date to delete a significant number of procedure codes from the current list. We may also propose to add some additional procedures to the list, beyond those recommended in response to our earlier proposed notice. When public comments on that proposed notice have been received and reviewed, we will publish our final determination regarding those proposed changes, and will then publish a complete list of covered codes in the *Federal Register*.

The expansion of the list of covered services, as measured by number of procedure codes, overstates the actual magnitude of changes. The codes are used to differentiate, in many cases, slight differences between procedures. For example, under the Eye and Ocular Adnexa System, Removal Cataract is broken down into 8 separate codes. Thus, even though this list includes more than four times as many procedure codes as those covered in the original list, we estimate that the number of types of procedures covered under this final notice is only about twice as many as under the previous rule. This, of course, depends on how one defines "type of procedure". We emphasize that the procedures that are covered in ASCs are those that we believe can be performed safely in ASCs under the

circumstances described in our regulations at 42 CFR 416.65.

When we initially promulgated the ASC payment rates in 1982, we used cost and charge data from approximately 40 ASCs to develop an indexing method for ranking each procedure based on a facility's charge for an individual procedure as compared to its average charge for all procedures offered. Thus, we could determine how a facility values a given procedure it offers. Using this indexing method, we established a four group classification system for payment purposes. Since such data were not available to permit the indexing of new procedures into the established payment groups, we relied on the medical expertise of our staff physicians to properly classify the newly added procedures into the appropriate payment groups. As previously stated, we recently completed a survey of over 500 Medicare participating ASCs from which we collected information relating to the facility overhead expenses and charge information on procedures performed in ASCs. If analysis of these new data warrant re-assignment of covered procedures to other payment groupings or revision of the four group classification system, such changes will be published in the *Federal Register* in the 1988 updating of the ASC payment rates.

We have used the most recent available version of the CPT-4 (Fourth Edition, 987 printing) for the codes included in this listing. The AMA revises the procedure codes included in CPT-4 annually. Section 9343 of Pub. L. 99-509 requires us to update the ASC list every two years. When we do this, we will use the most recent version of CPT-4 available at that time.

B. Suggested Procedures Not Added to the Expanded ASC List

Of the procedure codes referenced in the proposed notice many are included in the expanded list. The following procedures, identified by CPT-4 codes, have been excluded for these reasons:

Available information indicates these are not commonly performed on an inpatient basis or are doctor's office procedures:

- 10061 Incision—Incision and drainage of abscess (eg. carbuncle, suppurative hidradenitis, and other cutaneous or subcutaneous abscesses); complicated
- 10081 Incision—Incision and drainage of pilonidal cyst; complicated
- 10121 Incision—Incision and removal of foreign body, subcutaneous tissues; complicated
- 13120 Miscellaneous—Repair, complex, scalp, arms, and/or legs; 1.1 cm to 2.5 cm

- 13131 Miscellaneous—Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm
- 13151 Miscellaneous—Repair, complex, eyelids, nose, ears and/or lips; 1.1 to 2.5 cm
- 16010 Burns, Local Treatment—Dressings and/or debridement, initial or subsequent; under anesthesia, small
- 14000 Miscellaneous—Adjacent tissues transfer or rearrangement, trunk; defect 10 sq cm or less
- 14040 Miscellaneous—Adjacent tissues transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
- 15400 Miscellaneous—Application of xenograft (heterograft), skin
- 20910 General—Cartilage graft; costochondral
- 20924 General—Tendon graft, from a distance (e.g., palmaris, toe extensor, plantaris)
- 21400 General—Excision of benign cyst or tumor of mandible; simple
- 21030 General—Excision of benign tumor or cyst of facila bone other than mandible
- 21493 General—Treatment of closed or open hyoid fracture; without manipulation
- 24305 Humerus (Upper Arm) and Elbow—Tendon lengthening, single, each
- 25031 Humerus (Upper Arm) and Elbow—Incision and drainage; infected bursa
- 25624 Forearm and Wrist—Treatment of closed carpal scaphoid (navicular) fracture; with manipulation
- 28320 Hands and Fingers—Removal of implant from finger or hand
- 28641 Hands and Fingers—Treatment of carpometacarpal dislocation, thumb, with manipulation
- 28760 Hands and Fingers—Treatment of open distal phalangeal fracture, finger or thumb, with uncomplicated soft tissue closure, each
- 27323 Femur (Thigh Region) and Knee Joint—Biopsy, soft tissues; superficial
- 27604 Leg (Tibia and Fibula) and Ankle Joint—Incision and drainage; infected bursa
- 28022 Foot—Arthrotomy with exploration, drainage or removal of loose or foreign body;
- 28043 Foot—Excision, benign tumor; subcutaneous
- 28100 Foot—Excision or curettage of bone cyst or benign tumor, talus or calcaneus
- 28104 Foot—Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal bones, except talus or calcaneus
- 28106 Foot—Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal bones, except talus or calcaneus; with iliac or other autogenous bone graft (including obtaining graft)
- 28116 Foot—Osteotomy, excision of tarsal coalition
- 28119 Foot—Osteotomy, calcaneus; for spur, with or without plantar fascial release
- 28160 Foot—Hemiphalangectomy or interphalangeal joint excision, single, each
- 28192 Foot—Remove foreign body, deep
- 28236 Foot—Transfer of tendon, anterior tibial into tarsal bone
- 28238 Foot—Advancement of posterior tibial tendon with excision of accessory navicular bone (Kidner type procedure)
- 28288 Foot—Osteotomy, partial, exostectomy or condylectomy, single, metatarsal head, second through fifth, each metatarsal head, (separate procedure)
- 28460 Foot—Treatment of open tarsal bone fracture (except talus and calcaneus), with uncomplicated soft tissue closure, each
- 28480 Foot—Treatment of open metatarsal fracture, with uncomplicated soft tissue closure, each
- 30100 Nose—Excision—Biopsy, intranasal
- 30220 Nose—Insertion, nasal septal prosthesis (button)
- 31528 Larynx—Laryngoscopy, direct; with dilation, initial
- 40819 Larynx—Excision of frenum, labial or buccal (frenulectomy, frenulectomy, frenectomy)
- 41006 Tongue, Floor of Mouth—Intraoral incision and drainage of abscess, cyst, or hematoma of tongue or floor of mouth; sublingual, deep, suprathyroid
- 41008 Tongue, Floor of Mouth—Intraoral incision and drainage of abscess, cyst, or hematoma of tongue or floor of mouth; submandibular space
- 41017 Tongue, Floor of Mouth—Extraoral incision and drainage of abscess, cyst, or hematoma of floor of mouth; submandibular
- 41100 Tongue, Floor of Mouth—Biopsy of tongue; anterior two-thirds
- 41825 Dentoalveolar Structures—Excision of lesion or tumor (except listed above); without repair
- 42300 Salivary Gland and Ducts—Drainage of abscess; parotid, simple
- 42310 Salivary Gland and Ducts—Drainage of abscess; submaxillary or sublingual, intraoral
- 42510 Salivary Gland and Ducts—Parotid duct diversion, bilateral (Wilke type procedure); with ligation of both submandibular (Wharton's) ducts
- 42550 Salivary Gland and Ducts—Injection procedure for sialography
- 44385 Intestines—Fiberoptic evaluation of small intestinal (Kock) or pelvic pouch
- 45100 Rectum—Biopsy or anorectal wall, anal approach (eg, congenital megacolon)
- 45108 Rectum—Anorectal myomectomy
- 45150 Rectum—Division of stricture of rectum
- 45310 Rectum—Endoscopy—Proctosigmoidoscopy; for removal of polyp or papilloma
- 46050 Anus—Incision and drainage, perianal abscess, superficial
- 46210 Anus—Cryptectomy; single
- 50555 Kidney—Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy
- 50557 Kidney—Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration, with or without biopsy
- 51860 Bladder—Cystorrhaphy, suture or bladder wound, injury or rupture; simple
- 53260 Urethra—Excision or fulguration; urethral polyp(s), distal urethra
- 53270 Urethra—Excision or fulguration; Skene's glands
- 53442 Urethra—Removal of perineal prosthesis introduced for continence
- 56400 Vulva and Introitus—Incision—Incision and drainage, abscess of vulva, extensive
- 56500 Vulva and Introitus—Destruction—Destruction of lesion(s), vulva (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; chemical
- 56510 Vulva and Introitus—Destruction of condylomata, vulva, multiple; surgical excision
- 57700 Cervix Uteri—Cerclage of uterine cervix (tracheloplasty)
- 60000 Thyroid Gland—Incision and drainage of thyroglossal cyst, infected
- 64412 Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System—Injection, anesthetic agent; spinal accessory nerve
- 64413 Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System—Injection, anesthetic agent; cervical plexus
- 64435 Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System—Injection, anesthetic agent; paracervical (uterine) nerve
- 64508 Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System—Injection, anesthetic agent; carotid sinus (separate procedure)
- 64620 Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System—Destruction by neurolytic agent; intercostal nerve
- 64783 Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System—Excision of neuroma; hand or foot, each additional nerve, except same digit (list separately by this number)
- 65240 Eyeball—Removal of foreign body, intraocular; from lens (without extraction lens), magnetic extraction
- 65270 Eyeball—Repair of laceration; conjunctiva, with or without nonperforating laceration sclera, direct closure
- 65600 Anterior Segment—Cornea—Tattoo cornea, mechanical or chemical
- 66740 Anterior Segment—Iris, Ciliary Body—Cyclodialysis, initial
- 66761 Anterior Segment—Iris, Ciliary Body—Coreoplasty ("iridotomy") by photocoagulation; for glaucoma
- 66770 Anterior Segment—Iris, Ciliary Body—Destruction of cyst or lesion iris or ciliary body (nonexcisional procedure)

- 66820 Anterior Segment—Lens—Discission of secondary membranous cataract ("after cataract") and/or anterior hyaloid incisional technique (Ziegler or wheeler Knife)
- 67105 Posterior Segment—Retinal Detachment—Repair of retinal detachment photocoagulation (laser or xenon arc, one or more sessions) with drainage of subretinal fluid
- 67112 Posterior Segment—Retinal Detachment—Repair of retinal detachment (one or more stages, same hospitalization); previously operated upon, any technique
- 67141 Posterior Segment—Retinal Detachment—Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage, one or more sessions; cryotherapy, diathermy
- 67145 Posterior Segment—Retinal Detachment—Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage, one or more sessions; photocoagulation (laser or xenon arc)
- 68335 Ocular Adnexa—Conjunctiva—Repair of symblepharon; with free graft conjunctiva or buccal mucous membrane (includes obtaining graft)
- 68340 Ocular Adnexa—Conjunctiva—Repair of symblepharon; division of symblepharon with or without insertion of conformer or contact lens
- 68770 Ocular Adnexa—Lacrimal System—Closure of lacrimal fistula (separate procedure)
- 69222 Middle Ear—Debridement, mastoidectomy cavity, complex (e.g., with anesthesia or more than routine cleaning); unilateral
- 69223 Middle Ear—Debridement, mastoidectomy cavity, complex (e.g., with anesthesia or more than routine cleaning); bilateral
- 69540 Middle Ear—Excision—Excision aural polyp
- 92018 Eye/Ocular Adnexa—Ophthalmological examination and evaluation, under general anesthesia, with or without manipulation of globe for passive range of motion or other manipulation to facilitate diagnostic examination; complete
- 92019 Eye/Ocular Adnexa—Ophthalmological examination and evaluation, under anesthesia, with or without manipulation of globe for passive range of motion or other manipulation to facilitate diagnostic examination; limited

Available information indicates these are hospital inpatient procedures:

- 27332 Femur (thigh region) and Knee Joint—Excision—Arthrotomy, knee, for excision of semilunar cartilage (meniscectomy); medical OR lateral
- 27333 Excision—Arthrotomy, Knee, for excision of semilunar cartilage (meniscectomy); medial AND lateral
- 57200 Vagina—Repair—Colporrhaphy, suture of injury of vagina (nonobstetrical)

HCFA agrees with the American Academy of Orthopaedic Surgeons that the following are hospital inpatient procedures:

- 25350 Forearm and Wrist—Repair, Revision or Reconstruction—Osteotomy, radius, distal third
- 25355 Forearm and Wrist—Repair, Revision or Reconstruction—Osteotomy, middle or proximal third
- 25365 Forearm and Wrist—Repair, Revision or Reconstruction—Osteotomy, radius and ulna
- 27060 Pelvis and Hip Joint—Excision—Excision; ischial bursa
- 27062 Pelvis and Hip Joint—Excision—Excision; trochanteric bursa or calcification
- 27340 Femur (thigh region) and Knee Joint—Excision—Excision, prepatellar bursa
- 27600 Leg (tibia and fibula) and Ankle Joint—Incision—Fasciotomy, leg, anterior compartment, for closed space decompression
- 27602 Leg (tibia and fibula) and Ankle Joint—Incision—Fasciotomy, leg, anterior compartment, for closed space decompression; including posterior compartment decompression
- 28300 Foot—Repair, Revision or Reconstruction—Osteotomy; calcaneus (Dwyer or Chambers type procedure), with or without internal fixation
- 28304 Foot—Repair, Revision or Reconstruction—Osteotomy, midtarsal bones, other than calcaneus or talus

HCFA agrees with the American Academy of Orthopaedic Surgeons that the following procedures are obsolete:

- 28060 Foot—Excision—Fasciectomy, excision of plantar fascia; partial (separate procedure)
- 28150 Foot—Excision—Phalangectomy, single, each
- 28296 Foot—Repair, Revision or Reconstruction—Hallux valgus (bunion) correction, with or without sesamoidectomy; with metatarsal osteotomy (Mitchell or Lapidus type procedure)

HCFA agrees with the Society of Thoracic Surgeons that the following is a hospital procedure:

- 33219 Heart and Pericardium—Pacemaker—Repair of pacemaker; with replacement of pulse generator

No utilization data are available for the following procedure:

- 91010 Gastroenterology—Esophageal motility study

We will continue to consider comments on an ongoing basis. If new information is received about the above excluded procedures, or we receive additional suggested additions or revisions to the current list, we will continue to evaluate them for future ASC list expansions or revisions.

C. Procedures to be Deleted from the Current ASC List

As discussed above, we consulted with several medical organizations and reviewed their recommendations on the list of proposed ASC procedures. In several cases, it was recommended that a procedure on the current list be deleted as not conforming to the requirements of § 416.65. HCFA concurred with their recommended deletions and also identified other ASC procedures for which deletion is justified. Thus, we are deleting certain procedures from the current ASC list 90 days from the publication date of this notice.

We wish to reiterate that the following procedures are being deleted now as a result of recommendations and review flowing from our consideration of comments received on the February 16, 1984 proposed notice. Subsequent to our receipt of those comments and recommendations, our independent analysis of program data not available at the time of the proposed notice demonstrated that yet other procedures on the current list are commonly furnished in doctors' offices or do not otherwise meet the criteria of § 416.65. We are not deleting those procedure codes through this notice because we must offer an opportunity for public comment. Therefore, we intend to propose those other deletions in a separate notice to be published in the Federal Register at a later date.

Based on our review of comments and consultation on recommendations received in public comments, we have decided to delete the following codes:

- We agree with the American Academy of Orthopaedic Surgeons (AAOS) recommendation that the following are hospital procedures.
- 23105 Shoulder—Excision—Arthrotomy for synovectomy; glenohumeral joint
- 23106 Archomoclavicular, sternoclavicular joint
- 23480 Shoulder—Repair, Revision of Reconstruction—Osteotomy, clavicle, with or without internal fixation;
- 23485 with bone graft for nonunion or malunion (includes obtaining graft and/or necessary fixation)
- 24102 Humerus (Upper Arm) and Elbow—Excision—Arthrotomy, elbow; for synovectomy
- 24365 Humerus (Upper Arm) and Elbow—Repair, Revision and Reconstruction—Arthroplasty, radial head;
- 24368 with implant
- 25105 Forearm and Wrist—Excision—Arthrotomy, wrist joint; for synovectomy

- 25115 Forearm and Wrist—Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); flexors
- 25116 extensors (with or without transposition of dorsal reinaculum)
- 25118 Forearm and Wrist—Synovectomy, extensor tendon sheath, wrist, single compartment;
- 25119 with resection of distal ulna
- 26130 Hand and Fingers—Excision—Synovectomy, carpometacarpal joint
- 26565 Hand and Fingers—Repair, Revision or Reconstruction—Osteotomy for correction of deformity; metacarpal
- 26850 Hand and Fingers—Arthrodesis—Arthrodesis, metacarpophalangeal joint, with or without internal fixation;
- 26852 with autogenous graft (includes obtaining graft)
- 27625 Leg (tibia and fibula) and Ankle Joint—Arthrotomy, ankle, for synovectomy;
- 27626 including tenosynovectomy
- 27705 Leg (tibia and fibula) and Ankle Joint—Repair, Revision or Reconstruction—Osteotomy; tibia
- 27707 fibula
- 27709 tibia and fibula
- 28070 Foot—Repair—Excision—Synovectomy; intertarsal or tarsometatarsal joint, each
- 28302 Foot—Repair, Revision or Reconstruction—Osteotomy; talus
- We have determined that the following is a pediatric procedure, which should not have been included on the current ASC list:
- 31520 Larynx—Endoscopy—Laryngoscopy direct; for aspiration; diagnostic, newborn
- We agree with the American College of Obstetricians and Gynecologists (ACOG) that the following are hospital procedures:
- 56200 Female Genital System—Repair—(see also 56800) Perineoplasty, repair of perineum, nonobstetrical (separate procedure)
- 57000 Vagina—Incision—Colpotomy; with exploration
- 57135 Vagina—Excision—Excision of vaginal cyst or tumor
- We agree with ACOG, that the following is an office procedure.
- 56600 Vulva and Introitus—Excision—Biopsy of vulva (separate procedure)
- We agree with the American Academy of Ophthalmologists recommendation that the following are doctor's office procedures:
- 67800 Ocular Adnexa—Orbit—Excision or Removal of Lesion Involving More Than Skin (Ie, Involving Lid Margin, Tarsus, And/Or Palpebral Conjunctiva)—Excision chalazion; single
- 67805 multiple, different lids
- 68705 Ocular Adnexa—Lacrimal System—Repair—Correction of everted punctum, cautery

- 67915 Ocular Adnexa—Orbit—Repair Ectropion, Entropion—Repair of ectropion; thermocauterization
- 67922 Ocular Adnexa—Orbit—Repair Ectropion, Entropion—Repair entropion; thermocauterization

• HCFA staff physicians, in consultation with other practicing specialist physicians, have determined that the following should be deleted from the current list, since no facility fee should be allowed for any non-surgical procedure. This procedure involves supervision and interpretation only:

- 74740 Gynecological and Obstetrical—Hysterosalpingography; supervision and interpretation only

D. Changes in ASC Payment Groups

We made the following changes in the current assignment of codes to ASC payment groups based on comments we received from the Freestanding Ambulatory Surgical Association (FASA). We agreed with the revised group recommendation by FASA in all but one case. In the experience of HCFA medical staff, the resource allocation for procedure 11644 warranted Group 2 reimbursement, rather than the FASA recommendation of Group 3.

• The following procedures were moved from Group 1 to Group 2:

- 11626 Skin, Subcutaneous and Areolar Tissues—Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter over 4.0 cm
- 11646 Skin, Subcutaneous and Areola Tissues—Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter over 4.0 cm

• The following procedure was moved from Group 3 to Group 4:

- 64718 Nervous System—Exploration. Neurolysis or Nerve Decompression (Neuroplasty)—Neurolysis and/or transposition cranial nerve (specify)

• The following procedures were moved from Group 4 to Group 3:

- 66600 Anterior Segment-Iridectomy, with corneoscleral or corneal section; for removal of lesion
- 66625 peripheral for glaucoma (separate procedure)
- 66630 sector for glaucoma (separate procedure)
- 66635 "optical" (separate procedure)

E. Revision to CPT-4

• The following procedures were revised to conform to the most recent editions of CPT-4, as follows:

- 19121 was replaced with 19120—Excision of cyst, fibroadenoma or other benign tumor, aberrant breast tissue, duct lesion or nipple lesion (except 19140), male or female, one or more lesions

- 19141 was replaced with 19140—Mastectomy for gynecomastia through circumareolar or other incision
- 21350 was deleted from the CPT-4—Treatment of closed or open fracture of malar area, including zygomatic arch and malar tripod without manipulation
- 27375 was replaced with 29870—Arthroscopy-Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
- 27376 was replaced with 29870—Arthroscopy-Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
- 27377 was replaced with 29874—Arthroscopy-Arthroscopy, knee surgical; for removal of loose body or foreign body (eg, osteochondritis dissecans fragmentation, chondral fragmentation)
- 27378 was replaced with 29881—Arthroscopy-Arthroscopy, knee surgical; with meniscectomy (medial or lateral including any meniscal shaving)
- 43700 was replaced with 43235—Esophagus-Endoscopy-Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; complex diagnostic
- 43702 was replaced with 43239—Esophagus-Endoscopy-Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for biopsy and/or collection or specimen by brushing or washing
- 43709 was replaced with 43247—Esophagus-Endoscopy-Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for removal of foreign body
- 43711 was replaced with 43251—Esophagus-Endoscopy-Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for removal of polypoid lesion(s)
- 43712 was replaced with 43255—Esophagus—Endoscopy-Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for control of hemorrhage (eg, electrocoagulation, laser photocoagulation)
- 43714 was replaced with 43258—Esophagus-Endoscopy-Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for ablation of tumor or mucosal lesion (eg, electrocoagulation, laser photocoagulation)
- 49506 was replaced with 49505—Repair-Hernioplasty, Herniorrhaphy, Herniotomy—Repair inguinal hernia, age 5 or over
- 49551 was replaced with 49550—Repair-Hernioplasty, Herniorrhaphy, Herniotomy—Repair femoral hernia, groin incision

- 52100 was replaced with 52000—
Endoscopy-Cystourethroscopy; (separate procedure)
- 52105 was replaced with 52005—
Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive or radiologic service
- 52110 was replaced with 52010—
Endoscopy-Cystoscopy, Urethroscopy, Cystourethroscopy Notes-Cystourethroscopy, with ejaculatory duct catheterization, with or without irrigation, instillation, or duct radiography, exclusive of radiologic service
- 52202 was replaced with 52204—
Transurethral Surgery—
Cystourethroscopy, with biopsy
- 52212 was replaced with 52214—
Transurethral Surgery—
Cystourethroscopy, with fulguration (including cryosurgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands
- 52222 was replaced with 52224—
Transurethral Surgery—
Cystourethroscopy, with fulguration (including cryosurgery) or treatment of MINOR (less than 0.5 cm) lesion (s), with or without biopsy
- 52232 was replaced with 52234—
Transurethral Surgery—
Cystourethroscopy, with fulguration (including cryosurgery) and/or resection of, SMALL bladder tumor(s) (0.5 to 2.0 cm)
- 52800 was replaced with 52317—
Endoscopy-Transurethral Surgery (Urethra and Bladder)—Litholapaxy; crushing or fragmentation or calculus by any means in bladder and removal of fragments, simple; small (less than 2.5 cm)
- 54154 was replaced with 54152—Male Genital System—Excision—
Circumcision, clamp procedure; except newborn
- 66980 was replaced with 66983 or 66984—
Anterior Segment-Lens-Removal
Cataract-Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure)

V. Regulatory Impact Statement and Regulatory Flexibility Analysis

A. Requirements

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for documents such as this that are considered "major rules" because they are likely to result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete

with foreign-based enterprises in domestic or export markets. In addition, we prepare and publish a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that the document will not have a significant economic impact on a substantial number of small entities.

B. Entities Affected

A substantial number of small entities will be affected. Not only will ASCs (approximately 682 of which participate in Medicare, at present) be affected, but hospitals in many areas may be affected, depending on patients' choice of surgery site. The effect on some entities may be substantial. Although, for the reasons discussed below, we estimate the net impact of this notice on Medicare program expenditures to be negligible, we can assume that ASCs will benefit as a result of this expanded list of covered procedures. We also expect the number of Medicare participating ASCs to gradually increase, due to increased willingness of patients to use ASCs, changes in State certificate-of-need laws, continuing interest in health care cost containment, improved medical technology, and financial incentives resulting from the expanded list of covered procedures.

Individual physicians, group practices, HMOs, and other organized groups of practitioners are also considered small entities under the RFA. (Individuals, such as beneficiaries, are not.) To the extent that performance of the surgical procedures included on the ASC list is shifted from a hospital inpatient setting to either a hospital outpatient setting or an ASC, physicians (both surgeons and anesthesiologists) may benefit because, if they accept assignment, Medicare will pay them 100 percent of reasonable charges.

This proposed expansion of the list of covered ASC procedures will also affect payments to hospitals for procedures performed in their outpatient departments once section 9343(a) of Pub. L. 99-509 is implemented. That amendment enacted a new section 1833(i)(3) of the Act to provide that when hospital outpatient departments perform procedures approved for ASCs, the payment to the hospitals will be the lesser of:

- 80 percent of the hospital's aggregate cost or charges (less any applicable deductible); or
- 80 percent of the aggregate blended amount for those services based on a limit composed, in FY 1987, 75 percent of hospital costs and 25 percent of the ASC

rates, and, in FY 1988 and thereafter, 50 percent of hospital costs and 50 percent of the ASC rates.

Since we are developing separate regulations to implement section 9343(a), we will assess and discuss the effect of those limits in those documents.

C. Anticipated Economic Outcomes

We do not have data available now that would enable us to estimate quantitatively the effects of this notice on the economy but we estimate that its net impact on Medicare program expenditures, rounding to the nearest \$10 million, will be negligible. This notice will permit facility fees to be paid when procedures are furnished in an ASC that previously have been paid for only when furnished in hospitals. (The physicians furnishing ambulatory surgical services are paid regardless of site, but must collect deductible and coinsurance amounts from beneficiaries if the procedure is not on the ASC list.)

ASC payments are lower than either inpatient or outpatient hospital payments, and we therefore expect some program savings. Nonetheless, we do not expect a large volume of services to shift in setting from hospitals to ASCs. We believe that growth of ASCs would be likely to have beneficial, not adverse, effects on competition, investment, productivity, and innovation. We know of no compelling reasons to assume that the effects on employment, if any, would be adverse. This notice will not meet any of the criteria of E.O. 12291.

It is difficult to project accurately and quantitatively the overall economic impact of expanding and revising the list of covered procedures in ASCs. We expect that, to the extent that this expansion of the list of covered ASC services enables ASCs to compete more effectively with hospitals, prices related to the affected surgical services would decrease, not increase. We also expect that economies of production sought under the incentives of competition could reduce costs in many cases. However, if hospitals experience a decline in volume of these services, due to shifts to ASCs, their unit costs could increase. Further, the patterns of delivery of surgical services are constantly changing and are affected by a number of factors.

- In many States, certificate-of-need (CON) laws restrict the growth of new ASCs. This situation could change, however, as many State CON laws are being revised.
- If Medicare and private insurance payment rates for procedures performed in ASCs are updated in the future,

potential investors may perceive a greater financial incentive to fund more ASCs.

- The surgeon's or attending physician's views of the safety and efficacy of performing procedures in ASCs, as well as considerations of payment for services, may or may not be in favor of shifting more patients to ASCs, depending on a number of local variables.

- The costs of setting up an ASC vary a great deal, depending on the range of services to be provided. For example, an ASC specializing only in eye surgery would be much less expensive to build, equip, and staff, than a full-service ASC.

We expect the savings resulting from paying facility payments that are lower than outpatient hospital costs to be offset in two ways.

- Larger amounts will be paid by Medicare to some physicians, because Medicare pays physicians, as an incentive to shift surgical procedures, 100 percent of reasonable charges when a physician accepts assignment for a procedure on the ASC list performed in an ASC or in a hospital on an outpatient basis. (If a procedure is performed on an inpatient basis, or if the physician does not accept assignment, the physician

receives 80 percent of reasonable charges and the patient is liable for the 20 percent coinsurance amount.)

- When a service on the ASC list is furnished in an ASC, we will pay both physician and facility fees, whereas we pay only physician fees for services furnished in offices. Further, the physician is paid only 80 percent of the Medicare allowed charge for an office procedure. Therefore, there is an incentive to shift the site of service from the doctor's office to an ASC. To the extent that this occurs, our program expenditures will be increased.

We estimate that the net savings impact of this expansion of the list of covered ASC procedures would be less than \$10 million for FY 1987 and subsequent fiscal years.

D. Alternatives Considered

Alternatives to revising the list of procedures were not considered because updates are required by law. Alternative lists and items on the list were considered, as discussed earlier in this notice. However, the procedures contained in this notice are those we consider appropriate based on our best medical judgment.

We are not mandating where these procedures must be performed. The decision as to where the surgery will be performed is made by the patient and the patient's physician. The decision may include financial considerations, but also is motivated by such factors as the patient's general health, the presence or absence of complicating conditions, convenience of location or scheduling, or confidence in a particular facility.

E. Conclusion

We conclude that this notice will have a significant economic impact on a substantial number of small entities, and we have therefore provided a discussion that we believe presents the interaction of variables involved in assessing the impact. This discussion, in combination with the rest of the preamble of this notice serves as a regulatory flexibility analysis consistent with the RFA.

VI. Additions to the List of Covered Surgical Procedures for ASCs

On May 21, 1987, Medicare Part B coverage is available for facility services furnished in connection with the following surgical procedures when performed in an ambulatory surgical center.

CPT-4 code	Payment group	Description
Integumentary System		
Skin, Subcutaneous and Areolar Tissues		
Incision		
10141..	2	Incision and drainage of hematoma; complicated.
Excision debridement		
11042..	1	Debridement; skin, and subcutaneous tissue
11043..	1	Debridement; skin, subcutaneous tissue, and muscle
11044..	1	Debridement; skin, subcutaneous tissue, muscle, and bone.
Excision-benign lesions		
11471..	2	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with other closure. Miscellaneous
11772..	3	Excision of pilonidal cyst of sinus; complicated.
Repair-simple		
12006..	2	Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 20.1 cm to 30.0 cm.
12007..	2	Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); over 30.0 cm.
12017..	2	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm.
12018..	2	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm.
Repair-intermediate		
12036..	2	Layer closure of wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 20.1 cm to 30.0 cm.
12037..	2	Layer closure of wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); over 30.0 cm.
12046..	2	Layer closure of wounds of neck, hands, feet and/or external genitalia; 20.1 cm to 30.0 cm.
12047..	2	Layer closure of wounds of neck, hands, feet and/or external genitalia; over 30.0 cm.
12056..	2	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm.
12057..	2	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm.
Repair-complex		
13101..	1	Repair, complex, trunk; 2.6 cm to 7.5 cm.
13121..	1	Repair, complex, scalp, arms, and/or legs; 2.6 cm to 7.5 cm.
13132..	2	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm.
13152..	3	Repair, complex, eyelids, nose, ears, and/or lips; 2.6 cm to 7.5 cm.

CPT-4 code	Payment group	Description
13300..	3	Repair, unusual, complicated, over 7.5 cm, any area.
Adjacent tissue transfer or rearrangement		
14001..	3	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm.
14020..	3	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10 sq cm or less.
14021..	3	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10.1 sq cm to 30.0 sq cm.
14041..	3	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm.
14060..	3	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less.
14061..	3	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10.1 sq cm to 30.0 sq cm.
14300..	3	Adjacent tissue transfer or rearrangement, more than 30 sq cm, unusual or complicated, any area.
14350..	3	Filletted finger or toe flap, including preparation of recipient site.
Free skin grafts		
15200..	3	Full thickness graft, free, including direct closure of donor site, trunk; 20 sq cm or less.
15201..	3	Full thickness graft, free, including direct closure of donor site, trunk; each additional 20 sq cm.
15220..	3	Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs; 20 sq cm or less.
15221..	3	Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs; each additional 20 sq cm.
15240..	3	Full thickness graft, free, including direct closure of donor site, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 20 sq cm or less.
15241..	3	Full thickness graft, free, including direct closure of donor site, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 20 sq cm.
15260..	3	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips; 20 sq cm or less.
15261..	3	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips; each additional 20 sq cm.
15350..	3	Application of allograft (homograft), skin.
15410..	3	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; 100 sq cm or less.
15412..	3	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; between 101 and 160 sq cm.
15414..	3	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; between 161 and 230 sq cm.
15416..	3	Free transplantation of skin flap by microsurgical technique, including microvascular anastomosis; over 230 sq cm.
Repair		
Pedicle flaps (skin and deep tissues)		
15500..	4	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on trunk.
15505..	4	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on scalp, arms, or legs.
15510..	4	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on forehead, cheeks, chin, mouth, neck, axillae genitalia, hands, or feet.
15515..	4	Formation of tube pedicle without transfer, or major "delay" of large flap without transfer; on eyelids, nose, ears, or lips.
15540..	4	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to trunk.
15545..	4	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to scalp, arms, or legs.
15550..	4	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to forehead, cheeks, chin, mouth, neck, axillae, genitalia, or hands, feet.
15555..	4	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; to eyelids, nose, ears, or lips.
15580..	4	Primary attachment of open or tubed pedicle flap to recipient site requiring minimal preparation; cross finger pedicle flap, including free graft to donor site.
15600..	4	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at trunk.
15610..	4	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at scalp, arms, or legs.
15620..	4	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at forehead, cheeks, chin, neck, axillae, genitalia, hands (except 15625), or feet.
15625..	4	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; section pedicle of cross finger flap.
15630..	4	Intermediate "delay" of any flap, primary "delay" of small flap, or sectioning pedicle of tubed or direct flap; at eyelids, nose, ears, or lips.
15650..	4	Transfer, intermediate, of any pedicle flap (e.g., abdomen to wrist, Walking tube), any location.
15700..	4	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; trunk.
15710..	4	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; scalp, arms, or legs.
15720..	4	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands, or feet.
15730..	4	Excision of lesion and/or excisional preparation of recipient site and attachment of direct or tubed pedicle flap; eyelids, nose, ears, or lips.
Other grafts		
15740..	3	Graft; island pedicle flap.
15745..	4	Graft; myocutaneous flap.
15750..	4	Graft; neurovascular pedicle flap.
15755..	4	Graft; free flap (microvascular transfer).
15760..	3	Graft; composite (full thickness of external ear or nasal ala), including primary closure, donor area.
15770..	3	Graft; derma-fat-fascia.

CPT-4 code	Payment group	Description
Miscellaneous procedures		
15840..	4	Graft for facial nerve paralysis; free fascia graft (including obtaining fascia).
15841..	4	Graft for facial nerve paralysis; free muscle graft (including obtaining graft).
15842..	4	Graft for facial nerve paralysis; free muscle graft by microsurgical technique.
15845..	4	Graft for facial nerve paralysis; regional muscle transfer.
Pressure ulcers (decubitus ulcers)		
15920..	3	Excision, coccygeal pressure ulcer, with coccygectomy; with primary suture.
15922..	3	Excision, coccygeal pressure ulcer, with coccygectomy; with local or regional skin flap closure.
15931..	3	Excision, sacral pressure ulcer, with primary suture.
15933..	3	Excision, sacral pressure ulcer, with primary suture; with ostectomy.
15941..	3	Excision, ischial pressure ulcer, with primary suture; with ostectomy (ischiectomy).
15944..	3	Excision, ischial pressure ulcer, with local or regional skin flap closure.
15945..	3	Excision, ischial pressure ulcer, with local or regional skin flap closure; with ostectomy.
15946..	3	Excision, ischial pressure ulcer, with ostectomy, with muscle flap or myocutaneous flap closure.
15950..	3	Excision, trochanteric pressure ulcer, with primary suture.
15951..	3	Excision, trochanteric pressure ulcer, with primary suture; with ostectomy.
15952..	3	Excision, trochanteric pressure ulcer, with local rotation skin flap closure.
15953..	3	Excision, trochanteric pressure ulcer, with local rotation skin flap closure; with ostectomy.
15954..	3	Excision, trochanteric pressure ulcer, with bipedicle flap closure.
15955..	3	Excision, trochanteric pressure ulcer, with bipedicle flap closure; with ostectomy.
15956..	3	Excision, trochanteric pressure ulcer, with muscle or myocutaneous flap closure.
15958..	3	Excision, trochanteric pressure ulcer, with muscle or myocutaneous flap closure; with ostectomy.
15960..	3	Excision, heel pressure ulcer, with primary suture.
15961..	3	Excision, heel pressure ulcer, with primary suture; with ostectomy.
15964..	3	Excision, heel pressure ulcer, with skin flap closure.
15965..	3	Excision, heel pressure ulcer, with skin flap closure; with ostectomy.
15966..	3	Excision, heel pressure ulcer, with other flap closure.
15967..	3	Excision, heel pressure ulcer, with other flap closure; with ostectomy.
15970..	3	Excision, leg pressure ulcer, with primary suture.
15971..	3	Excision, leg pressure ulcer, with ostectomy.
15972..	3	Excision, leg pressure ulcer, with local skin flap(s).
15973..	3	Excision, leg pressure ulcer, with local skin flap(s); with ostectomy.
15974..	3	Excision, leg pressure ulcer, with muscle or myocutaneous flap closure.
15975..	3	Excision, leg pressure ulcer, with muscle or myocutaneous flap closure; with ostectomy.
15980..	3	Excision, knee pressure ulcer, with local skin flap closure.
15981..	3	Excision, knee pressure ulcer, with local skin flap closure; with ostectomy.
15982..	3	Excision, knee pressure ulcer, with other flap closure.
15983..	3	Excision, knee pressure ulcer, with other flap closure; with ostectomy.
Burns, local treatment		
16015..	1	Dressing and/or debridement, initial or subsequent; under anesthesia, medium or large, or with major debridement. Breast
Incision		
19020..	1	Mastotomy with exploration or drainage of abscess, deep.
Excision		
19160..	4	Mastectomy, partial.
19180..	4	Mastectomy, simple, complete.
19182..	4	Mastectomy, subcutaneous.
Musculoskeletal System		
General		
Incision		
20005..	1	Incision of soft tissue abscess (e.g., secondary to osteomyelitis); deep or complicated.
Excision		
20205..	1	Biopsy, muscle; deep.
20225..	3	Biopsy, bone, trocar or needle; deep (vertebral body; femur).
20240..	2	Biopsy, excisional; superficial (e.g., ilium, sternum, spinous process, ribs, trochanter of femur).
20245..	3	Biopsy, excisional, deep (e.g., humerus, ischium, femur).
20250..	4	Biopsy, vertebral body, open; thoracic.
20251..	4	Biopsy, vertebral body, open; lumbar or cervical
Introduction or Removal		
20525..	2	Removal of foreign body in muscle; deep or complicated.
20650..	2	Insertion of wire or pin with application of skeletal traction, including removal (separate procedure).
20660..	2	Application of tongs or caliper, including removal (separate procedure).
20661..	2	Application of halo; including removal cranial.
20662..	2	Application of halo; pelvic.
20663..	2	Application of halo; femoral.
20665..	2	Removal of tongs or halo applied by another physician.
20680..	3	Removal of implant; deep (e.g., buried wire, pin, screw, metal band, nail, rod or plate).

CPT-4 code	Payment group	Description
Grafts (or Implants)		
20900..	3	Bone graft, any donor area; minor or small (e.g., dowel or button).
20902..	4	Bone graft, any donor area; major or large.
20912..	4	Cartilage graft; nasal septum.
20920..	4	Fascia lata graft; by stripper.
20922..	4	Fascia lata graft; by incision and area exposure, complex or sheet.
20926..	4	Tissue grafts, other (e.g., paratenon, fat, dermis, etc.).
Miscellaneous		
20955..	4	Bone graft with microvascular anastomosis; fibula.
20960..	4	Bone graft with microvascular anastomosis; rib.
20962..	4	Bone graft with microvascular anastomosis; other bone graft (specify).
20969..	4	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, rib, metatarsal, or great toe.
20970..	4	Free osteocutaneous flap with microvascular anastomosis; iliac crest.
20971..	4	Free osteocutaneous flap with microvascular anastomosis; rib.
20972..	4	Free osteocutaneous flap with microvascular anastomosis; metatarsal.
20973..	4	Free osteocutaneous flap with microvascular anastomosis; great toe with web space.
20975..	2	Electrical stimulation to aid bone healing; invasive (operative).
Head		
Incision		
21010..	3	Arthrotomy, temporomandibular joint; unilateral.
21011..	3	Arthrotomy, temporomandibular joint; bilateral General
Excision		
21034..	4	Excision of malignant tumor of facial bone other than mandible.
21044..	4	Excision of malignant tumor of mandible.
21050..	4	Arthrectomy, temporomandibular joint; unilateral.
21060..	4	Meniscectomy, temporomandibular joint; unilateral.
21061..	4	Meniscectomy, temporomandibular joint; bilateral.
Introduction or Removal		
21100..	4	Application of halo type appliance for maxillofacial fixation, includes removal (separate procedure).
Fracture and/or Dislocation		
21320..	1	Manipulative treatment, nasal bone fracture; with stabilization.
21325..	3	Open treatment of nasal fracture; uncomplicated.
21330..	4	Open treatment of nasal fracture; complicated, with internal and/or external skeletal fixation.
21335..	4	Open treatment of nasal fracture; with concomitant open treatment of fractured septum.
21338..	4	Open treatment of nasoethmoid fracture; without external fixation.
21340..	4	Treatment of closed or open nasoethmoid complex fracture, with splint, wire or headcap fixation, including repair of canthal ligaments and/or the nasolacrimal apparatus.
21365..	4	Open treatment of closed or open complicated, (e.g., multiple fractures), or malar area, including zygomatic arch and malar tripod, with internal skeletal fixation and multiple surgical approaches.
21450..	4	Treatment of closed or open mandibular fracture; without manipulation.
21451..	4	Treatment of closed or open mandibular fracture; with manipulation, may include external fixation.
21452..	4	Treatment of open mandibular fracture; without manipulation.
21453..	4	Treatment of open mandibular fracture; with manipulation.
21480..	2	Uncomplicated treatment of temporomandibular dislocation, initial or subsequent.
21485..	3	Complicated manipulative treatment of temporomandibular dislocation, initial or subsequent.
21490..	4	Open treatment of temporomandibular dislocation
21494..	3	Treatment of closed or open hyoid fracture; with manipulation.
21495..	4	Open treatment of closed or open hyoid fracture.
Neck (soft tissues) and thorax		
Incision		
21501..	1	Incision and drainage, deep abscess or hematoma.
21502..	3	Incision and drainage, deep abscess or hematoma; with partial rib osteotomy.
21510..	3	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
21555..	1	Excision benign tumor; subcutaneous.
Excision		
21556..	2	Excision, benign tumor; deep; subfascial, intramuscular.
21600..	3	Excision of rib, partial.
21610..	3	Costotransversectomy (separate procedure).
Abdomen		
Excision		
22900..	2	Excision, abdominal wall tumor, subfacial (e.g., desmoid). Shoulder
Incision		
23000..	3	Removal of subdeltoid (or intratendinous) calcareous deposits.
23020..	3	Capsular contracture release (Sever type procedure) for Erb's palsy.
23030..	1	Incision and drainage; deep abscess or hematoma.

CPT-4 code	Payment group	Description
23035..	2	Incision, deep, with opening of cortex (e.g., for osteomyelitis or bone abscess).
23040..	4	Arthrotomy, glenohumeral joint, for infection, with exploration, drainage or removal of foreign body.
23044..	4	Arthrotomy with exploration, drainage or removal of foreign body, acromioclavicular, sternoclavicular joint.
Excision		
23066..	1	Biopsy, soft tissues; deep.
23076..	1	Excision, benign tumor; deep, subfascial or intramuscular.
23100..	4	Arthrotomy for biopsy, glenohumeral joint.
23101..	4	Arthrotomy for biopsy or for excision of torn cartilage, acromioclavicular, sternoclavicular joint.
23130..	4	Acromionectomy, partial or total.
23140..	4	Excision or curettage of bone cyst or benign tumor of clavicle or scapula.
23150..	4	Excision or curettage of bone cyst or benign tumor of proximal humerus.
23180..	3	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), clavicle.
23182..	3	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), scapula.
23184..	3	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), proximal humerus.
23190..	3	Ostectomy of scapula, partial (e.g., superior medial angle).
23195..	3	Resection humeral head.
Introduction or Removal		
23331..	2	Removal of foreign body; deep (e.g., Neer prosthesis removal).
Repair, Revision of Reconstruction		
23405..	3	Tenomyotomy; single.
23406..	3	Tenomyotomy; multiple through same incision.
Fracture and/or Dislocation		
23505..	2	Treatment of closed clavicular fracture; with manipulation.
23515..	4	Open treatment of closed or open clavicular fracture, with or without internal or external skeletal fixation.
23605..	2	Treatment of closed humeral (surgical or anatomical neck) fracture; with manipulation.
23610..	4	Treatment of open humeral (surgical or anatomical neck) fracture, with uncomplicated soft tissue closure.
23625..	2	Treatment of closed greater tuberosity fracture; with manipulation.
23630..	4	Open treatment of closed or open greater tuberosity fracture, with or without internal or external skeletal fixation.
23655..	1	Treatment of closed shoulder dislocation, with manipulation; requiring anesthesia.
23658..	4	Treatment of open shoulder dislocation, with uncomplicated soft tissue closure.
23660..	4	Open treatment of closed or open shoulder dislocation.
23665..	2	Treatment of closed shoulder dislocation, with fracture of greater tuberosity, with manipulation.
23670..	4	Open treatment of closed or open shoulder dislocation, with fracture of greater tuberosity.
23675..	2	Treatment of closed shoulder dislocation, with surgical or anatomical neck fracture, with manipulation.
23680..	4	Open treatment of closed or open shoulder dislocation, with surgical or anatomical neck fracture.
Manipulation		
23700..	2	Manipulation under anesthesia, including application of fixation apparatus (dislocation excluded). Humerus (upper arm) and elbow
Incision		
23930..	1	Incision and drainage; deep abscess or hematoma.
23935..	2	Incision, deep, with opening of (e.g., cortex for osteomyelitis or bone abscess).
24000..	2	Arthrotomy, elbow, for infection, with exploration, drainage or removal of foreign body.
Excision		
24075..	2	Excision, benign tumor; subcutaneous.
24076..	2	Excision, benign tumor; deep, subfascial or intramuscular.
24100..	4	Arthrotomy, elbow; for synovial biopsy only.
24101..	4	Arthrotomy, elbow; with joint exploration, with or without biopsy, with or without removal of foreign body.
24110..	3	Excision, or curettage of bone cyst or benign tumor, humerus.
24115..	4	Excision or curettage of bone cyst or benign tumor, humerus; with primary autogenous graft (includes obtaining graft).
24116..	4	Excision or curettage of bone cyst or benign tumor, humerus; with homogenous or other nonautogenous graft.
24120..	3	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process.
24125..	4	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with primary autogenous graft (includes obtaining graft).
24126..	4	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with homogenous or other nonautogenous graft.
24130..	3	Excision, radial head.
24140..	2	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis), humerus.
24145..	2	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), radial head or neck.
24147..	2	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), olecranon process.
24155..	4	Resection of elbow joint (arthrectomy).
Introduction or removal		
24160..	2	Implant removal; elbow joint.
24164..	2	Implant removal; radial head.
24201..	1	Removal of foreign body; deep.
Repair revision and reconstruction		
24301..	3	Muscle or tendon transfer, any type, single (excluding 24320-24331).
24310..	3	Tenotomy, open, elbow to shoulder, single, each.

CPT-4 code	Payment group	Description
24330..	4	Flexor-plasty, elbow, (e.g., Steindler type advancement).
24331..	4	Flexor-plasty, elbow, (e.g., Steindler type advancement); with extensor advancement.
24340..	4	Tenodesis for rupture of biceps tendon at elbow.
24342..	4	Reinsertion of ruptured biceps tendon, distal, with or without tendon graft (includes obtaining graft).
24356..	4	Fasciotomy, lateral or medial (e.g., "tennis elbow" or epicondylitis); with partial osteotomy.
24420..	4	Osteoplasty, humerus (e.g., shortening or lengthening) (excluding 64876).
24470..	4	Hemiepiphyseal arrest (e.g., for cubitus varus or valgus, distal humerus).
24495..	4	Decompression fasciotomy, forearm, with brachial artery exploration.
Fracture and/or dislocation		
24505..	1	Treatment of closed humeral shaft fracture; with manipulation.
24506..	2	Treatment of closed humeral shaft fracture; percutaneous insertion of pin or rod.
24510..	3	Treatment of open humeral shaft fracture, with uncomplicated soft tissue closure.
24515..	4	Open treatment of closed or open humeral shaft fracture, with or without internal or external skeletal fixation.
24530..	1	Treatment of closed supracondylar or transcondylar fracture, without manipulation.
24531..	2	Treatment of closed supracondylar or transcondylar fracture, without manipulation; with traction (pin or skin).
24535..	1	Treatment of closed supracondylar or transcondylar fracture, with manipulation.
24536..	2	Treatment of closed supracondylar or transcondylar fracture, with manipulation; with traction (pin or skin).
24538..	2	Treatment of closed supracondylar or transcondylar fracture, with manipulation; with percutaneous skeletal fixation.
24540..	4	Treatment of open supracondylar or transcondylar fracture, with uncomplicated soft tissue closure.
24542..	4	Treatment of open supracondylar or transcondylar fracture, with uncomplicated soft tissue closure; with traction (pin or skin).
24545..	4	Open treatment of closed or open supracondylar or transcondylar fracture, with or without internal or external skeletal fixation.
24565..	1	Treatment of closed epicondylar fracture, medial or lateral; with manipulation.
24570..	3	Treatment of open epicondylar fracture, medial or lateral; with uncomplicated soft tissue closure.
24575..	4	Open treatment of closed or open epicondylar fracture, medial or lateral, with or without internal or external skeletal fixation.
24577..	1	Treatment of closed condylar fracture, medial or lateral; with manipulation.
24578..	3	Treatment of open condylar fracture, medial or lateral with uncomplicated soft tissue closure.
24579..	4	Open treatment of closed or open condylar fracture, medial or lateral, with or without internal or external skeletal fixation.
24580..	1	Treatment of closed comminuted elbow fracture (fracture distal humerus and/or proximal ulna radius), treatment with traction, (pin or skin); without manipulation.
24581..	1	Treatment of closed comminuted elbow fracture (fracture distal humerus and/or proximal ulna radius), treatment with traction, (pin or skin); without manipulation.
24583..	4	Treatment of open comminuted elbow fracture (fracture distal humerus and/or proximal ulna and/or proximal radius), with uncomplicated soft tissue closure.
24585..	4	Open treatment of closed or open comminuted elbow fracture (fracture distal humerus and/or proximal ulna and/or proximal radius), with or without internal or external skeletal fixation.
24586..	4	Open treatment of closed or open comminuted elbow fracture (fracture distal humerus and/or proximal ulna and/or proximal radius), with or without internal or external skeletal fixation; with elbow resection.
24605..	1	Treatment of closed elbow dislocation; requiring anesthesia.
24610..	3	Treatment of open elbow dislocation, with uncomplicated soft tissue closure.
24615..	3	Open treatment of closed or open elbow dislocation.
24620..	2	Treatment of closed Monteggia type of fracture dislocation at elbow (fracture proximal end of ulna with dislocation of radial head).
24625..	4	Treatment of open Monteggia type of fracture dislocation at elbow (fracture proximal end of ulna with dislocation of radial head), with uncomplicated soft tissue closure.

CPT-4 code	Payment group	Description
24635	4	Open treatment of closed or open Monteggia type of fracture dislocation at elbow (fracture proximal end of ulna with dislocation of radial head), with or without internal or external skeletal fixation.
24655..	1	Treatment of closed radial head or neck fracture; with manipulation with complicated soft tissue closure.
24665..	4	Open treatment of closed or open radial head or neck fracture, with or without internal fixation or radial head excision.
24666..	4	Open treatment of closed or open radial head or neck fracture, with or without internal fixation or radial head excision; with implant.
24675..	1	Treatment of closed ulnar fracture, proximal end (olecranon process); with manipulation.
24680..	3	Treatment of open ulnar fracture, proximal end (olecranon process); with uncomplicated soft tissue closure.
24685..	4	Open treatment of closed or open ulnar fracture, proximal end (olecranon process), with or with without internal or external skeletal fixation.
		Forearm and Wrist
Incision		
25005..	2	Tendon sheath incision; at wrist for other stenosing tenosynovitis.
25028..	1	Incision and drainage, deep abscess or hematoma.
25035..	2	Incision, deep, with opening of cortex (e.g., for osteomyelitis or bone abscess).
25040..	2	Arthrotomy, radiocarpal or mediocarpal joint, for infection, with exploration, drainage, or removal of loose or foreign body.
Excision		
25066..	1	Biopsy, soft tissues; deep.
25076..	1	Excision, benign tumor, deep, subfascial or intramuscular.
25085..	3	Capsulotomy, wrist (e.g., for contracture).
25100..	2	Arthrotomy, wrist joint; for biopsy.
25101..	3	Arthrotomy, wrist joint; with joint exploration, with or without biopsy, with or without removal of foreign body.
25107..	3	Arthrotomy distal radioulnar joint for repair of triangular cartilage complex.
25110..	3	Excision, lesion of tendon sheath.
25120..	3	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process).
25125..	4	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with primary autogenous graft (includes obtaining graft).

CPT-4 code	Payment group	Description
25126..	4	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with homogenous or other nonautogenous graft.
25130..	3	Excision or curettage of bone cyst or benign tumor of carpal bones.
25135..	3	Excision or curettage of bone cyst or benign tumor of carpal bones; with primary autogenous graft (includes obtaining graft).
25136..	4	Excision or curettage of bone cyst or benign tumor of carpal bones; with homogenous or other nonautogenous graft.
25145..	2	Sequestrectomy (e.g., for osteomyelitis or bone abscess).
25146..	2	With suction irrigation. Sequestrectomy (e.g., for osteomyelitis or bone abscess).
25150..	2	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis); ulna.
25151..	2	Partial excision (craterization, saucerization or diaphysectomy) of bone (e.g., for osteomyelitis); radius.
25210..	3	Carpectomy; one bone.
25215..	3	Carpectomy; all bones of proximal row.
25230..	3	Radial styloidectomy (separate procedure).
25240..	3	Excision distal ulna (Darrach type procedure).
25248..	2	Exploration for removal of deep foreign body.
Repair, revision or reconstruction		
25274..	4	Repair, tendon or muscle, extensor, secondary, with tendon graft (includes obtaining graft), each tendon.
25280..	3	Lengthening or shortening of flexor or extensor tendon, single, each tendon.
25290..	3	Tenotomy, open, single, flexor or extensor tendon, each tendon.
25295..	3	Tenolysis, single flexor or extensor tendon, each tendon.
25300..	3	Tenodesis at wrist; flexors of fingers.
25301..	3	Tenodesis at wrist; extensors of fingers.
25315..	3	Flexor origin slide for cerebral palsy.
25316..	3	Flexor origin slide for cerebral palsy; with tendon(s) transfer.
25317..	3	Flexor origin slide for Volkmann contracture.
25318..	3	Flexor origin slide for Volkmann contracture; with tendon(s) transfer.
25320..	4	Capsulorrhaphy or reconstruction, capsulectomy, wrist (includes synovectomy, resection of capsule, tendon insertions).
25390..	4	Osteoplasty radius OR ulna; shortening.
25391..	4	Osteoplasty, radius OR ulna; lengthening with autogenous bone graft.
25392..	4	Osteoplasty, radius AND ulna; shortening (excluding 64876).
25393..	4	Osteoplasty, radius AND ulna; lengthening with autogenous bone graft.
25450..	4	Epiphyseal arrest by epiphysiodesis or stapling; distal radius OR ulna.
25455..	4	Epiphysial arrest by epiphysiodesis or stapling; distal radius AND ulna.
Fracture and/or Dislocation		
25505..	1	Treatment of closed radial shaft fracture; with manipulation.
25510..	3	Treatment of open radial shaft fracture, with uncomplicated soft tissue closure.
25515..	4	Open treatment of closed or open radial shaft fracture, with or without internal or external skeletal fixation.
25535..	1	Treatment of closed ulnar shaft fracture; with manipulation.
25540..	3	Treatment of open ulnar shaft fracture, with uncomplicated soft tissue closure.
25545..	4	Open treatment of closed or open ulnar shaft fracture, with or without internal or external skeletal fixation.
25565..	1	Treatment of closed radial and ulnar shaft fractures; with manipulation.
25570..	3	Treatment of open radial and ulnar shaft fractures, with uncomplicated soft tissue closure.
25575..	4	Open treatment of closed or open radial and ulnar shaft fractures, with or without internal or external skeletal fixation.
25605..	1	Treatment of closed distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid; with manipulation.
25610..	2	Treatment of closed, complex, distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, requiring manipulation; without external skeletal fixation or percutaneous pinning.
25611..	2	Treatment of closed, complex, distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, requiring manipulation; percutaneous pinning or pins and plaster technique.
25615..	3	Treatment of open distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, with uncomplicated soft tissue closure.
25620..	4	Open treatment of closed or open distal radial fracture (e.g., Colles or Smith type) or epiphyseal separation, with or without fracture of ulnar styloid, with or without internal or external skeletal fixation.
25626..	3	Treatment of open carpal scaphoid (navicular) fracture, with uncomplicated soft tissue closure.
25628..	4	Open treatment of closed or open carpal scaphoid (navicular) fracture, with or without skeletal fixation.
25635..	1	Treatment of closed carpal bone fracture (excluding carpal scaphoid (navicular)); with manipulation, each bone.
25640..	4	Treatment of open carpal bone fracture (excluding carpal scaphoid (navicular)), with uncomplicated soft tissue closure, each bone.
25645..	4	Open treatment of closed or open carpal bone fracture (excluding carpal scaphoid (navicular)), each bone.
25660..	1	Treatment of closed radiocarpal or intercarpal dislocation, one or more bones, with manipulation.
25665..	3	Treatment of open radiocarpal or intercarpal dislocation, one or more bones, with uncomplicated soft tissue closure.
25670..	4	Open treatment of closed or open radiocarpal or intercarpal dislocation, one or more bones.
25675..	1	Treatment of closed distal radioulnar dislocation with manipulation.
25676..	3	Open treatment of closed or open distal radioulnar dislocation, acute or chronic.
25680..	1	Treatment of closed trans-scaphoperilunar type of fracture dislocation, with manipulation.
25685..	3	Open treatment of closed or open trans-scaphoperilunar type of fracture dislocation.
25690..	1	Treatment of lunate dislocation, with manipulation.
25695..	3	Open treatment of lunate dislocation.

CPT-4 code	Payment group	Description
Hands and fingers		
Incision		
26011..	1	Drainage of finger abscess; complicated (e.g., felon, etc).
26020..	1	Drainage of tendon sheath, one digit and/or palm.
26025..	1	Drainage of palmar bursa; single, ulnar or radial.
26030..	1	Drainage of palmar bursa; multiple or complicated.
26034..	2	Incision, deep, with opening of cortex (e.g., for osteomyelitis or bone abscess).
26035..	2	Decompression fingers and/or hand, injection injury (e.g., grease gun, etc.).
26070..	2	Arthrotomy, for infection, with exploration, drainage or removal of loose or foreign body; carpometacarpal joint.
27075..	2	Arthrotomy with exploration, drainage or removal of loose or foreign body; metacarpophalangeal joint.
26080..	2	Arthrotomy with exploration, drainage or removal of loose or foreign body; interphalangeal joint, each.
Excision		
26100..	3	Arthrotomy for synovial biopsy; carpometacarpal joint.
26105..	3	Arthrotomy for synovial biopsy; metacarpophalangeal joint.
26110..	3	Arthrotomy for synovial biopsy; interphalangeal joint, each.
26115..	3	Excision of benign tumor; subcutaneous.
26116..	3	Excision of benign tumor; deep, subfascial, intramuscular.
26124..	4	Fasciectomy, palmar, complicated, requiring skin grafting (includes obtaining graft); with single digit involvement.
26126..	4	Fasciectomy, palmar, complicated, requiring skin grafting (includes obtaining graft); each additional digit.
26135..	4	Synovectomy, metacarpophalangeal joint including intrinsic release and extensor hood reconstruction, each digit.
26160..	3	Excision of lesion of tendon sheath or capsule (e.g., cyst or ganglion).
26170..	3	Excision of tendon, palm, flexor, single (separate procedure), each.
26180..	3	Excision of tendon, finger, flexor (separate procedure).
26200..	3	Excision or curettage of bone cyst or benign tumor of metacarpal.
26205..	3	Excision or curettage of bone cyst or benign tumor of metacarpal; with autogenous graft (includes obtaining graft).
26210..	3	Excision or curettage of bone cyst or benign tumor of proximal, middle or distal phalanx.
26215..	3	Excision or curettage of bone cyst or benign tumor of proximal middle or distal phalanx; with autogenous graft (includes obtaining graft).
26230..	3	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); metacarpal.
26235..	3	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); proximal or middle phalanx.
26250..	4	Radical resection (ostectomy) for tumor, metacarpal.
26255..	4	Radical resection (ostectomy) for tumor, metacarpal; with autogenous graft (includes obtaining graft).
26261..	4	Radical resection (ostectomy) for tumor, proximal or middle phalanx; with autogenous graft (includes obtaining graft)
Repair, revision or reconstruction		
26440..	3	Tenolysis, simple, flexor tendon; palm OR finger, single, each tendon.
26442..	3	Tenolysis, simple, flexor tendon; palm AND finger, each tendon.
26445..	3	Tenolysis, extensor tendon, dorsum of hand or finger; each tendon.
26449..	4	Tenolysis, complex, extensor tendon, dorsum of hand or finger, including hand and forearm.
26471..	2	Tenodesis; for proximal interphalangeal joint stabilization.
26474..	2	Tenodesis; for distal joint stabilization.
26476..	3	Tendon lengthening, extensor, single, each.
26477..	3	Tendon shortening, extensor, single, each.
26490..	4	Opponens plasty; sublimis tendon transfer type.
26492..	4	Opponens plasty; tendon transfer with graft (includes obtaining graft).
26494..	4	Opponens plasty; hypothenar muscle transfer.
26496..	4	Opponens plasty; other methods.
26497..	4	Tendon transfer to restore intrinsic function; ring and small finger.
26498..	4	Tendon transfer to restore intrinsic function; all four fingers.
26499..	4	Correction claw finger; other methods.
26500..	4	Tendon pulley reconstruction; with local tissues (separate procedure).
26502..	4	Tendon pulley reconstruction; with tendon or fascial graft (includes obtaining graft) (separate procedure).
26508..	4	Thenar muscle release for thumb contracture.
26510..	4	Cross intrinsic transfer.
26516..	2	Capsulodesis for M-P joint stabilization; single digit.
26517..	2	Capsulodesis for M-P joint stabilization; two digits.
26518..	3	Capsulodesis for M-P joint stabilization; three or four digits.
26542..	4	Primary repair of collateral ligament, metacarpophalangeal joint; with local tissue.
26552..	4	Reconstruction thumb with toe.
26555..	4	Positional change of other finger.
26557..	4	Toe to finger transfer; first stage.
26558..	4	Toe to finger transfer; each delay.
26559..	4	Toe to finger transfer; second stage.
26568..	4	Osteoplasty for lengthening of metacarpal or phalanx.
26570..	4	Bone graft, (includes obtaining graft); metacarpal.
26574..	4	Bone graft, (includes obtaining graft); phalanx.
Fractures and/or dislocations		
26605..	1	Treatment of closed metacarpal fracture, single; with manipulation, each bone.
26607..	2	Treatment of closed metacarpal fracture, single, with manipulation, with skeletal fixation, each bone.
26610..	2	Treatment of open metacarpal fracture, single, with uncomplicated soft tissue closure, each bone.
26645..	1	Treatment of closed carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation.

CPT-4 code	Payment group	Description
26650..	2	Treatment of closed carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation; with skeletal fixation.
26655..	3	Treatment of open carpometacarpal fracture dislocation, thumb (Bennett fracture), with uncomplicated soft tissue closure.
26660..	3	Treatment of open carpometacarpal fracture dislocation, thumb (Bennett fracture), with uncomplicated soft tissue closure; with skeletal fixation.
26665..	3	Open treatment of closed or open carpometacarpal fracture dislocation, thumb (Bennett fracture), with or without internal or external skeletal fixation.
26675..	1	Treatment of closed carpometacarpal dislocation, other than Bennett fracture, single, with manipulation; requiring anesthesia.
26676..	2	Treatment of closed carpometacarpal dislocation, other than Bennett fracture, single, with manipulation; with percutaneous pinning.
26680..	2	Treatment of open carpometacarpal dislocation, other than Bennett fracture, single, with uncomplicated soft closure.
26685..	3	Open treatment of closed or open carpometacarpal dislocation, other than Bennett fracture; single, with or without internal or external skeletal fixation.
26686..	3	Open treatment of closed or open carpometacarpal dislocation, other than Bennett fracture; complex, multiple or delayed reduction.
26705..	1	Treatment of closed metacarpophalangeal dislocation, single, with manipulation; requiring anesthesia.
26706..	2	Treatment of closed metacarpophalangeal dislocation, single, with manipulation; with percutaneous pinning.
26710..	2	Treatment of open metacarpophalangeal dislocation, single, with uncomplicated soft tissue closure.
26715..	3	Open treatment of closed or open metacarpophalangeal dislocation, single, with or without internal or external skeletal fixation.
26727..	2	Treatment of unstable phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with manipulation, requiring traction or fixation, each.
26730..	2	Treatment of open phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with uncomplicated soft tissue closure, each.
26735..	3	Open treatment of closed or open phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with or without internal or external skeletal fixation, each.
26744..	2	Treatment of open articular fracture, involving metacarpophalangeal or proximal interphalangeal joint; with uncomplicated soft tissue closure, each.
26746..	3	Open treatment of closed or open articular fracture, involving metacarpophalangeal or proximal interphalangeal joint, each.
26765..	3	Open treatment of closed or open distal phalangeal fracture, finger or thumb, each.
26780..	2	Treatment of open interphalangeal joint dislocation, single, with uncomplicated soft tissue closure.
26785..	3	Open treatment of closed or open interphalangeal joint dislocation, single.
		Pelvis and Hip Joint
Incision		
26990..	2	Incision and drainage; deep abscess or hematoma.
26991..	2	Incision and drainage; infected bursa.
26992..	2	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
27000..	3	Tenotomy, adductor, subcutaneous, closed (separate procedure).
27001..	4	Tenotomy, adductor, subcutaneous, open; unilateral.
27002..	4	Tenotomy, adductor, subcutaneous, open; bilateral.
27003..	4	Tenotomy, adductor, subcutaneous, open, with obturator neurectomy; unilateral.
27004..	4	Tenotomy, adductor, subcutaneous, open, with obturator neurectomy; bilateral.
27030..	4	Arthrotomy, hip, for infection, with drainage.
27033..	4	Arthrotomy, hip, for exploration or removal of loose or foreign body.
27035..	4	Hip joint denervation, intrapelvic or extrapelvic intra-articular branches of sciatic, femoral or obturator nerves.
Excision		
27040..	4	Biopsy, soft tissues; superficial.
27041..	4	Biopsy, soft tissues; deep.
27047..	4	Excision, benign tumor; subcutaneous.
27048..	4	Excision, benign tumor; deep, subfascial, intramuscular.
27052..	4	Arthrotomy for biopsy; hip joint.
27065..	4	Excision of bone cyst or benign tumor; superficial (wing of ilium, symphysis pubis, or greater trochanter of femur) with or without autogenous bone graft.
27066..	4	Excision of bone cyst or benign tumor; deep, with or without bone graft.
27080..	4	Coccygectomy, primary.
Introduction and/or removal		
27087..	2	Removal of foreign body; deep.
27095..	1	Injection procedure for hip arthrography; with anesthesia.
Fractures and/or dislocations		
27201..	4	Treatment of open coccygeal fracture.
27202..	4	Open treatment of closed or open coccygeal fracture.
Manipulation		
27275..	2	Manipulation, hip joint, requiring general anesthesia.

CPT-4 code	Payment group	Description
Femur (Thigh Region) and Knee Joint		
Incision		
27301..	2	Incision and drainage of deep abscess, infected bursa, or hematoma.
27303..	2	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
27310..	4	Arthrotomy, knee, for infection, with exploration, drainage or removal of foreign body.
Excision		
27324..	2	Biopsy, soft tissues; deep.
27327..	1	Excision, benign tumor; subcutaneous.
27328..	2	Excision, benign tumor; deep, subfascial, or intramuscular.
27330..	4	Arthrotomy, knee; for synovial biopsy only.
27345..	4	Excision of synovial cyst of popliteal space (Baker's cyst).
27350..	4	Patellectomy or hemipatellectomy.
27355..	4	Excision or curettage of bone cyst or benign tumor of femur.
27360..	4	Partial excision (craterization, saucerization or diaphysectomy) of bone, (e.g., for osteomyelitis), femur, proximal tibia and/or fibula.
Introduction and/or removal		
27372..	3	Removal foreign body, deep.
Repair, Revision or Reconstruction		
27390..	4	Tenotomy, open, hamstring, knee to hip; single.
27391..	4	Tenotomy, open, hamstring, knee to hip; multiple, one leg.
27392..	4	Tenotomy, open, hamstring, knee to hip; multiple, bilateral.
27393..	4	Lengthening of hamstring, tendon; single.
27394..	4	Lengthening of hamstring, tendon; multiple, one leg.
27395..	4	Lengthening of hamstring, tendon; multiple, bilateral.
27396..	4	Transplant, hamstring tendon to patella; single.
27397..	4	Transplant, hamstring tendon to patella; multiple.
27400..	4	Tendon or muscle transfer, hamstrings to femur (Eggers type procedure).
27420..	4	Reconstruction for recurrent dislocating patella; (Hauser type procedure).
27422..	4	Reconstruction for recurrent dislocating patella; with extensor realignment and/or muscle advancement or release (Campbell, Goldwaith, etc., type procedure).
27424..	4	Reconstruction for recurrent dislocating patella; with patellectomy.
27425..	4	Lateral retinacular release (any method).
27430..	4	Quadriceps plasty (Bennett or Thompson type).
27435..	4	Capsulotomy, knee, posterior capsular release.
Fracture and/or dislocations		
27522..	3	Treatment of open patellar fracture, with uncomplicated soft tissue closure.
27524..	4	Open treatment of closed or open patellar fracture, with repair and/or excision.
Excision		
27532..	1	Treatment of closed tibial fracture, proximal (plateau); with manipulation.
Fractures and/or dislocations		
27534..	3	Open treatment of closed tibia fracture, proximal, (plateau), with uncomplicated soft tissue closure.
Excision		
2227552..	1	Treatment of closed knee dislocation; requiring anesthesia.
27562..	1	Treatment of closed patellar dislocation; requiring anesthesia.
Fractures and/or dislocations		
27564..	4	Treatment of open patellar dislocation, with uncomplicated soft tissue closure.
27666..	4	Open treatment of closed or open patellar, dislocation, with or without partial or total patellectomy.
Manipulation		
27570..	2	Manipulation of knee joint under general anesthesia (includes application of traction or other fixation devices).
Incision		
27603..	2	Incision and drainage; deep abscess or hematoma.
27607..	2	Incision, deep with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
27610..	2	Arthrotomy, ankle, with exploration, drainage or removal of loose or foreign body.
27612..	4	Arthrotomy, ankle, posterior capsular release with or without Achilles tendon lengthening.
Leg (Tibia and Fibula) and Ankle Joint		
Excision		
27620..	3	Arthrotomy, ankle, for biopsy.
27630..	3	Excision of lesion of tendon sheath or capsule (e.g., cyst or ganglion).
27635..	3	Excision or curettage of bone cyst or benign tumor, tibia or fibula.
27637..	4	Excision or curettage of bone cyst, or benign tumor, tibia or fibula; with primary autogenous graft (includes obtaining graft).
27638..	4	Excision or curettage of bone cyst, or benign tumor, tibia or fibula; with primary homogenous graft.
27640..	4	Partial excision (craterization, saucerization, or diaphysectomy) of bone, (e.g., for osteomyelitis); tibia.
27641..	4	Partial excision (craterization, saucerization, or diaphysectomy) of bone, (e.g., for osteomyelitis); fibula.
Repair, Revision or Reconstruction		
27675..	4	Repair for dislocating peroneal tendons; without fibular osteotomy.
27680..	3	Tenolysis, including tibia, fibula and ankle flexor; single.

CPT-4 code	Payment group	Description
27681..	4	Tenolysis, including tibia, fibula and ankle flexor; multiple (through same incision), each.
27685..	3	Lengthening or shortening of tendon; single (separate procedure).
27686..	4	Lengthening or shortening of tendon; multiple (through same incision), each.
27690..	4	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (e.g., anterior tibial extensors into midfoot).
27691..	4	Transfer or transplant of single tendon (with muscle redirection or rerouting); anterior tibial or posterior tibial through interosseous space.
27692..	4	Transfer or transplant of single tendon (with muscle redirection or rerouting); each additional tendon.
Fractures and/or Dislocations		
27756..	4	Open treatment of closed or open tibial shaft fracture, with internal skeletal fixation; simple.
27758..	4	Open treatment of closed or open tibial shaft fracture, with internal or external skeletal fixation; complicated.
27764..	3	Treatment of open distal tibial fracture (medial malleolus), with uncomplicated soft tissue closure.
27766..	3	Open treatment of closed or open distal tibial fracture (medial malleolus), with fixation.
27781..	1	Treatment of closed proximal fibula or shaft fracture; with manipulation.
27782..	3	Treatment of open proximal fibula or shaft fracture, with uncomplicated soft tissue closure.
27784..	4	Open treatment of closed or open proximal fibula or shaft fracture, with or without internal or external skeletal fixation.
27790..	3	Treatment of open distal fibula fracture (lateral malleolus), with uncomplicated soft tissue closure.
27792..	4	Open treatment of closed or open distal fibular fracture (lateral malleolus), with fixation.
27802..	1	Treatment of closed tibia and fibula fractures, shafts; with manipulation.
27804..	3	Treatment of open tibia and fibula fractures, shafts, with uncomplicated soft tissue closure (e.g., "pins above and below").
27842..	1	Treatment of ankle dislocation; requiring anesthesia.
27844..	3	Treatment of open ankle dislocation, with uncomplicated soft tissue closure.
27846..	4	Open treatment of closed or open ankle dislocation.
27848..	4	Open treatment of closed or open ankle dislocation; with fixation.
Manipulation		
27860..	1	Manipulation of ankle under general anesthesia (includes application of traction or other fixation apparatus). Foot
Incision		
28002..	2	Deep infection, below fascia, requiring deep dissection, with or without tendon sheath involvement; single bursal space, specify.
28003..	2	Deep infection, below fascia, requiring deep dissection, with or without tendon sheath involvement; multiple areas.
28005..	2	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess).
28035..	4	Tarsal tunnel release (posterior tibial nerve decompression).
Excision		
28045..	2	Excision benign tumor; deep, subfascial, intramuscular.
28050..	3	Arthrotomy for synovial biopsy; intertarsal or tarsometatarsal joint.
28062..	4	Fasciectomy, excision of plantar fascia; radical (separate procedure).
28102..	4	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with iliac or other autogenous bone graft (includes obtaining graft).
28103..	4	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with homogenous bone graft.
28107..	3	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal bones, except talus or calcaneus; with homogenous bone graft.
28118..	3	Osteotomy, calcaneus; partial.
28120..	3	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) of bone (e.g., for osteomyelitis), talus or calcaneus.
28122..	3	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis), tarsal or metatarsal bone, except talus or calcaneus.
28140..	3	Metatarsectomy.
28171..	3	Radical resection for tumor; tarsal (except talus or calcaneus).
28173..	3	Radical resection for tumor; metatarsal.
28175..	3	Radical resection for tumor; phalanx.
Introduction and/or Removal		
28193..	2	Remove foreign body; complicated.
Repair Revision or Reconstruction		
28250..	2	Division of plantar fascia and muscle ("Steindler stripping") (separate procedure).
28260..	3	Capsulotomy, midfoot; medial release only (separate procedure).
28261..	3	Capsulotomy, midfoot; with tendon lengthening.
28296..	4	Hallux valgus (bunion) correction, with or without sesamoidectomy; with metatarsal osteotomy (e.g., Mitchel, Chevron, or concentric type procedures).
28297..	4	Hallux valgus (bunion) correction, with or without sesamoidectomy; Lapidus type procedure.
28315..	3	Sesamoidectomy, first toe (separate procedure).
28320..	4	Repair of nonunion or malunion; tarsal bones (calcaneus, talus, etc).
28322..	4	Repair of nonunion or malunion; metatarsal, with or without bone graft (includes obtaining graft).
Fracture and/or Dislocation		
28405..	1	Treatment of closed calcaneal fracture; with manipulation including Cotton or Bohler type reductions.
28406..	2	Treatment of closed calcaneal fracture; with manipulation and skeletal fixation.

CPT-4 code	Payment group	Description
28420..	4	Open treatment of closed or open calcaneal fracture, with or without internal or external skeletal fixation; with primary iliac or other autogenous bone graft (includes obtaining graft).
28435..	1	Treatment of closed talus fracture; with manipulation.
28436..	2	Treatment of closed talus fracture; with manipulation and percutaneous pinning.
28465..	4	Open treatment of closed or open tarsal bone fracture (except talus and calcaneus), with or without internal or external skeletal fixation, each.
28485..	4	Open treatment of closed or open metatarsal fracture, with or without internal or external skeletal fixation, each.
28500..	3	Treatment of open fracture great toe, phalanx or phalanges, with uncomplicated soft tissue closure.
28505..	3	Open treatment of closed or open fracture great toe, phalanx or phalanges, with or without internal or external skeletal fixation.
28520..	2	Treatment of open fracture, phalanx or phalanges, other than great toe, with uncomplicated soft tissue closure, each.
28525..	3	Open treatment of closed or open fracture, phalanx or phalanges, other than great toe, with or without internal or external skeletal fixation, each.
28545..	1	Treatment of closed tarsal bone dislocation; requiring anesthesia.
28546..	2	Treatment of closed tarsal bone dislocation, with percutaneous skeletal fixation.
28555..	4	Open treatment of closed or open tarsal bone dislocation, with or without internal or external skeletal fixation.
28575..	1	Treatment of closed talotarsal joint dislocation; requiring anesthesia.
28585..	4	Open treatment of closed or open talotarsal joint dislocation, with or without internal or external skeletal fixation.
28605..	1	Treatment of closed tarsometatarsal joint dislocation; requiring anesthesia.
28606..	2	Treatment of closed tarsometatarsal joint dislocation, with percutaneous skeletal fixation.
28615..	4	Open treatment of closed or open tarsometatarsal joint dislocation, with or without internal or external skeletal fixation.
28645..	4	Open treatment of closed or open metatarsophalangeal joint dislocation.
28670..	3	Treatment of open interphalangeal joint dislocation, with uncomplicated soft tissue closure.
28675..	4	Open treatment of closed or open interphalangeal joint dislocation.
Arthroscopy		
29870..	4	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure).
29874..	4	Arthroscopy, knee, surgical; for removal of loose body or foreign body (e.g., osteochondritis dissecans fragmentation, chondral fragmentation).
29875..	4	Arthroscopy, knee, surgical; synovectomy, limited (e.g., plica or shelf resection).
29876..	4	Synovectomy, major, two or more compartments (e.g., medial to lateral).
29877..	4	Debridement/shaving of articular cartilage (chondroplasty).
29881..	4	Arthroscopy, knee, surgical; with meniscectomy (medial or lateral including any meniscal shaving).
29887..	4	Drilling for intact osteochondritis dissecans lesion with internal fixation.
Respiratory System		
Nose		
Excision		
30116..	2	Excision, nasal polyp(s), extensive; bilateral.
30117..	2	Excision, intranasal lesion; internal approach.
30118..	2	Excision, intranasal lesion; external approach (lateral rhinotomy).
30125..	3	Excision dermoid cyst, nose; complex, under bone or cartilage.
30150..	4	Rhinectomy; partial.
30160..	4	Rhinectomy; total.
Removal Foreign Body		
30310..	1	Removal of foreign body, intranasal; requiring general anesthesia.
30320..	2	Removal foreign body; by lateral rhinotomy.
Repair		
30400..	4	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip.
30410..	4	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip.
30420..	4	Rhinoplasty, primary; including major septal repair.
30430..	4	Rhinoplasty, secondary; minor revision (small amount of nasal tip work).
30435..	4	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies).
30450..	4	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies).
30520..	4	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft.
30580..	4	Repair fistula; oromaxillary (combine with 31030 if antrotomy is included).
30600..	4	Repair fistula; oronasal.
Other Procedures		
30915..	4	Ligation arteries; ethmoidal.
30920..	4	Ligation arteries; internal maxillary artery, transantral. Accessory Sinuses
Incision		
31032..	4	Sinusotomy, maxillary (antrotomy); radical unilateral (Caldwell-Luc) with removal antrochoanal polyps.
31033..	4	Sinusotomy, maxillary (antrotomy); radical, bilateral (Caldwell-Luc) with removal antrochoanal polyps.
31070..	2	Sinusotomy frontal; external, simple (trephine operation). Larynx
Endoscopy		
31513..	2	Laryngoscopy, indirect (separate procedure); with vocal cord injection.
31527..	2	Laryngoscopy, direct; with insertion of obturator.

CPT-4 code	Payment group	Description
31528..	2	Laryngoscopy, direct; with dilatation, initial.
31576..	1	Laryngoscopy, flexible fiberoptic; with biopsy.
31577..	1	Laryngoscopy, flexible fiberoptic; with removal of foreign body.
31578..	1	Laryngoscopy, flexible fiberoptic; with removal of lesion. Trachea and Bronchi
Incision		
31600..	2	Tracheostomy, planned (separate procedure).
31612..	1	Tracheal puncture, percutaneous for aspiration of mucus (transtracheal aspiration).
31613..	2	Tracheostoma revision; simple, without flap rotation.
31614..	2	Tracheostoma revision; complex, with flap rotation.
Endoscopy		
31615..	1	Tracheobronchoscopy through established tracheostomy incision.
31622..	1	Bronchoscopy; diagnostic, (flexible original), with or without cell washing or brushing.
31628..	1	Bronchoscopy; with transbronchial lung biopsy, with or without fluoroscopic guidance.
31631..	1	Bronchoscopy; with tracheal dilation and placement of tracheal stent.
31641..	1	Bronchoscopy; with destruction of tumor or relief of stenosis by any method other than excision (eg. laser).
31646..	1	Bronchoscopy; with therapeutic aspiration of tracheobronchial tree, subsequent.
31656..	1	Bronchoscopy; with injection of contrast material for segmental bronchography (fiberscope only).
31659..	1	Bronchoscopy; with other bronchoscopic procedures.
Introduction		
31700..	1	Catheterization, transglottic (separate procedure).
31708..	1	Instillation of contrast material for laryngography or bronchography, without catheterization.
31710..	1	Catheterization for bronchography, with or without instillation of contrast material.
31715..	1	Transtracheal injection for bronchography.
31717..	1	Catheterization with bronchial brush biopsy.
31719..	1	Transtracheal (percutaneous) introduction of indwelling tube for therapy (tickle tube).
31720..	1	Catheter aspiration (separate procedure); nasotracheobronchial.
Cardiovascular System		
Repair, Ligation and Other Procedures		
37609..	1	Ligation or biopsy, temporal artery.
37735..	4	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia; unilateral.
37737..	4	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia; bilateral.
37760..	4	Ligation and perforators, subfascial, radical (Linton Type), with or without skin graft.
37785..	3	Ligation, division and/or excision of secondary varicose veins (clusters) of leg; unilateral.
37787..	3	Ligation, division and/or excision of secondary varicose veins (clusters) of leg; bilateral.
Hemic and Lymphatic System		
Lymph Nodes and Lymphatic Channels		
Incision		
38305..	1	Drainage of lymph node abscess or lymphadenitis; extensive.
38308..	1	Lymphangiectomy or other operations on lymphatic channels.
Excision		
38530..	3	Biopsy or excision of lymph node(s); internal mammary node(s) (separate procedure).
38542..	3	Dissection; deep jugular node(s).
38550..	3	Excision of cystic hygroma, axillary or cervical, without deep neurovascular dissection; simple.
38555..	4	Excision of cystic hygroma, axillary or cervical, without deep neurovascular dissection; complex.
Radical Lymphadenectomy (Radical Resection of Lymph Nodes)		
38700..	4	Suprahyoid lymphadenectomy; unilateral.
38701..	4	Suprahyoid lymphadenectomy; bilateral.
38740..	3	Axillary lymphadenectomy; superficial.
38745..	3	Axillary lymphadenectomy; complete.
38760..	3	Inguinofemoral lymphadenectomy, superficial, including Cloquet's node (separate procedure); unilateral.
38761..	3	Inguinofemoral lymphadenectomy, superficial, including Cloquet's node (separate procedure); bilateral.
Introduction		
38790..	1	Injection procedure for lymphangiography; unilateral.
38791..	1	Injection procedure for lymphangiography; bilateral.
Digestive System		
Lips		
Excision		
40525..	3	Excision lip; full thickness, reconstruction with local flap (Estlander or fan).
40527..	3	Excision lip; full thickness, reconstruction with cross lip flap (Abbe-Estlander).
40530..	3	Resection of lip, more than one-fourth, without reconstruction.
Repair (Cheiloplasty)		
40650..	3	Repair lip, full thickness; vermilion only.

CPT-4 code	Payment group	Description
40654.....		Repair lip, full thickness; over one as half vertical height, or complex. Vestibule of Mouth
Incision		
40801..	1	Drainage of abscess, cyst, hematoma, vestibule of mouth; complicated.
40805..	1	Removal of embedded foreign body; complicated
Excision, destruction		
40814..	2	Excision of lesion of mucosa and submucosa; with complex repair.
40816..	2	Excision of lesion of mucosa and submucosa; complex with excision of underlying muscle.
40818..	2	Excision of mucosa as donor graft
Repair		
40831..	2	Closure of laceration; over 2.6 cm or complex.
40840..	2	Vestibuloplasty; anterior.
40842..	2	Vestibuloplasty; posterior, unilateral.
40843..	2	Vestibuloplasty; posterior, bilateral.
40844..	3	Vestibuloplasty; entire arch.
40845..	4	Vestibuloplasty; complex.
Tongue, Floor of Mouth		
Excision		
41114..	2	Excision of lesion of tongue with closure; with local tongue flap.
41115..	1	Excision of lingual frenum (frenotomy).
41116..	1	Excision lesion of floor of mouth.
41120..	3	Glossectomy; less than one-half tongue.
Repair		
41251..	3	Repair laceration up to 2 cm; posterior one-third of tongue. Dentoalveolar Structures
Incision		
41806..	2	Removal embedded foreign body; from bone.
Excision, destruction		
41826..	2	Excision of lesion or tumor (except listed above); with simple repair.
41827..	3	Excision of lesion or tumor (except listed above); with complex repair. Palate, Uvula
Excision, destruction		
42104..	1	Excision, lesion of palate, uvula; without closure.
42106..	1	Excision, lesion of palate, uvula; with simple primary closure.
42107..	1	Excision, lesion of palate, uvula; with local flap closure.
42120..	2	Resection of palate or extensive resection of lesion.
42140..	2	Uvulectomy, excision of uvula.
Repair		
42182..	1	Repair laceration of palate; over 2 cm or complex. Salivary Gland and Ducts
Incision		
42305..	1	Drainage of abscess; parotid, complicated.
42320..	1	Drainage of abscess; submaxillary external.
42325..	2	Fistulization of sublingual salivary cyst (ranula).
42335..	2	Sialolithotomy; submandibular (submaxillary), complicated, intraoral.
42340..	2	Sialolithotomy; parotid, extraoral or complicated intraoral.
Excision		
42408..	2	Excision of sublingual salivary cyst (ranula).
42410..	4	Excision of parotid tumor or parotid gland; lateral lobe, without nerve dissection.
42440..	4	Excision of submandibular (submaxillary) gland.
42450..	4	Excision of sublingual gland.
Repair		
42500..	3	Plastic repair of salivary duct, sialodochoplasty; primary or simple.
42505..	4	Plastic repair of salivary duct, sialodochoplasty; secondary or complicated.
42507..	4	Parotid duct diversion, bilateral (Wilke type procedure).
42508..	4	Parotid duct diversion, bilateral (Wilke type procedure); with excision of one submandibular gland.
42509..	4	Parotid duct diversion, bilateral (Wilke type procedure); with excision of both submandibular glands.
Other procedures		
42600..	1	Closure salivary fistula.
42665..	1	Ligation salivary duct, intraoral. Pharynx, Adenoids, and Tonsils
Incision		
42720..	1	Incision and drainage abscess; retropharyngeal or parapharyngeal, intraoral approach.
42725..	1	Incision and drainage abscess; retropharyngeal or parapharyngeal, external approach.

CPT-4 code	Payment group	Description
Excision		
42806..	2	Biopsy; nasopharynx, survey for unknown primary lesion.
42808..	1	Excision of lesion of pharynx.
42860..	2	Excision of tonsil tags.
42870..	2	Excision lingual tonsil (separate procedure).
42880..	2	Excision nasopharyngeal lesion (e.g., fibroma).
Repair		
42900..	2	Suture pharynx for wound or injury.
42950..	4	Pharyngoplasty (plastic or reconstructive operation on pharynx).
Other procedures		
42955..	2	Pharyngostomy (fistulization of pharynx, external for feeding). Esophagus
Endoscopy		
43204..	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for injection sclerosis of esophageal varices.
43219..	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for insertion of plastic tube or stent.
43226..	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for insertion of wire to guide dilation.
43227..	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
43228..	1	Esophagoscopy, rigid or flexible fiberoptic (specify); for ablation of tumor or mucosal lesion.
43235..	1	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; complex diagnostic.
43239..	1	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for biopsy and/or collection of specimen by brushing or washing.
43247..	1	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for removal of foreign body.
43251..	1	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for removal of polypoid lesion(s).
43255..	1	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
43258..	1	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; for ablation of tumor or mucosal lesion (e.g., electrocoagulation, with laser photocoagulation).
43260..	2	Endoscopic retrograde cholangiopancreatography (ERCP), with or without specimen collection.
43262..	2	Endoscopic retrograde cholangiopancreatography (ERCP), with or without specimen collection; for sphincterotomy/papillotomy.
43263..	2	Endoscopic retrograde cholangiopancreatography (ERCP), with or without specimen collection; for pressure measurement of sphincter of Oddi.
43264..	2	Endoscopic retrograde cholangiopancreatography (ERCP), with or without specimen collection; for removal of stone(s) from biliary and/or pancreatic ducts.
Manipulation		
43450..	1	Dilation of esophagus, by unguided sound or bougie single or multiple passes; initial session.
43451..	1	Dilation of esophagus, by unguided sound or bougie single or multiple passes; subsequent session.
43453..	1	Dilation of esophagus, over guide wire or string.
43455..	1	Dilation of esophagus, by balloon or Stark dilator.
43456..	1	Dilation of esophagus by balloon or Stark dilator; retrograde. Intestines (Except Rectum)
Enterostomy-external fistulization of intestines (separate procedure)		
44345..	4	Revision of colostomy; complicated reconstruction in depth.
44346..	4	Revision of colostomy; with repair of paracolostomy Lemia.
Endoscopy, small bowel and stomal		
44360..	1	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; diagnostic.
44361..	1	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for biopsy and/or collection of specimen by brushing or washing.
44363..	1	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for removal of foreign body.
44364..	1	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for removal of polypoid lesion(s).
44366..	1	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
44369..	1	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum; for ablation of tumor or mucosal lesion (e.g., laser).
44380..	1	Fiberoptic ileoscopy through stoma.
44382..	1	Fiberoptic ileoscopy through stoma; with biopsy and/or collection of specimen by brushing or washing.
44388..	1	Fiberoptic colonoscopy through colostomy.
44389..	1	Fiberoptic colonoscopy through colostomy; for biopsy and/or collection of specimen by brushing or washing.
44390..	1	Fiberoptic colonoscopy through colostomy; for removal of foreign body.
44391..	1	Fiberoptic colonoscopy through colostomy; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
44392..	1	Fiberoptic colonoscopy through colostomy; for removal of polypoid lesion(s). Rectum
Incision		
45000..	3	Transrectal drainage of pelvic abscess.

CPT-4 code	Payment group	Description
45005..	1	Incision and drainage of submucosal abscess, rectum.
45020..	2	Incision and drainage of deep supralelevator, pelvirectal, or retrorectal abscess.
Excision		
45170..	3	Excision of rectal tumor, simple, transanal approach.
45180..	3	Excision and/or electrodesiccation of malignant tumor of rectum, transanal approach; palliative.
45181..	3	Excision and/or electrodesiccation of malignant tumor of rectum, transanal approach; therapeutic.
Endoscopy		
45355..	1	Colonoscopy, with standard sigmoidoscope, transabdominal via colotomy, single or multiple.
45360..	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; diagnostic procedure.
45365..	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for biopsy and/or collection of specimen by brushing or washing.
45367..	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for removal of foreign body.
45368..	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
45370..	1	Colonoscopy, fiberoptic, beyond 25 cm to splenic flexure; for removal of polypoid lesion(s).
45378..	1	Colonoscopy, fiberoptic, beyond splenic flexure; diagnostic procedure.
45379..	1	Colonoscopy, fiberoptic, beyond splenic flexure; for removal of foreign body.
45380..	1	Colonoscopy, fiberoptic, beyond splenic flexure; for biopsy and/or collection of specimen by brushing or washing.
45382..	1	Colonoscopy, fiberoptic, beyond splenic flexure; for control of hemorrhage (e.g., electrocoagulation, laser photocoagulation).
45385..	1	Colonoscopy, fiberoptic, beyond splenic flexure; for removal of polypoid lesion(s).
Repair		
45500..	4	Proctoplasty; for stenosis.
45505..	4	Proctoplasty; for prolapse of mucous membrane.
45521..	1	Perirectal injection of sclerosing solution for prolapse; hospital.
45560..	4	Repair of rectocele (separate procedure).
Manipulation		
45900..	1	Reduction of procidentia (separate procedure) under anesthesia.
45915..	1	Removal of fecal impaction or foreign body (separate procedure) under anesthesia.
Anus		
Incision		
46000..	2	Fistulotomy, subcutaneous.
46040..	2	Incision and drainage of ischioirectal and/or perirectal abscess (separate procedure).
46045..	2	Incision and drainage of intramural, intramuscular or submucosal abscess, transanal, under anesthesia.
46080..	2	Sphincterotomy, anal, division of sphincter (separate procedure).
Excision		
46200..	2	Fissurectomy, with or without sphincterotomy.
46211..	2	Cryptectomy; multiple (separate procedure).
46260..	2	Hemorrhoidectomy, internal and external, complex or extensive.
46261..	2	Hemorrhoidectomy, internal and external, complex or extensive; with fissurectomy.
46285..	2	Fistulectomy; second stage.
Anus		
Introduction		
46750..	4	Sphincteroplasty, anal, for incontinence or prolapse; adult.
46753..	4	Graft (Thiersch operation) for rectal incontinence and/or prolapse.
46754..	4	Removal of Thiersch wire or suture.
46760..	4	Sphincteroplasty, anal, for incontinence, adult, muscle transplant.
Destruction		
46924..	1	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), extensive, any method.
46937..	2	Cryosurgery of rectal tumor; benign.
46938..	2	Cryosurgery of rectal tumor; malignant.
Abdomen, Peritoneum, and Omentum		
Incision		
49000..	4	Exploratory laparotomy, exploratory celiotomy (separate procedure).
Endoscopy		
49302..	4	Peritoneoscopy with guided transhepatic cholangiography; without biopsy.
49303..	1	Peritoneoscopy with guided transhepatic cholangiography; with biopsy.
Introduction		
49400..	1	Pneumoperitoneum; initial.
49401..	1	Pneumoperitoneum; subsequent.
49420..	1	Insertion of intraperitoneal cannula or catheter for drainage or dialysis; temporary.
49421..	1	Insertion of intraperitoneal cannula or catheter for drainage or dialysis; permanent.
49425..	1	Peritoneal-venous shunt (e.g., Le Vein shunt).
49426..	1	Revision of peritoneal-venous shunt.
Repair		

CPT-4 code	Payment group	Description
Hernioplasty, Herniorrhaphy, Herniotomy		
49510..	4	Repair inguinal hernia, age 5 or over; with orchiectomy, with or without implantation of prosthesis.
49540..	4	Repair lumbar hernia.
49552..	4	Repair femoral hernia, Henry approach.
49570..	4	Repair epigastric hernia, peritoneal fat (separate procedure); simple.
49575..	4	Repair epigastric hernia, peritoneal fat (separate procedure); complex.
49581..	4	Repair umbilical hernia; age 5 or over.
49590..	4	Repair spigelian hernia.
Urinary System		
Kidney		
Incision		
50020..	3	Drainage of perirenal or renal abscess (separate procedure).
50040..	4	Nephrostomy, nephrotomy with drainage.
Excision		
50200..	1	Renal biopsy, percutaneous by trocar or needle.
50205..	4	Renal biopsy, percutaneous; by surgical exposure of kidney.
Introduction		
50390..	1	Aspiration and/or injection of renal cyst or pelvis by needle, percutaneous.
50392..	1	Introduction of intracatheter or catheter into renal pelvis for drainage and/or injection, percutaneous.
50393..	1	Introduction of ureteral catheter or stent into ureter through renal pelvis for drainage and/or injection, percutaneous.
50394..	1	Injection procedure for pyelography (as nephrostogram, pyelostogram, antegrade pyeloureterograms) through nephrostomy or pyelostomy tube, or indwelling ureteral catheter (separate procedure).
50396..	1	Manometric studies through nephrostomy or pyelostomy tube, or indwelling ureteral catheter.
50398..	1	Change of nephrostomy or pyelostomy tube.
Endoscopy		
50553..	1	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50559..	1	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance with or without biopsy and/or fulguration.
50561..	1	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus.
50570..	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service.
50572..	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50576..	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration, with or without biopsy.
50578..	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance, with or without biopsy and/or fulguration.
50580..	1	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus.
Ureter		
Introduction		
50684..	1	Injection procedure for ureterography or ureteropyelography through ureterostomy or indwelling ureteral catheter (separate procedure).
50690..	1	Injection procedure for visualization of ilial conduit and/or ureteropyelography, exclusive of radiologic service (separate procedure).
Endoscopy		
50953..	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50955..	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy.
50957..	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration, with or without biopsy.
50959..	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance with or without biopsy and/or fulguration (not including provision of material).
50961..	1	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus.
50970..	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service.
50972..	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization.
50974..	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy.

CPT-4 code	Payment group	Description
50976..	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration, with or without biopsy.
50978..	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with insertion of radioactive substance, with or without biopsy and/or fulguration (not including provision of material).
50980..	1	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus. Bladder
Incision		
51005..	1	Aspiration of bladder; by trocar or intracatheter.
51010..	1	Aspirations of bladder; with insertion of suprapubic catheter.
Introduction		
51600..	1	Injection procedure for cystography or voiding urethrocytography.
51605..	1	Injection procedure and placement of chain for contrast and/or chain urethrocytography.
51610..	1	Injection procedure for retrograde urethrocytography.
51710..	1	Change of cystostomy tube; complicated. Bladder
Repair		
51865..	4	Cystorrhaphy, suture of bladder wound, injury or rupture; complicated.
51900..	4	Closure of vesicovaginal fistula, abdominal approach. Ureter
Endocopy-cystoscopy, urethroscopy cystourethroscopy notes		
52005..	1	Cystourethroscopy; with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service.
52007..	1	Cystourethroscopy; with ureteral catheterization and brush biopsy of ureter and/or renal pelvis.
52010..	1	Cystourethroscopy; with ejaculatory duct catheterization, with or without irrigation, instillation, or duct radiography, exclusive of radiologic service. Bladder
Transurethral surgery (urethra, and bladder)		
52204..	3	Cystourethroscopy, with biopsy.
52214..	3	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands.
52224..	3	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of MINOR (less than 0.5 cm) lesion(s), with or without biopsy.
52234..	3	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; SMALL bladder tumor(s) (0.5 to 2.0 cm).
52235..	3	Cystourethroscopy, with fulguration (including cryosurgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm).
52240..	3	Cystourethroscopy, with fulguration (including cryosurgery) and/or resection of; LARGE bladder tumor(s).
52250..	3	Cystourethroscopy, with insertion of radioactive substance, with or without biopsy or fulguration.
52260..	3	Cystourethroscopy, with dilation of bladder for interstitial cystitis; general or conduction (spinal) anesthesia.
52270..	3	Cystourethroscopy, with internal urethrotomy; female.
52275..	3	Cystourethroscopy, with internal urethrotomy; male.
52276..	3	Cystourethroscopy with direct vision internal urethrotomy.
52277..	3	Cystourethroscopy, with resection of external sphincter (sphincterotomy).
52281..	3	Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy and injection procedure for cystography, male or female.
52283..	3	Cystourethroscopy, with steroid injection into stricture.
52285..	3	Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: urethral meatotomy, urethral dilation, internal urethrotomy, lysis of urethrovaginal septal fibrosis, lateral incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone.
52290..	3	Cystourethroscopy; with ureteral meatotomy, unilateral or bilateral.
52300..	3	Cystourethroscopy; with resection or fulguration of ureterocele(s), unilateral or bilateral.
52305..	3	Cystourethroscopy; with incision or resection of orifice of bladder diverticulum, single or multiple.
52310..	4	Cystourethroscopy, with removal of foreign body calculus or ureteral stent from urethra or bladder; simple.
52315..	4	Cystourethroscopy, with removal of foreign body calculus or ureteral stent from urethra or bladder; complicated.
52317..	4	Litholapaxy: crushing of fragmentation or calculus by any means in bladder and removal of fragments simple; small (less than 2.5 c.m.).
52318..	4	Litholapaxy: crushing of fragmentation or calculus by any means in bladder and removal of fragments, simple; complicated or large (over 2.5 c.m.).
52320..	4	Cystourethroscopy (including ureteral catheterization); with removal of ureteral calculus.
52330..	4	Cystourethroscopy (including ureteral catheterization); with manipulation, without removal of ureteral calculus.
52332..	4	Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type).
52335..	3	Cystourethroscopy, with ureteroscopy and/or pyeloscopy (includes dilation of the ureter by any method).
Transurethral surgery (vesical neck and prostate)		
52340..	3	Cystourethroscopy with incision, fulguration, or resection of bladder neck and/or posterior urethra (congenital valves, obstructive hypertrophic mucosal folds).
52500..	3	Transurethral resection of bladder neck (separate procedure).
Transurethral surgery (urethra and bladder)		

CPT-4 code	Payment group	Description
52601..	4	Transurethral resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included).
52606..	4	Transurethral fulguration for postoperative bleeding occurring after the usual follow-up time.
52612..	4	Transurethral resection of prostate; first stage of two-stage resection (partial resection).
52614..	4	Transurethral resection of prostate; second stage of two-stage resection (resection completed).
52620..	4	Transurethral resection; of residual obstructive tissue after 90 days postoperative.
52630..	4	Transurethral resection; of regrowth of obstructive tissue longer than one year postoperative.
52640..	4	Transurethral resection; of postoperative bladder neck contracture.
52650..	4	Transurethral cryosurgical removal of prostate (postoperative irrigations and aspiration of sloughing tissue included).
52700..	4	Transurethral drainage of prostatic abscess.
		Urethra
Incision		
53000..	2	Urethrotomy or urethrostomy, external (separate procedure); pendulous urethra.
53010..	2	Urethrotomy or urethrostomy, external (separate procedure); perineal urethra, external.
53020..	2	Meatotomy, cutting of meatus (separate procedure); except infant.
53040..	2	Drainage of deep periurethral abscess.
Excision		
53220..	3	Excision or fulguration of carcinoma of urethra.
53230..	3	Excision of urethral diverticulum (separate procedure); female.
53235..	3	Excision of urethral diverticulum (separate procedure); male.
53240..	3	Marsupialization of urethral diverticulum, male or female.
53265..	3	Excision or fulguration; urethral caruncle.
53275..	3	Excision or fulguration; urethral prolapse.
Repair		
53400..	4	Urethroplasty; first stage, for fistula, diverticulum, or stricture, e.g., Johannsen type.
53405..	4	Urethroplasty; second stage (formation of urethra), including urinary diversion.
53410..	4	Urethroplasty, one-stage reconstruction of male anterior urethra.
53420..	4	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; first stage.
53425..	4	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; second stage.
53430..	4	Urethroplasty, reconstruction of female urethra.
53440..	4	Operation for correction of male urinary incontinence, with or without introduction of prosthesis.
53447..	4	Removal, repair or replacement of inflatable sphincter including pump and/or reservoir and/or cuff.
53449..	4	Surgical correction of hydraulic abnormality of inflatable sphincter device.
53450..	4	Urethromeatoplasty, with mucosal advancement.
53460..	4	Urethromeatoplasty, with partial excision of distal urethral segment (Richardson type procedure).
Suture		
53502..	4	Urethrorrhaphy, suture of urethral wound or injury, female.
53510..	4	Urethrorrhaphy, suture of urethral wound or injury; perineal.
53515..	4	Urethrorrhaphy, suture of urethral wound or injury; prostatomembranous.
53520..	4	Closure of urethrostomy or urethrocutaneous fistula, male (separate procedure).
		Male Genital System
		Penis
Incision		
54001..	1	Slitting of prepuce, dorsal or lateral (separate procedure); except newborn.
Excision		
54105..	1	Biopsy of penis; deep structures.
54110..	3	Excision of penile plaque (Peyronie disease).
54115..	3	Removal of foreign body from deep penile tissue (e.g., plastic implant).
54120..	3	Amputation of penis; partial.
54125..	4	Amputation of penis; complete.
54152..	2	Circumcision, clamp procedure; except newborn.
54161..	2	Circumcision, surgical excision other than clamp or dorsal slit; except newborn.
Introduction		
54205..	1	Injection procedure for Peyronie disease; with surgical exposure of plaque.
54220..	1	Irrigation of corpora cavernosa for priapism.
54230..	1	Injection procedure for corpora cavernosography.
Repair		
54440..	4	Plastic operation of penis for injury.
		Testis
Excision		
54505..	1	Biopsy of testis, incisional (separate procedure; unilateral).
54506..	1	Bilateral.
54510..	1	Excision of local lesion of testis.
54530..	3	Orchiectomy, radical, for tumor; inguinal approach.
Repair		
54670..	2	Suture or repair of testicular injury.

CPT-4 code	Payment group	Description
54680..	4	Transplantation of testis(es) to thigh (because of scrotal destruction). Epididymis
Excision		
54700..	2	Incision and drainage of epididymis, testis and/or scrotal space (e.g., abscess or hematoma).
54820..	1	Exploration of epididymis, with or without biopsy.
54830..	2	Excision of local lesion of epididymis.
54860..	3	Epididymectomy; unilateral.
54861..	3	Epididymectomy; bilateral.
Repair		
54900..	3	Epididymovasostomy, anastomosis of epididymis to vas deferens; unilateral.
54901..	3	Epididymovasostomy, anastomosis of epididymis to vas deferens; bilateral. Tunica vaginalis
Repair		
55060..	3	Repair of hydrocele (Bottle type).
Incision		
55120..	1	Removal of foreign body in scrotum. Scrotum
Excision		
55150..	3	Resection of scrotum.
Repair		
55175..	3	Scrotoplasty; simple.
55180..	3	Scrotoplasty; complicated. Vas deferens
Repair		
55400..	3	Vasovasostomy, vasovasorrhaphy; unilateral.
55401..	3	Vasovasostomy, vasovasorrhaphy; bilateral. Spermatic cord
Excision		
55500..	3	Excision of hydrocele of spermatic cord, unilateral (separate procedure).
55520..	3	Excision of lesion of spermatic cord (separate procedure).
55535..	4	Excision of varicocele or ligation of spermatic veins for varicocele; abdominal approach.
55540..	4	Excision of varicocele or ligation of spermatic veins for varicocele; with hernia repair. Seminal vesicles
Incision		
55605..	1	Vesiculotomy; complicated.
Excision		
55650..	4	Vesiculectomy, any approach; unilateral.
55651..	4	Vesiculectomy, any approach; bilateral.
55680..	4	Excision of Mullerian duct cyst. Prostate
Incision		
55720..	1	Prostatotomy, external drainage of prostatic abscess, any approach; simple. Female Genital System Vagina
Perineum		
56000..	2	Incision and drainage of perineal abscess (nonobstetrical). Vulva and introitus
Incision		
56440..	3	Marsupialization of Bartholin's gland cyst.
Destruction		
56515..	3	Destruction of lesion(s), vulva; extensive, any method.
Excision		
56740..	3	Excision of Bartholin's gland or cyst. Vagina
Incision		
57020..	1	Colpocentesis (separate procedure).
Excision		
57105..	3	Biopsy of vaginal mucosa; extensive, requiring suture (including cysts).
57103..	3	Excision of vaginal septum.
Repair		

CPT-4 code	Payment group	Description
57268..	4	Repair of enterocele, vaginal approach (separate procedure). Cervix uteri
Excision		
57520..	2	Biopsy of cervix, circumferential (cone), with or without dilation and curettage, with or without Sturmdorff type repair.
Repair		
57720..	3	Trachelorrhaphy, plastic repair of uterine cervix, vaginal approach.
Manipulation		
57820..	2	Dilation and curettage of cervical stump. Ovary
Excision		
58900..	4	Biopsy of ovary, unilateral or bilateral (separate procedure). Endocrine System Thyroid gland
Excision		
60200..	3	Excision of cyst or adenoma of thyroid, or transection of isthmus.
60220..	4	Total thyroid lobectomy, unilateral.
60225..	4	Total thyroid lobectomy, unilateral; with contralateral subtotal lobectomy, including isthmus. Nervous System Skull, Meninges, and Brain
Puncture for injection, drainage or aspiration		
61020..	1	Ventricular puncture through previous burr hole, frontanelle, suture, or implanted ventricular catheter/reservoir; without injection.
61026..	1	Ventricular puncture through previous burr hole, frontanelle, suture, or implanted ventricular catheter/reservoir; with injection of drug or other substance for diagnosis or treatment.
61050..	1	Cisternal or lateral cervical puncture; without injection (separate procedure).
61070..	1	Puncture of shunt tubing or reservoir for aspiration or injection procedure. Spine and Spinal Cord
Puncture for injection, drainage, or aspiration		
62270..	1	Spinal puncture, lumbar diagnostic.
62273..	1	Injection, lumbar epidural, of blood or clot patch.
62274..	1	Injection of anesthetic substance, diagnostic or therapeutic; subarachnoid or subdural, simple.
62276..	1	Injection of anesthetic substance, diagnostic or therapeutic; subarachnoid or subdural, differential.
62277..	1	Injection of anesthetic substance, diagnostic or therapeutic; subarachnoid or subdural, continuous.
62278..	1	Injection of anesthetic substance, diagnostic or therapeutic; epidural or caudal, single.
62279..	1	Injection of anesthetic substance, diagnostic or therapeutic; epidural or caudal, continuous.
62288..	1	Injection of substance other than anesthetic, contrast, or neurolytic solutions; subarachnoid (separate procedure).
62289..	1	Injection of substance other than anesthetic, contrast, or neurolytic solutions; epidural or caudal. Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System
Introduction/injection of anesthetic agent (nerve block), diagnostic or therapeutic—somatic nerves		
64408..	1	Injection, anesthetic agent; vagus nerve.
64410..	1	Injection, anesthetic agent; phrenic nerve.
64415..	1	Injection, anesthetic agent; brachial plexus.
64417..	1	Injection, anesthetic agent; axillary nerve.
64420..	1	Injection, anesthetic agent; intercostal nerve, single.
64421..	1	Injection, anesthetic agent; intercostal nerves, multiple, regional block.
64430..	1	Injection, anesthetic agent; pudendal nerve.
64442..	1	Injection, anesthetic agent; paravertebral facet joint nerve, lumbar, single level.
64443..	1	Injection, anesthetic agent; paravertebral facet joint nerve, lumbar, each additional level.
Sympathetic nerves		
64510..	2	Injection, anesthetic agent; stellate ganglion (cervical sympathetic).
64520..	2	Injection, anesthetic agent; lumbar or thoracic (paravertebral sympathetic).
64530..	2	Injection, anesthetic agent; celiac plexus, with or without radiologic monitoring.
Destruction by neurolytic agent (eg, chemical, thermal, electrical, radiofrequency)—somatic nerves		
64600..	2	Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch.
64605..	2	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale.
64610..	2	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale under radiologic monitoring.
64622..	2	Destruction by neurolytic agent; paravertebral facet joint nerve, lumbar, single level.
64630..	2	Destruction by neurolytic agent; pudendal nerve.
Exploration, neurolysis or nerve decompression (neuroplasty)		
64712..	3	Neurolysis, major peripheral nerve, arm or leg; sciatic nerve.
64713..	3	Neurolysis, major peripheral nerve, arm or leg; brachial plexus.
64714..	3	Neurolysis, major peripheral nerve, arm or leg; lumbar plexus.
64722..	3	Decompression; unspecified nerve(s) (specify).
64726..	3	Decompression; plantar digital nerve.

CPT-4 code	Payment group	Description
64727..	4	Internal neurolysis by dissection, with or without microdissection (list separately in addition to code for primary neuroplasty).
Transection or avulsion of nerve		
64732..	3	Transection or avulsion of; supraorbital nerve.
64734..	3	Transection or avulsion of; infraorbital nerve.
64736..	3	Transection or avulsion of; mental nerve.
64738..	3	Transection or avulsion of; inferior alveolar nerve by osteotomy.
64740..	3	Transection or avulsion of; lingual nerve.
64742..	3	Transection or avulsion of; facial nerve, differential or complete.
64744..	3	Transection or avulsion of; greater occipital nerve.
64772..	3	Transection or avulsion of other spinal nerve, extradural.
Excision-somatic nerves		
64774..	3	Excision of neuroma; cutaneous nerve, surgically identifiable.
64776..	3	Excision of neuroma; digital nerve, one or both, same digit.
64778..	3	Excision of neuroma; digital nerve, each additional digit (list separately by this number).
64782..	3	Excision of neuroma; hand or foot, except digital nerve.
64784..	3	Excision of neuroma; major peripheral nerve, except sciatic.
64786..	3	Excision of neuroma; sciatic nerve.
64787..	3	Insertion of plastic cap on nerve end.
64788..	3	Excision of neurofibroma or neurolemmoma; cutaneous nerve.
64790..	3	Excision of neurofibroma or neurolemmoma; major peripheral nerve.
64795..	3	Biopsy of nerve.
Excision-sympathetic nerves		
64802..	4	Sympathectomy, cervical; unilateral.
64803..	4	Sympathectomy, cervical; bilateral.
Nerve repair by suture (neurorrhaphy)		
64830..	4	Microdissection and/or microrepair of nerve (list separately in addition to code for nerve repair).
64831..	4	Suture of digital nerve, hand or foot; one nerve.
64832..	4	Suture of digital nerve, hand or foot; each additional digital nerve.
64834..	4	Suture of one nerve, hand or foot; common sensory nerve.
64835..	4	Suture of one nerve, hand or foot; median motor thenar.
64836..	4	Suture of one nerve, hand or foot; ulnar motor.
64837..	4	Suture of each additional nerve, hand or foot.
64840..	4	Suture of posterior tibial nerve.
64856..	4	Suture of major peripheral nerve, arm or leg, except sciatic; including transportation.
64857..	4	Suture of major peripheral nerve, arm or leg, except sciatic; without transposition.
64872..	4	Suture of nerve; requiring secondary or delayed suture (list separately in addition to code for primary neurorrhaphy).
64874..	4	Suture of nerve; requiring extensive proximal mobilization, or transposition of nerve (list separately in addition to code for nerve suture).
64876..	4	Suture of nerve; requiring shortening of bone of extremity (list separately in addition to code for nerve suture).
Neurorrhaphy with nerve graft		
64890..	4	Nerve graft (includes obtaining graft), single strand, hand or foot; up to 4 cm length.
64891..	4	Nerve graft (includes obtaining graft), single strand, hand or foot; more than 4 cm length.
64892..	4	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length.
64893..	4	Nerve graft (includes obtaining graft), single strand, arm or leg; more than 4 cm length.
64895..	4	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; up to 4 cm length.
64896..	4	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length.
64897..	4	Nerve graft (includes obtaining graft), multiple strands (cable), arm or leg; up to 4 cm length.
64898..	4	Nerve graft (includes obtaining graft), multiple strands (cable), arm or leg; more than 4 cm length.
64901..	4	Nerve graft, each additional nerve; single strand.
64902..	4	Nerve graft, each additional nerve; multiple strands (cable).
64905..	4	Nerve pedicle transfer; first stage.
64907..	4	Nerve pedicle transfer; second stage.
Eye/Ocular Adnexa		
Eyeball		
Removal of eye		
65110..	4	Exenteration of orbit (does not include skin graft), removal of orbital contents; only.
Secondary implant procedures		
65130..	3	Insertion of ocular implant secondary; after evisceration, in scleral shell.
65135..	3	Insertion of ocular implant secondary; after enucleation, muscles not attached to implant.
65140..	3	Insertion of ocular implant secondary; after enucleation muscles attached to implant.
65150..	3	Reinsertion of ocular implant; with or without conjunctival graft.
65155..	3	Reinsertion of ocular implant; with use of foreign material for reinforcement and/or attachment of muscles to implant.
65175..	3	Removal of ocular implant.
Removal of ocular foreign body		
65245..	4	Removal of foreign body, intraocular; from lens (without extraction lens), nonmagnetic extraction.
65260..	4	Removal of foreign body, intraocular; from posterior segment, magnetic extraction, anterior or posterior route.
65265..	4	Removal of foreign body, intraocular; from posterior segment, nonmagnetic extraction.

CPT-4 code	Payment group	Description
Repair of laceration of eyeball		
65272..	2	Repair of laceration; conjunctiva, by mobilization and rearrangement, without hospitalization.
65280..	4	Repair of laceration; cornea and/or sclera, perforating, not involving uveal tissue.
65285..	4	Repair of laceration; cornea and/or sclera, perforating, with reposition or resection of uveal tissue.
65290..	3	Repair of wound, extraocular muscle, tendon and/or Tenon's capsule.
		Anterior Segment—Cornea
Excision		
65400..	1	Excision of lesion, cornea (keratectomy, lamellar, partial), except pterygium.
65410..	1	Biopsy of cornea.
65426..	1	Excision or transposition of pterygium, with graft.
Keratoplasty		
65710..	4	Keratoplasty (corneal transplant), lamellar; autograft.
65720..	4	Keratoplasty (corneal transplant), lamellar; homograft, fresh.
65725..	4	Keratoplasty (corneal transplant), lamellar; homograft, preserved.
65730..	4	Keratoplasty (corneal transplant), penetrating (except in aphakia); autograft.
65740..	4	Keratoplasty (corneal transplant), penetrating (except in aphakia); homograft, fresh.
65745..	4	Keratoplasty (corneal transplant), penetrating (except in aphakia); homograft, preserved.
65750..	4	Keratoplasty (corneal transplant), penetrating, in aphakia.
		Anterior Segment—Anterior Chamber
Incision		
65800..	1	Paracentesis of anterior chamber of eye (separate procedure); with diagnostic aspiration of aqueous.
65805..	1	Paracentesis of anterior chamber of eye (separate procedure); with therapeutic release of aqueous.
65810..	4	Paracentesis of anterior chamber of eye (separate procedure); with removal of vitreous and/or dissection of anterior hyaloid membrane, with or without air injection.
65815..	1	Paracentesis of anterior chamber of eye (separate procedure); with removal of blood, with or without irrigation and/or air injection.
Other Procedures		
65865..	1	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); goniosynechia.
65870..	1	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); anterior synechia, except goniosynechia.
65875..	1	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); posterior synechia.
65880..	1	Severing adhesions of anterior segment of eye, incisional technique (with or without injection of air or liquid) (separate procedure); corneovitreal adhesions.
65900..	4	Removal of epithelial downgrowth, anterior chamber eye.
65920..	4	Removal of implanted material, anterior segment eye.
65930..	4	Removal of blood clot, anterior segment eye.
66020..	1	Injection, anterior chamber (separate procedure); air or liquid.
66030..	1	Injection, anterior chamber (separate procedure); medication.
		Anterior Segment—Anterior Sclera
Excision		
66130..	4	Excision of lesion, sclera.
66150..	4	Fistulization of sclera for glaucoma; trephination with iridectomy.
66155..	4	Fistulization of sclera for glaucoma; thermocauterization with iridectomy.
66160..	4	Fistulization of sclera for glaucoma; sclerotomy with punch of scissors, with iridectomy.
66165..	4	Fistulization of sclera for glaucoma; iridencleisis or iridotaxis.
66170..	4	Fistulization of sclera for glaucoma; trabeculectomy ab externo
Repair		
66220..	4	Repair of scleral staphyloma; without graft.
66225..	4	Repair of scleral staphyloma; with graft.
Revision Operation Wound		
66250..	4	Revision or repair of operative wound of anterior segment, any type, early or late, major or minor procedure.
		Anterior Segment—Iris, Ciliary Body
Iridotomy, Iridectomy		
66500..	1	Iridotomy by stab incision (separate procedure); except transfixion.
66505..	1	Iridotomy by stab incision (separate procedure); with transfixion as for iris bombe.
66605..	3	Iridectomy with corneoscleral or corneal section; with cyclotherapy.
Repair		
66680..	4	Repair of iris, ciliary body (as for iridodialysis).
66682..	4	Suture of iris, ciliary body (separate procedure) with retrieval of suture through small incision (e.g., McCannel suture).
Destruction		
66700..	1	Cyclodiathermy; initial.
66701..	1	Cyclodiathermy; subsequent.
66720..	1	Cyclocryotherapy; initial.
66721..	3	Cyclocryotherapy; subsequent.

CPT-4 code	Payment group	Description
66741..	3	Cyclodialysis; subsequent.
66762..	3	Coreoplasty by photocoagulation (one or more sessions) (eg, for improvement of vision). Anterior Segment-Lens
Incision		
66821..	1	Discission of secondary membranous cataract ("after cataract") and/or anterior hyaloid; laser surgery (one or more stages).
Removal Cataract		
66915..	4	Expression of lens, linear, one or more stages.
66945..	4	Extraction of lens with or without iridectomy in presence of fistulization bleb and/or by temporal, inferior or inferotemporal route, intracapsular or extracapsular.
66984..	4	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or phacoemulsification technique.
Posterior Segment-Vitreous		
67005..	4	Removal of vitreous, anterior approach (open sky technique of limbal incision); partial removal.
67010..	4	Removal of vitreous, anterior approach (open sky technique of limbal incision); subtotal removal with mechanical vitrectomy (such as VISC or Rotoextractor).
67015..	2	Aspiration or release of vitreous, subretinal or choroidal fluid, pars plana approach (posterior sclerotomy).
67025..	2	Injection of vitreous substitute, pars plana approach (separate procedure) excludes air or balanced salt solutions.
67030..	2	Discission of vitreous strands (without removal), pars plana approach.
67036..	4	Virectomy, mechanical, pars plana approach. Posterior Segment-Retinal Detachment
Repair		
67101..	4	Repair of retinal detachment, one or more sessions, same hospitalization, cryotherapy or diathermy, with or without drainage or subretinal fluid.
67107..	4	Repair of retinal detachment (one or more stages, same hospitalization); scleral buckling (such as lamella excision, imbrication or encircling procedure), with or without implant, may include procedures 67101-67105.
67108..	4	Repair of retinal detachment (one or more stages, same hospitalization); with vitrectomy, any method, with or without air tamponade, may include procedures 67101-67107 and/or removal of lens by same technique.
67109..	4	Repair of retinal detachment (one or more stages, same hospitalization); by technique other than 67101-67108.
67120..	4	Removal of implanted material, posterior segment, extraocular. Posterior Segment-Other Procedures
Destruction-Retina, Choroid		
67208..	1	Destruction of localized lesion of retina (e.g., maculopathy, choroidopathy, small tumors), one or more sessions; cryotherapy, diathermy.
67218..	1	Destruction of localized lesion of retina or choroid (e.g., choroidopathy), one or more stages; radiation by implantation of source (includes removal of source).
67227..	1	Destruction of extensive or progressive retinopathy (e.g., diabetic retinopathy), one or more sessions; cryotherapy, diathermy.
Scleral Repair		
67250..	4	Scleral reinforcement (separate procedure); without graft.
67255..	4	Scleral reinforcement (separate procedure); with graft. Ocular Adnexa-Extraocular Muscles
67320..	3	Transposition of extraocular muscle (e.g., for paretic muscle), one or more stages, one or more muscles, with displacement of plane of action more than 5mm.
67331..	3	Strabismus surgery on patient previously operated on; not involving reoperation of muscles.
67332..	3	Strabismus surgery on patient previously operated on; involving reoperation of muscles.
Other Procedures		
67350..	3	Biopsy of extraocular muscle. Ocular Adnexa-Orbit
Exploration, Excision		
67400..	4	Orbitotomy without bone flap (frontal approach); for exploration, with or without biopsy.
67405..	4	Orbitotomy without bone flap (frontal approach); with drainage only.
67412..	4	Orbitotomy without bone flap (frontal approach); with removal of lesion.
67413..	4	Orbitotomy without bone flap (frontal approach); with removal of foreign body.
67415..	1	Transconjunctival or aspirational biopsy.
Other Procedures		
67550..	4	Orbital implant (implant outside muscle cone); insertion.
67560..	4	Orbital implant (implant outside muscle cone); removal or revision. Ocular Adnexa-Eyelids
Incision		
67715..	1	Canthotomy (separate procedure).
Excision or Removal of Lesion Involving More Than Skin (IE, Involving Lid Margin, Tarsus, and/or Palpebral Conjunctiva)		
67830..	3	Correction of trichiasis; incision of lid margin.
67835..	2	Correction of trichiasis; incision of lid margin, with free mucous membrane graft.
Tarsorrhaphy		

CPT-4 code	Payment group	Description
67880..	1	Construction of intermarginal adhesions, median tarsorrhaphy, or canthorrhaphy.
67882..	3	Construction of intermarginal adhesions, median tarsorrhaphy, or canthorrhaphy; with transposition of tarsal plate.
Repair, Blepharoptosis, Lid Retraction		
67901..	1	Repair of blepharoptosis; frontalis muscle technique with suture.
67902..	3	Repair of blepharoptosis; frontalis muscle technique with fascial sling (includes obtaining fascia).
67903..	3	Repair of blepharoptosis; (tarso) levator resection, internal approach.
67904..	3	Repair of blepharoptosis; (tarso) levator resection, external approach.
67906..	3	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia).
67907..	3	Repair of blepharoptosis; superior rectus tendon transplant.
67908..	1	Repair of blepharoptosis; conjunctivo-tarso-levator resection (Fasanella-Servat type).
67909..	1	Reduction of overcorrection of ptosis.
Reconstructive Surgery, Blepharoplasty Involving More Than Skin (ie, Involving Lid Margin, Tarsus, and/or Palpebral Conjunctiva)		
67935..	2	Suture of recent wound, eyelid, involving lid margin, tarsus, and/or palpebral conjunctiva) direct closure; full thickness.
67961..	3	Excision and repair of eyelid, involving lid margin, tarsus, conjunctiva, canthus, or full thickness, may include preparation for skin graft or pedicle flap with adjacent tissue transfer or rearrangement; up to one-fourth of lid margin.
67966..	3	Excision and repair of eyelid, involving lid margin, tarsus, conjunctiva, or full thickness, may include preparation for skin graft or pedicle flap with adjacent tissue transfer or rearrangement; over one-fourth of lid margin.
67971..	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; up to two-thirds of eyelid, one stage or first stage.
67973..	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; total eyelid, lower, one stage or first stage.
67974..	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; total eyelid, upper, one stage or first stage.
67975..	3	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; second stage. Ocular Adnexa-Conjunctiva
Excision, Destruction		
68130..	1	Excision of lesion, conjunctiva; with adjacent sclera.
Conjunctivoplasty		
68320..	2	Conjunctivoplasty; with conjunctival graft or extensive rearrangement.
68325..	2	Conjunctivoplasty; with buccal mucous membrane graft (includes obtaining graft).
68326..	2	Conjunctivoplasty, reconstruction cul-de-sac; with conjunctival graft or extensive rearrangement.
68328..	3	Conjunctivoplasty, reconstruction cul-de-sac; with buccal mucous membrane graft (includes obtaining graft).
Other Procedures		
68360..	2	Conjunctival flap; bridge or partial (separate procedure).
68362..	2	Conjunctival flap; total (such as Gunderson thin flap or purse string flap). Ocular Adnexa-Lacrimal System
Excision		
68500..	3	Excision of lacrimal gland (dacryoadenectomy), except for tumor; total.
68505..	3	Excision of lacrimal gland (dacryoadenectomy), except for tumor; partial.
68510..	3	Biopsy of lacrimal gland.
68520..	3	Excision of lacrimal sac (dacryocystectomy).
Excision		
68540..	4	Excision of lacrimal gland tumor; frontal approach involving osteotomy.
68550..	4	Excision of lacrimal gland tumor; frontal approach.
Repair		
68720..	3	Dacryocystorhinostomy (fistulization of lacrimal sac to nasal cavity).
68745..	3	Conjunctivorhinostomy (fistulization of conjunctiva to nasal cavity); without tube.
68750..	3	Conjunctivorhinostomy (fistulization of conjunctiva to nasal cavity); with insertion of tube or stent.
Auditory System		
External Ear		
Excision		
69105..	1	Biopsy external auditory canal.
69110..	2	Excision external ear; partial, simple repair.
69120..	3	Excision external ear; complete amputation.
69140..	2	Excision exostosis(es), external auditory canal.
69145..	2	Excision soft tissue lesion, external auditory canal.
69150..	4	Radical excision external auditory canal lesion; without neck dissection. Middle Ear
Incision		
69440..	3	Middle ear exploration through postauricular or ear canal incision.
69450..	3	Tympanolysis, transcanal.
Repair		
69632..	4	Tympanoplasty without mastoidectomy (including canalplasty, atticotomy and/or middle ear surgery), initial or revision; with ossicular chain reconstruction, e.g., postfenestration.

CPT-4 code	Payment group	Description
69633..	4	Tympanoplasty without mastoidectomy (including canalplasty, atticotomy and/or middle ear surgery), initial or revision; with ossicular chain reconstruction and synthetic prosthesis (e.g., total ossicular replacement prosthesis, TORP).
69635..	4	Tympanoplasty with antrotomy or mastoidectomy (including canalplasty, atticotomy, middle ear surgery, and/or tympanic membrane repair); without ossicular chain reconstruction.
69636..	4	Tympanoplasty with antrotomy or mastoidectomy (including canalplasty, atticotomy, middle ear surgery, and/or tympanic membrane repair); with ossicular chain reconstruction.
69637..	4	Tympanoplasty with antrotomy or mastoidectomy (including canalplasty, atticotomy, middle ear surgery, and/or tympanic membrane repair); with ossicular chain reconstruction and synthetic prosthesis (e.g., total ossicular replacement prosthesis, TORP).
69641..	4	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); without ossicular chain reconstruction.
69642..	4	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); with ossicular chain reconstruction.
69643..	4	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); with intact or reconstructed wall, without ossicular chain reconstruction.
69644..	4	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); with intact or reconstructed canal wall, with ossicular chain reconstruction.
69645..	4	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); radical or complete, without ossicular chain reconstruction.
69646..	4	Tympanoplasty with mastoidectomy (including canalplasty, middle ear surgery, tympanic membrane repair); radical or complete, with ossicular chain reconstruction.
69661..	4	Stapedectomy with reestablishment of ossicular continuity, with or without use of foreign material; with footplate drill out.
69666..	4	Repair oval window fistula.
69667..	4	Repair round window fistula.
69670..	4	Mastoid obliteration (separate procedure).
69676..	4	Tympanic neurectomy; unilateral.
69677..	4	Tympanic neurectomy; bilateral.
External Ear		
Other procedures		
69700..	2	Closure postauricular fistula, mastoid (separate procedure). Middle Ear
Other procedures		
69720..	4	Decompression facial nerve, intratemporal; lateral to geniculate ganglion.
69725..	4	Decompression facial nerve, intratemporal; including medial to geniculate ganglion.
69740..	4	Suture facial nerve, intratemporal, with or without graft or decompression; lateral to geniculate ganglion.
69745..	4	Suture facial nerve, intratemporal, with or without graft or decompression; including medial to geniculate ganglion.

(Section 1833(i)(1) of the Social Security Act
(42 U.S.C. 1395(i)(1); 42 CFR 416.65))

(Catalog of Federal Domestic Assistance
Program No. 13.774, Medicare—
Supplementary Medical Insurance Program)

Dated: March 14, 1987.

William L. Roper,
*Administrator, Health Care Financing
Administration.*

[FR Doc. 87-8930 Filed 4-20-87; 8:45 am]

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**Tuesday
April 21, 1987**

Part III

Department of Education

**Office of Elementary and Secondary
Education**

34 CFR Part 230

**Drug-Free Schools and Communities;
Hawaiian Natives Program; Notice of
Proposed Rulemaking**

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education

34 CFR Part 230

Drug-Free Schools and Communities—Hawaiian Natives Program

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to issue regulations governing the Drug-Free Schools and Communities—Hawaiian Natives Program. This program is authorized by section 4134 of the recently enacted Drug-Free Schools and Communities Act of 1986. Under this program, the Department provides financial assistance to organizations primarily serving and representing Hawaiian Natives to plan, conduct, and administer activities authorized by the Act.

DATE: All comments on these proposed regulations must be received on or before May 21, 1987.

ADDRESS: Comments should be addressed to Mr. Dick Hays, Chairman, OESE Drug-Free Schools Task Force, U.S. Department of Education, 400 Maryland Avenue, SW., Mail Stop: 6277, Washington, DC 20202. Telephone: (202) 732-4599.

FOR FURTHER INFORMATION CONTACT: Mr. Allen King, OESE Drug-Free Schools Task Force, U.S. Department of Education, 400 Maryland Avenue, SW., Mail Stop: 6277, Washington, DC 20202. Telephone: (202) 732-4599.

SUPPLEMENTARY INFORMATION:**Background**

The Drug-Free Schools and Communities Act ("the Act"), which was signed by the President on October 27, 1986, authorizes a variety of alcohol and drug abuse prevention programs for fiscal years 1987, 1988, and 1989.

Section 4112(a)(3) of the Act provides that from the total amount appropriated for programs under the Act for any fiscal year, 0.2 percent must be reserved for programs for Hawaiian Natives under section 4134. From the sums reserved, the Secretary makes awards to organizations primarily serving and representing Hawaiian Natives to plan, conduct, and administer programs, or portions thereof, that are authorized by and consistent with the provisions of the Act for the benefit of Hawaiian Natives. The organizations must be recognized by the Governor of the State of Hawaii (section 4134(a)).

The Hawaiian Natives Program is subject to applicable law protecting

students' rights in research, experimental programs, and testing. See section 439 of the General Education Provisions Act (20 U.S.C. 1232h) and its implementing regulations in 34 CFR Part 98.

Summary of Major Provisions

The proposed regulations state that programs must be provided for Hawaiian Natives. The proposed regulations also specify that the Secretary provides financial assistance through grants or cooperative agreements (§ 230.3) and establish the criteria that the Secretary uses to evaluate applications for funding (§ 230.21).

Executive Order 12291

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. The only organizations eligible to receive awards are those recognized by the Governor of Hawaii as primarily serving and representing Hawaiian Natives.

Paperwork Reduction Act of 1980

These proposed regulations do not contain any information collection requirements covered by the Paperwork Reduction Act of 1980.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for further inspection, during and after the comment period, in Room 2135, 400 Maryland Avenue, SW., Washington, DC between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in the proposed regulations.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 230

Drug abuse, Education, Elementary and secondary education, Grant programs—education, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Number 84.199, Drug-Free Schools and Communities—Hawaiian Natives Program)

Dated: April 3, 1987.

William J. Bennett,

Secretary of Education.

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 230 to Chapter II to read as follows:

PART 230—DRUG-FREE SCHOOLS AND COMMUNITIES—HAWAIIAN NATIVES PROGRAM**Subpart A—General**

Sec.

- 230.1 What is the Drug-Free Schools and Communities—Hawaiian Natives Program?
- 230.2 Who is eligible to apply for an award?
- 230.3 What activities may the Secretary fund?
- 230.4 What regulations apply?
- 230.5 What definitions apply?

Subpart B—[Reserved]**Subpart C—How Does the Secretary make an Award?**

- 230.20 How does the Secretary evaluate an application?
- 230.21 What selection criteria does the Secretary use?

Subpart D—What Conditions Must Be Met After an Award?

- 230.30 What conditions must a grantee meet in coordinating services?

Authority: 20 U.S.C. 4644, unless otherwise noted.

Subpart A—General**§ 230.1 What is the Drug-Free Schools and Communities—Hawaiian Natives Program?**

The Drug Free Schools and Communities—Hawaiian Natives Program provides financial assistance to organizations primarily serving and representing Hawaiian Natives to plan, conduct, and administer programs for Hawaiian Natives that are authorized by and consistent with the Drug-Free

Schools and Communities Act of 1986 (the "Act").

(Authority: 20 U.S.C. 4644)

§ 230.2 Who is eligible to apply for an award?

Any organization primarily serving and representing Hawaiian Natives, that is recognized by the Governor of Hawaii, may apply for a grant or cooperative agreement under this program.

(Authority: 20 U.S.C. 4644)

§ 230.3 What activities may the Secretary fund?

The Secretary provides assistance to plan, conduct, and administer activities that are authorized by and consistent with the Act for the benefit of Hawaiian Natives. These activities may include, but are not limited to, the following:

(a) Local broadly-based programs for drug and alcohol abuse prevention, early intervention, rehabilitation referral, and education for all age groups.

(b) Training programs concerning drug abuse education and prevention for teachers, counselors, other educational personnel, parents, local law enforcement officials, judicial officials, other public service personnel, and community leaders.

(c) The development and distribution of educational and informational materials to provide public information (through the media and otherwise) for the purpose of achieving a drug-free society.

(d) Technical assistance to help community-based organizations and local and intermediate educational agencies and consortia in the planning and implementation of drug abuse prevention, early intervention, rehabilitation referral, and education programs.

(e) Activities to encourage the coordination of drug abuse education and prevention programs with related community efforts and resources.

(Authority: 20 U.S.C. 4132(a)(1-5), 4644)

§ 230.4 What regulations apply?

The following regulations apply to the Drug-Free Schools and Communities—Hawaiian Natives Program:

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 74 (Administration of Grants), Part 75 (Direct Grant Programs), Part 77 (Definitions That Apply to Department Programs), and Part 78 (Education Appeal Board).

(b) The regulations in this Part 230.

(Authority: 20 U.S.C. 4644)

§ 230.5 What definitions apply?

(a) *Definitions in the Act.* The following terms used in this part are defined in the Act:

Hawaiian Native (Section 4134(b))
Drug abuse education and prevention (Section 4141(b)(1))

(b) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1:

Applicant
Application
Department
EDGAR
Grant
Secretary

(c) *Other definitions.* The following definition also applies to this part: "Act" means the Drug-Free Schools and Communities Act of 1986.

(Authority: 20 U.S.C. 4644)

Subpart B—[Reserved]

Subpart C—How Does the Secretary Make an Award?

§ 230.20 How does the Secretary evaluate an application?

(a) The Secretary evaluates an application for a grant or cooperative agreement on the basis of the criteria in § 230.21.

(b) The Secretary awards up to 100 points for these criteria.

(c) The maximum possible score for each criterion is indicated in parentheses.

(Authority: 20 U.S.C. 4644)

§ 230.21 What selection criteria does the Secretary use?

The Secretary uses the following selection criteria in evaluating each application:

(a) *Understanding of problems and needs.* (15 points) The Secretary reviews each application to determine how adequately the applicant has identified problems and needs related to alcohol and drug abuse among Hawaiian Natives.

(b) *Plan to address problems and needs.* (30 points) The Secretary reviews each application to determine the quality of the proposed plan to address the identified problems and needs.

(c) *Coordination with other activities, balance of services.* (15 points) The Secretary reviews each application to determine—

(1) The degree to which the applicant has coordinated with State and other organizations administering alcohol and drug abuse programs in developing the application;

(2) The adequacy of the applicant's plans for coordination with State and

national alcohol and drug abuse prevention activities; and

(3) The adequacy of the applicant's plans to achieve balance in providing services among Hawaiian Natives.

(d) *Management plan.* (15 points) The Secretary reviews each application to determine the quality of the plan of operation for the applicant's program, including—

(1) The extent to which the plan is effective and ensures proper and efficient administration of the program;

(2) The manner in which the plan provides for the applicant's use of resources and personnel to achieve its objectives;

(3) The adequacy of the resources the applicant plans to use—including facilities, equipment, and supplies;

(4) How the plan will ensure that the program will select participants, who are otherwise eligible to participate, for activities without regard to race, color, sex, age, or handicapping condition; and

(5) The schedules of work and completion dates for activities identified in the plan.

(e) *Quality of key personnel.* (20 points) (1) The Secretary reviews each application to determine the quality of key personnel proposed for the program, including—

(i) The qualifications of the program director;

(ii) The qualifications of each of the other key personnel;

(iii) The time that each person referred to in paragraphs (e)(1) (i) and (ii) of this section will commit to the program; and

(iv) How the applicant, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, sex, national origin, age, or handicapping condition.

(2) To determine personnel qualifications under paragraphs (e)(1) (i) and (ii) of this section, the Secretary considers—

(i) Experience and training in alcohol and drug abuse education and prevention; and

(ii) Any other qualifications that pertain to the quality of the program and services, including the capacity for training, evaluation, and dissemination.

(f) *Evaluation plan.* (5 points) The Secretary reviews each application to determine the quality of the applicant's plan to evaluate the effectiveness of the proposed program, including the extent to which the methods of evaluation are appropriate, are objective, and produce data that are quantifiable.

(Authority: 20 U.S.C. 4644)

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