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federal register

TUESDAY, MARCH 22, 1977

THE NATIONAL ARCHIVES OF THE UNITED STATES • 1934 •

highlights

HOW TO USE THE FEDERAL REGISTER

Seattle, Washington workshops on March 30 and 31, 1977. Reservations required: Dorothy Clegg, 206–442–5556.

(Details: 42 FR 11933, March 1, 1977)

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H.R. 1746.....Pub. L. 95–12
To amend the United Nations Participation Act of 1945 to halt the importation of Rhodesian chrome. (Mar. 18, 1977; 91 Stat. 22) Price: $.35.

The six-month trial period ended August 6. The program is being continued on a voluntary basis (see OFR notice, 41 FR 32914, August 6, 1976). The following agencies have agreed to remain in the program:

Monday	Tuesday	Wednesday	Thursday	Friday
NRC	USDA/ASCS		NRC	USDA/ASCS
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DOT/NHTSA	USDA/FNS		DOT/NHTSA	USDA/FNS
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DOT/OPSO	LABOR		DOT/OPSO	LABOR
	HEW/FDA			HEW/FDA

Documents normally scheduled on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

ATTENTION: For questions, corrections, or requests for information please see the list of telephone numbers appearing on opposite page.

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Title 3—The President

Executive Order 11978 • March 18, 1977

Relating to Trade and Other Transactions Involving Southern Rhodesia

By virtue of the authority vested in me by Section 5 of the United Nations Participation Act of 1945, as amended (22 U.S.C. 287c), and Section 301 of Title 3 of the United States Code, and as President of the United States of America, Section 4 of Executive Order No. 11419 of July 29, 1968, is hereby amended by adding thereto the following subsection:

"(c) The Secretary of the Treasury may exempt from the provisions of this Order, and Executive Order No. 11322, as amended, any shipment of chromium in any form which is in transit to the United States on March 18, 1977.".

Jimmy Carter

THE WHITE HOUSE,
March 18, 1977.

[FR Doc.77-8604 Filed 3-18-77;1:51 pm]

rules and regulations

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

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

Title 1—General Provisions

CHAPTER IV—MISCELLANEOUS AGENCIES (PRIVACY REGULATIONS)

PART 460—RULES FOR IMPLEMENTING OPEN MEETINGS WITHIN THE BOARD FOR INTERNATIONAL BROADCASTING

Government in the Sunshine Act; Implementation

On FEBRUARY 16, 1977, there was published in the FEDERAL REGISTER (42 FR 9388) a notice of proposed implementation of rules by the Board for International Broadcasting concerning Pub. L. 94-409 of September 13, 1976, the Government in the Sunshine Act. Interested parties were given the opportunity to submit comments on the proposed rules, no later than March 12, 1977.

No comments have been received, and the proposed rules are hereby adopted without change and are set forth below.

Effective date: March 12, 1977.

Signed at Washington, D.C.

WALTER R. ROBERTS,
Executive Director.

Sec.

460.1 General policies.
460.2 Definitions.
460.3 Requirement of open meetings.
460.4 Ground on which meetings may be closed.
460.5 Procedures for announcing meetings.
460.6 Procedures for closing meetings.
460.7 Reconsideration of opening or closing a meeting.
460.8 Recordkeeping of closed meeting.

AUTHORITY: Pub. L. 93-129, 87 Stat. 456.

§ 460.1 General policies.

The Board for International Broadcasting will provide the public with the fullest practical information regarding its decisionmaking processes while protecting the rights of individuals and its abilities to carry out its responsibilities.

§ 460.2 Definitions.

The following definitions apply:

(a) The term "agency" includes any establishment in the executive branch of the government headed by a collegial body composed of two or more individual members, a majority of whom are appointed to such position by the President with the advice and consent of the Senate, and any subdivision thereof authorized to act on behalf of the agency. The Board for International Broadcasting is a government agency headed by a five-member Board, all of whom are appointed by the President with the advice and consent of the Senate, and is therefore an "agency" under these terms.

(b) The term "meeting" means the deliberation of this Board where such deliberations determine or result in the joint conduct or disposition of official Board business.

(c) The term "member" means an individual who belongs to the Board who has been appointed by the President and confirmed by the Senate.

§ 460.3 Requirement of open meetings.

Members shall not jointly conduct or dispose of agency business other than in accordance with this section. Except as provided in § 460.4 every portion of every meeting of the agency shall be open to public observation.

§ 460.4 Grounds on which meetings may be closed.

The Board shall open every portion of every meeting of the agency for public observation except where the agency determines that such portion or portions of its meeting or the disclosure of such information is likely to:

(a) Disclose matters that are:

(1) Specifically authorized under criteria established by an Executive order to be kept secret in the interests of national defense or foreign policy and

(2) In fact properly classified pursuant to such Executive Order;

(b) Relate solely to the internal personnel rules and practice of the agency;

(c) Disclose matters specifically exempted from disclosure by statute: *Provided*, That such statute:

(1) Requires that the matters be withheld from the public in such manner as to leave no discretion on the issue, or

(2) Established practical criteria for withholding or refers to particular types of matters to be withheld;

(d) Disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(e) Involve accusing any person of a crime, or formally censuring any person;

(f) Disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;

(g) Disclose investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records, but only to the extent that the production of such records or information would:

(1) Interfere with enforcement proceedings,

(2) Deprive a person of a right to a fair trial of an impartial adjudication,

(3) Constitute an unwarranted invasion of personal privacy,

(4) Disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential source,

(5) Disclose investigative techniques and procedures, or

(6) Endanger the life or physical safety of law enforcement personnel;

(h) Disclose information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action. This shall not apply in any instance where the Board has already disclosed to the public the content or nature of its proposed action, or where the Board is required by law to make such disclosure on its own initiative prior to taking final Board action on such proposal;

(i) Specifically concern the Board's issuance of a subpoena, or the Board's participation in a civil action or proceeding, an action in a foreign court or international tribunal, or an arbitration, or the initiation, conduct or disposition by the Board of a particular case of formal agency adjudication pursuant to the procedures in section 554, of this title or otherwise involving a determination on the record after opportunity for a hearing.

§ 460.5 Procedures for announcing meetings.

(a) In the case of each meeting, the Board shall make public, at least one week before the meeting, the time, place, and subject matter of the meeting, whether it is to be open or closed to the public, and the name and phone number of the official designated by the Board to respond to requests for information about the meeting. Such announcement shall be made unless a majority of the Members of the Board determine by a recorded vote that the Board requires that such a meeting be called at an earlier date, in which case the Board shall make public announcement of the time, place and subject matter of such meeting and whether open or closed to the public, at the earliest practical time.

(b) Immediately following the public announcement, the Board will publish it in the FEDERAL REGISTER.

§ 460.6 Procedures for closing meetings.

(a) The closing of a meeting shall occur only when:

(1) A majority of the membership of the Board votes to take such action. A separate vote of the Board members shall be taken with respect to each Board meeting a portion or portions of which are proposed to be closed to the public pursuant to § 460.4, or with respect to any information which is proposed to be withheld under § 460.4. A single vote may be taken with respect to a series of

meetings, a portion or portions of which are proposed to be closed to the public, or with respect to any information concerning such series of meetings, so long as each meeting in such series involves the same particular matters and is scheduled to be held no more than thirty days after the initial meeting in such series. The vote of each Board member participating in such vote shall be recorded and no proxies shall be allowed.

(2) Whenever any person whose interests may be directly affected by a portion of a meeting requests that the Board close such portion to the public for any of the reasons referred to in § 460.4 (e), (f) or (g), the Board, upon request of any of its Board members, shall take a recorded vote, whether to close such portion of the meeting.

(b) Within one day of any vote taken, the Board shall make publicly available a written copy of such vote reflecting the vote of each member on the question and full written explanation of its action closing the entire or portion of the meeting together with a list of all persons expected to attend the meeting and their affiliation.

(c) The Board shall announce the time, place and subject matter of the meeting at least eight (8) days before the meeting.

(d) For every closed meeting, the Executive Director of the Board shall publicly certify that, in his or her opinion, the meeting may be closed to the public and shall state each relevant exemptive provision. A copy of such certification, together with a statement from the presiding officer of the meeting setting forth the time and place of the meeting, and the persons present, shall be retained by the Board.

§ 460.7 Reconsideration of opening or closing a meeting.

The time or place of a Board meeting may be changed following the public announcement only if the Board publicly announces such change at the earliest practicable time. The subject matter of a meeting, or the determination of the agency to open or close a meeting, or portion of meeting, to the public, may be changed following the public announcement only if a majority of the Board members determines by a recorded vote that Board business so requires and that no earlier announcement of the change was possible, and the Board publicly announces such change and the vote of each member upon such change at the earliest practicable time.

§ 460.8 Recordkeeping of closed meetings.

(a) The Board shall maintain a written record of the proceedings of each meeting, or portion of a meeting, closed to the public.

(b) The Board, after review by the Executive Director shall make promptly available to the public in a place easily accessible to the public, the written record of the discussion of any time on the agenda, or any item of the testimony of any witness received at the Board meeting, except for such item or items of such discussion or testimony as the Board determines to contain information which may be withheld under § 460.4. Copies of such record, disclosing the identity of each speaker, shall be furnished to any person at the actual cost of duplication. The Board shall maintain a detailed written copy of the minutes of each meeting, or portion of a meeting, closed to the public, for a period of at least two years after such meeting, or until one year after the conclusion of any Board proceeding with respect to which the meeting or portion was held, whichever occurs later.

[FR Doc.77-8419 Filed 3-21-77;8:45 am]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Department of Agriculture

Section 213.3313 is amended to show that one position of Director of Agricultural Economics is excepted under Schedule C.

Effective on March 22, 1977, § 213.3313 (n) (1) is added as set out below.

§ 213.3313 Department of Agriculture.

(n) *Agricultural Economics.* • • •

(1) Director of Agricultural Economics.

(5 U.S.C. 3301, 3302, E.O. 10577; 3 CFR 1954–58 Comp., p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77-8423 Filed 3-21-77;8:45 am]

PART 213—EXCEPTED SERVICE

Department of Defense

AGENCY: Civil Service Commission.

ACTION: Final Rule.

SUMMARY: This amendment excepts from the competitive service under Schedule C one position of Assistant to the Secretary of Defense for Legislative Affairs because it is a supervisory position over noncompetitive employees.

EFFECTIVE DATE: March 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Thomas H. Meyer, 202–632–4695.

Accordingly, 5 CFR 213.3306(a)(8) is amended as set forth below:

§ 213.3306 Department of Defense.

(a) *Office of the Secretary.* • • •

(8) Two Assistants to the Secretary of Defense for Legislative Affairs.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp., p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77-8614 Filed 3-21-77;8:45 am]

Title 7—Agriculture

SUBTITLE A—OFFICE OF THE SECRETARY OF AGRICULTURE

PART 1—ADMINISTRATIVE REGULATIONS

Rules of Practice for Formal Adjudicatory Administrative Proceedings Instituted by the Secretary; Clarification of Scope

On January 4, 1977 (42 FR 743), there were published new "Rules of Practice Governing Formal Adjudicatory Administrative proceedings Instituted By The Secretary." 7 CFR 1.131(a) sets forth the authority under several statues for the holding of formal administrative adjudicatory proceedings. Among the authorities cited is section 6(c) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499f(c)). Section 6 (c) authorizes hearings both for reparation proceedings to rsolve contract disputes between private parties, and for proceedings to determine whether there have been violations of section 2 of the Act (7 U.S.C. 499b).

For purposes of clarification, the rules of practice contained in Title 7, Subtitle A, Part 1, Subpart H (7 CFR 1.130 through 7 CFR 1.151) cover only those formal adjudicatory proceedings authorized by section 6(c) of the Perishable Agricultural Commodities Act, 1930 to determine whether there have been violations of section 2 thereof. The rules of practice for reparation proceedings under the Act continue to be covered by 7 CFR 47.1 through 47.25, and 7 CFR 47.46.

In view of the above, the introductory paragraph of 7 CFR 1.131(a) is changed to read as follows:

---

§ 1.131 Scope and applicability of this subpart.

(a) The rules of practice in this subpart shall be applicable to all adjudicatory proceedings under the statutory provisions listed below as those provisions have been or may be amended from time to time,[1] except that those rules shall not be applicable to reparation proceedings under section 6(c) of the Perishable Agricultural Commodities Act, 1930. The provisions of 7 CFR 1.26 shall be inapplicable to the proceedings covered by this subpart.

• • • • •

Since the above change is for the purpose of clarification only, such change is effective March 22, 1977.

Dated: March 16, 1977.

BOB BERGLAND,
Secretary of Agriculture.

[FR Doc.77-8455 Filed 3-21-77;8:45 am]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Navel Orange Regulation 404, Amendment 1]

PART 907—NAVEL ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Limitation of Handling

PREAMBLE

This regulation increases the quantity of California-Arizona Navel oranges that may be shipped to fresh market during the weekly regulation period March 11–17, 1977. The quantity that may be shipped is increased due to improved market conditions for Navel oranges. The regulation and this amendment are issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended, and Marketing Order No. 907.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 907, as amended (7 CFR Part 907), regulating the handling of Navel oranges grown in Arizona and designated part of California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations and information submitted by the Navel Orange Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such Navel oranges, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The need for an increase in the quantity of oranges available for handling during the current week results from changes that have taken place in the marketing situation since the issuance of Navel Orange Regulation 404 (42 FR 13269). The marketing picture now indicates that there is a greater demand for Navel oranges than existed when the regulation was made effective. Therefore, in order to provide an opportunity for handlers to handle a sufficient volume of Navel oranges to fill the current market demand thereby making a greater quantity of Navel oranges available to meet such increased demand, the regulation should be amended, as hereinafter set forth.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule-making procedure, and postpone the effective date of this amendment until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this amendment is based became available and the time when this amendment must become effective in order to effectuate the declared policy of the act is insufficient, and this amendment relieves restriction on the handling of Navel oranges grown in Arizona and designated part of California.

(b) *Order, as amended.* The provisions in paragraph (b)(1) (i), and (ii) of § 907.704 (Navel Orange Regulation 404 (42 F.R. 13269)) are hereby amended to read as follows:

"(i) District 1: 1,296,000 cartons;

"(ii) District 2: 304,000 cartons."

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

Dated: March 16, 1977.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.77-8457 Filed 3-21-77;8:46 am]

[Lemon Regulation 83, Amendment 1]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

PREAMBLE

This regulation increases the quantity of California-Arizona lemons that may be shipped to fresh market during the weekly regulation period March 13–19, 1977. The quantity that may be shipped is increased due to improved market conditions for California-Arizona lemons. The regulation and this amendment are issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended, and Marketing Order No. 910.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such lemons, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The need for an increase in the quantity of lemons available for handling during the current week results from changes that have taken place in the marketing situation since the issuance of Lemon Regulation 83 (42 FR 13534). The marketing picture now indicates that there is a greater demand for lemons than existed when the regulation was made effective. Therefore, in order to provide an opportunity for handlers to handle a sufficient volume of lemons to fill the current market demand thereby making a greater quantity of lemons available to meet such increased demand, the regulation should be amended, as hereinafter set forth.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking procedure, and postpone the effective date of this amendment until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this amendment is based became available and the time when this amendment must become effective in order to effectuate the declared policy of the act is insufficient, and this amendment relieves restriction on the handling of lemons grown in California and Arizona.

(b) *Order, as amended.* Paragraph (b)(1) of § 910.383 (Lemon Regulation 83 (42 FR 13534) is hereby amended to read as follows:

§ 910.383 Lemon Regulation 83

* * * * *

(b) The quantity of lemons grown in California and Arizona which may be handled during the period March 13, 1977 through March 19, 1977, is hereby fixed at 240,000 cartons."

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

Dated: March 16, 1977.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.77-8456 Filed 3-21-77;8:45 am]

Title 8—Aliens and Nationality

CHAPTER I—IMMIGRATION AND NATURALIZATION SERVICE, DEPARTMENT OF JUSTICE

Organizations, Duties, and Proceedings; Designation of Dallas, Texas as District Office; Establishment of Suboffices at Oklahoma City, Oklahoma and Louisville, Kentucky

AGENCY: Immigration and Naturalization Service.

ACTION: Final Rule.

SUMMARY: The purpose of the regulations set forth in this order is to redesignate the suboffice of this Service at Dallas, Texas as a district office and to establish suboffices at Oklahoma City, Oklahoma and Louisville, Kentucky.

EFFECTIVE DATE: April 1, 1977.

FOR FURTHER INFORMATION CONTACT:

James G. Hoofnagle, Jr., Instructions Officer, Immigration and Naturalization Service, 425 "I" Street, N.W., Washington, D.C. 20536. (202–376–8373).

SUPPLEMENTARY INFORMATION: Pursuant to section 552 of Title 5 of the United States Code (80 Stat. 383), as amended by Pub. L. 93–502 (88 Stat. 1561), and the authority contained in section 103 of the Immigration and Nationality Act (66 Stat. 173; 8 U.S.C. 1103), 28 CFR 0.105(b) and 8 CFR 2.1, the following amendments as set forth herein are prescribed to Parts 100, 103 and 242 of Chapter I of Title 8 of the Code of Federal Regulations.

Effective April 1, 1977, the suboffice of this Service located at Dallas, Texas will be redesignated as a District Office (District No. 20). The Dallas district office will have jurisdiction over the State of Oklahoma and also over several counties in the State of Texas currently under the jurisdiction of the Houston, Tex. district (District No. 38). Also, the

Service will open a suboffice under the jurisdiction of the Dallas district office in Oklahoma City, Oklahoma. The Officer-in-Charge of that suboffice will have the authority to issue warrants of arrest and notices of hearing as provided in 8 CFR 242.1(a). In addition, the Service will open a suboffice in Louisville, Kentucky which will be under the jurisdiction of the New Orleans, Louisiana district. The suboffice at Dallas is being redesignated as a District Office and the new suboffices are being opened at Oklahoma City and Louisville in order to provide better service to the public and provide for more effective management and supervision of Service operations in the areas to be served by those offices.

In order to effect the above-described organizational changes, the substantive and conforming regulatory amendments described and set forth below will be made to Title 8 of the Code of Federal Regulations.

In 8 CFR 100.4(a) the second sentence will be amended to include reference to District No. 20 in the list of offices under the jurisdiction of the Southern Region. In 8 CFR 100.4(b) District No. 20 (Dallas, Texas) will be added, to have jurisdiction over the State of Oklahoma and the indicated counties in the State of Texas. Also, District No. 38 (Houston, Texas) will be revised by deleting those counties over which the Dallas district will assume jurisdiction on April 1, 1977. 8 CFR 100.4(c)(1) will be amended by adding Louisville, Kentucky and Oklahoma City, Oklahoma in alphabetical sequence to reflect the establishment of those suboffices; and Dallas, Texas will be deleted from that listing because it is being redesignated as a district office.

A conforming amendment will be made in 8 CFR 103.10 by deleting "Dallas, Tex." from the listing of offices therein because Dallas will become a district office, and records requested under the Freedom of Information Act will be available from the Dallas district office beginning April 1, 1977.

Since it has been determined that the Officer-in-Charge at Oklahoma City, Oklahoma is to have the authority to issue warrants of arrest and notices of hearing, 8 CFR 242.1(a) will be amended by adding "Oklahoma City, Okla." to the list of offices set forth in that paragraph. 8 CFR 241.1(a) will be further amended by deleting "Dallas, Tex.", and "San Diego, Calif.", because both of these offices are district offices.

PART 100—STATEMENT OF ORGANIZATION

In the light of the foregoing, the following amendments, as set forth below, are hereby prescribed to Title 8 of Chapter I of the Code of Federal Regulations.

In § 100.4(a), the second sentence is amended to read as follows:

§ 100.4 Field Service.

* * * * *

(a) *Regional offices.* * * * The Southern Regional Office, located in Dallas, Texas, has jurisdiction over district 6, 14, 15, 20, 26, 28 and 38 and Border Patrol Sectors 15, 16, 17, 18, 19, 20, and 21. * * *

* * * * *

Section 100.4(b) is amended by adding District No. 20, Dallas, Texas, in numerical sequence, to have jurisdiction over the State of Oklahoma and the counties in the State of Texas as indicated below:

(b) *District offices.* * * *

* * * * *

(20) *Dallas, Texas.* The district office in Dallas, Texas, has jurisdiction over the State of Oklahoma, and the following counties in the State of Texas: Anderson, Andrews, Archer, Armstrong, Bailey, Baylor, Borden, Bosque, Bowie, Briscoe, Camp, Carson, Cass, Castro, Cherokee, Childress, Clay, Cochran, Collin, Collingsworth, Comanche, Cooke, Cottle, Crosby, Dallam, Dallas, Dawson, Deaf Smith, Delta, Denton, Dickens, Donley, Eastland, Ellis, Erath, Fannin, Fisher, Floyd, Foard, Franklin, Freestone, Gaines, Garza, Gray, Grayson, Gregg, Hale, Hall, Hamilton, Hansford, Hardeman, Harrison, Hartley, Haskell, Hemphill, Henderson, Hill, Hockley, Hood, Hopkins, Houston, Howard, Hunt, Hutchinson, Jack, Johnson, Kaufman, Kent, King, Knox, Lamar, Lamb, Leon, Limestone, Lipscomb, Lubbock, Lynn, Marion, Martin, Mitchell, Montague, Moore, Morris, Motley, Navarro, Nolan, Ochiltree, Oldham, Palo Pinto, Panola, Parker, Parmer, Potter, Rains, Randall, Red River, Roberts, Rockwall, Rusk, Scurry, Shackleford, Sherman, Smith, Somervell, Stephens, Stonewall, Swisher, Tarrant, Terry, Throckmorton, Titus, Upshur, Van Zandt, Wheeler, Wichita, Wilbarger, Wise, Wood, Yoakum, and Young.

* * * * *

In § 100.4(b), District No. 38 is revised, and as revised reads as follows:

(38) *Houston, Texas.* The district office in Houston, Texas has jurisdiction over the following counties in the State of Texas: Angelina, Austin, Brazoria, Chambers, Colorado, Fort Bend, Galveston, Grimes, Hardin, Harris, Jasper, Jefferson, Liberty, Madison, Matagorda, Montgomery, Nocogdoches, Newton, Orange, Polk, Sabine, San Augustine, San Jacinto, Shelby, Trinity, Tyler, Walker, Waller, Washington, and Wharton.

* * * * *

In § 100.4(c)(1), the list of offices therein enumerated is amended by adding in alphabetical sequence "Louisville, Ky.", and "Oklahoma City, Okla.", and by deleting "Dallas, Tex." As amended § 100.4(c)(1) reads as follows:

(c) *Suboffices.* * * *

(1) *Interior locations.*

Albany, N.Y.	Oklahoma City, Okla.
Albuquerque, N. Mex.	Pittsburgh, Pa.
Boise, Idaho	Reno, Nev.
Cincinnati, Ohio	Sacramento, Calif.
Fairbanks, Alaska	Salt Lake City, Utah
Fresno, Calif.	St. Louis, Mo.
Harlingen, Tex.	Spokane, Wash.
Las Vegas, Nev.	Syracuse, N.Y.
Louisville, Ky.	Tucson, Ariz.
Memphis, Tenn.	

* * * * *

PART 103—POWERS AND DUTIES OF SERVICE OFFICERS; AND AVAILABILITY OF SERVICE RECORDS

In § 103.10(a)(1), the first sentence is amended by deleting "Dallas, Tex." As amended, the first sentence of § 103.10(a)(1) reads as follows:

§ 103.10 Requests for records under the Freedom of Information Act.

(a) *Place and manner of requesting records*—(1) *Place.* Records shall be made available in the Central Office, each regional office, any district office, and the following offices; Agana, Guam; Albany, N.Y.; Cincinnati, Ohio; Hammond, Ind.; Harlingen, Tex.; Las Vegas, Nev.; Memphis, Tenn.; Milwaukee, Wis.; Norfolk, Va.; Pittsburg, Pa.; Providence, R.I.; Reno, Nev.; St. Louis, Mo.; Salt Lake City, Utah; Spokane, Wash.; additionally, in particular cases, a district director may designate any other Service office. * * *

* * * * *

PART 242—PROCEEDINGS TO DETERMINE DEPORTABILITY OF ALIENS IN THE UNITED STATES: APPREHENSION, CUSTODY, HEARING, AND APPEAL

In § 242.1(a), the third sentence is amended by adding "Oklahoma City, Okla." to the offices shown in that sentence, in alphabetical sequence, and by deleting "Dallas, Tex.", and "San Diego, Calif." As amended, the third sentence of § 242.1(a) reads as follows:

§ 242.1 Order to show cause and notice of hearing.

(a) *Commencement* * * * Orders to show cause may be issued by district directors, acting district directors, deputy district directors, assistant district directors for investigations, and officers in charge at Albany, N.Y.; Cincinnati, Ohio; Hammond, Ind.; Harlingen, Tex.; Milwaukee, Wis.; Norfolk, Va.; Oklahoma City, Okla.; Pittsburgh, Pa.; Providence, R.I.; Salt Lake City, Utah; St. Louis, Mo.; Spokane, Wash.

(Sec. 103, 66 Stat. 173; 8 U.S.C. 1103.)

Compliance with the provisions of section 553 of Title 5 of the United States Code (80 Stat. 383) as to notice of proposed rule making and delayed effective date is unnecessary in this instance because the amendments contained in this order relate to agency organization and management.

Effective date: The amendments contained in this order shall be effective April 1, 1977.

Dated: March 16, 1977.

L. F. CHAPMAN, JR.,
Commissioner of Immigration and Naturalization.

[FR Doc.77-8413 Filed 3-21-77;8:45 am]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

SUBCHAPTER A—PROCEDURES AND RULES OF PRACTICE

IMPLEMENTATION OF GOVERNMENT IN THE SUNSHINE ACT

PART 4—MISCELLANEOUS RULES

Correction

In FR Doc. 77-7373, appearing on page 13538 of the issue for Friday, March 11, 1977, the following corrections should be made on page 13541.

1. Column 1, § 4.15(a)(3) *Announcements of changes in meetings*, the citation reading 5 U.S.C. 552(e)(2) should read 5 U.S.C. 552b(e)(2).

2. Middle column, § 4.15(c)(2) *Closed meetings*, the citation reading 5 U.S.C. 552(c)(10) should read 5 U.S.C. 552b(c)(10).

Dated: March 17, 1977.

JAMES A. TOBIN,
Acting Secretary.

[FR Doc.77-8476 Filed 3-21-77;8:45 am]

Title 21—Food and Drugs

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

[FRL 700-7; FAP6H5141/R29]

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 561—TOLERANCES FOR PESTICIDES IN ANIMAL FEEDS ADMINISTERED BY THE ENVIRONMENTAL PROTECTION AGENCY

Aldicarb

On September 1, 1976, notice was given (41 FR 36834) that Union Carbide Corp., 1730 Pennsylvania Ave. NW, Washington DC 20006 had filed a petition (FAP 6H5141) with the Environmental Protection Agency (EPA). This petition proposed that 21 CFR 561.30 be amended by establishing a regulation permitting the use of the insecticide and nematocide aldicarb (2-methyl-2-methylthio) propionaldehyde 0-(methylcarbamoyl) oxime on growing oranges with a tolerance limitation of 0.6 part per million (ppm) in dried citrus pulp for the insecticide-nematocide and its cholinesterase-inhibiting metabolites 2-methyl-2-(methylsulfinyl) propionaldehyde 0-(methylcarbamoyl) oxime and 2-methyl-2-(methylsulfonyl) propionaldehyde 0-(methylcarbamoyl) oxime. (A related document concerning the establishment of a tolerance for residues of this pesticide in or on the raw agricultural commodity oranges at 0.3 ppm appears elsewhere in today's FEDERAL REGISTER.). No comments were received by the Agency in response to this notice of filing.

The data submitted in the petition and other relevant material have been evaluated, and it is concluded that the pesticide can be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136 et seq.). Therefore, the regulation is being established as proposed.

Any person adversely affected by this regulation may, on or before April 21, 1977, file written objections with the Hearing Clerk, Environmental Protection Agency, Rm. 1019, East Tower, 401 M St. SW, Washington DC 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections.

If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by the grounds legally sufficient to justify the relief sought.

Effective on March 22, 1977, 21 CFR 561 is amended as set forth below.

Dated: March 11, 1977.

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

(Sec. 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).)

21 CFR 561.30 is revised to read as follows:

* * * * *

§ 561.30 Aldicarb.

Tolerances are established for combined residues of the insecticide and nematocide aldicarb (2-methyl-2-(methylthio)-propionaldehyde *O*-(methylcarbamoyl) oxime) and its cholinesterase-inhibiting metabolites 2-methyl-2-(methylsulfinyl) propionaldehyde *O*-(methylcarbamoyl) oxime and 2-methyl-2-(methylsulfonyl)-propionaldehyde *O*-(methylcarbamoyl) oxime in the following processed feeds when present therein as a result of the application of this pesticide to growing crops:

Feed:	*Parts per million*
Citrus pulp, dried	0.6
Cottonseed hulls	0.3

* * * * *

[FR Doc.77-8269 Filed 3-21-77;8:45 am]

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

[Order No. 706-77]

PART 15—DEFENSE OF CERTAIN SUITS AGAINST FEDERAL EMPLOYEES, AND CERTIFICATION AND DEFENSE OF CERTAIN SUITS AGAINST PROGRAM PARTICIPANTS UNDER THE NATIONAL SWINE FLU IMMUNIZATION PROGRAM OF 1976

Procedures to be Followed in Case of Suit Against Certain Federal Employees

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: Existing Justice Department regulations set forth certain procedures to be followed in connection with the Department's defense of civil actions against certain Federal employees arising out of their operation of motor vehicles within the scope of their employment, or on account of their performance of medical care, treatment or investigation in the scope of their office or employment with the Public Health Service or the Veterans Administration Department of Medicine and Surgery. This order amends the existing regulations to expand their coverage to take account of recently enacted legislation dealing with medical personnel in the Departments of State, Defense and Transportation, the armed forces, the Central Intelligence Agency and the National Aeronautics and Space Administration. This order also includes new regulations to apply to suits against program participants as that term is defined in the National Swine Flu Immunization Program of 1976.

EFFECTIVE DATE: March 14, 1977.

FOR FURTHER INFORMATION CONTACT:

Neil R. Peterson, Civil Division, Department of Justice, Washington, D.C. 20530 (202-739-4393).

By virtue of the authority vested in me by 5 U.S.C. 301, 10 U.S.C. 1089, 22 U.S.C. 817, 28 U.S.C. 509, 510 and 2679, 38 U.S.C. 4116, and 42 U.S.C. 233, 247b and 2458a, Part 15 of Chapter I of Title 28, Code of Federal Regulations, is amended as follows:

1. The caption for Part 15 is revised to read as set forth above.

2. The table of contents for Part 15 is revised to read as follows:

Sec.
15.1 Expeditious delivery of process and pleadings.
15.2 Providing data bearing upon scope of employment or program participant status.
15.3 Removal and defense of suits.

AUTHORITY: 5 U.S.C. 301, 10 U.S.C. 1089, 22 U.S.C. 817, 28 U.S.C. 509, 510 and 2679, 38 U.S.C. 4116, and 42 U.S.C. 233, 2476 and 2458a.

3. Section 15.1 is revised to read as follows:

§ 15.1 Expeditious delivery of process and pleadings.

(a) Any Federal employee against whom a civil action or proceeding is brought for damages to property, or for personal injury or death, on account of the employee's operation of a motor vehicle in the scope of his office or employment with the Federal Government or on account of the employee's performance of medical care, treatment, or investigation in the scope of his office or employment with the Public Health Service, the Veterans Administration Department of Medicine and Surgery, the Department of State (including the the Armed Forces, the Department of Defense, the Central Intelligance Agency, Agency for International Development), or the National Aeronautics and Space Administration shall promptly deliver all process and pleadings served upon the employee, or an attested true copy thereof, to the employee's immediate superior or to whoever is designated by the head of the employee's department or agency to receive such papers. If the action is brought against an employee's estate this procedure shall apply to the

employee's personal representative. In addition, upon the employee's receipt of such process or pleadings, or any prior information regarding the commencement of such a civil action or proceeding, the employee shall immediately so advise his superior or the designee thereof by telephone or telegraph. The superior or designee shall promptly furnish the United States attorney for the district embracing the place wherein the action or proceeding is brought and the Chief of the Torts Section, Civil Division, Department of Justice, with information concerning the commencement of such action or proceeding, and copies of all process and pleadings therein.

(b) Any program participant as that term is defined in 42 U.S.C. 247b(k)(2)(B) against whom a civil action or proceeding is brought for damages for personal injury or wrongful death on account of the administration of swine flu vaccine under the National Swine Flu Immunization Program of 1976 (or the personal representative or successor of such program participant, if the action is brought against the estate or successor of such program participant) shall promptly deliver all process and pleadings served upon such program participant, or an attested true copy thereof, to the Assistant Section Chief for Swine Flu Litigation, Torts Section, Civil Division, U.S. Department of Justice, Washington, D.C. 20530, and to the Department Claims Officer, Office of the General Counsel, Department of Health, Education and Welfare, Washington, D.C. 20201. The Assistant Section Chief for Swine Flu Litigation shall promptly furnish copies of the papers to the United States attorney for the district embracing the place wherein the action or proceeding is brought.

4. The present text of § 15.2 is designated as paragraph (a), the heading for § 15.2 is revised and a new paragraph (b) is added to read as follows:

§ 15.2 Providing data bearing upon scope of employment or program participant status.

* * * * *

(b) A program participant as that term is defined in 42 U.S.C. 247b(k)(2)(B) shall deliver all information in the participant's possession or reasonably available to the participant concerning the participant's status as a program participant to the Assistant Section Chief for Swine Flu Litigation, Torts Section, Civil Division, U.S. Department of Justice, Washington, D.C. 20530, upon request and within such time as shall be fixed.

5. Section 15.3 is revised to read as follows:

§ 15.3 Removal and defense of suits.

(a) The United States Attorneys are authorized to make the certifications provided for in 10 U.S.C. 1089(c), 22 U.S.C. 817(c), 28 U.S.C. 2679(d), 38 U.S.C. 4116(c), and 42 U.S.C. 233(c) and 2458a(c) with respect to civil actions or proceedings brought against Federal employees in their respective districts. Such a certification may be withdrawn if a further evaluation of the relevant facts or the consideration of new or additional evidence calls for such action. The making, withholding, or withdrawing of certifications, and the removal and defense of, or the refusal to remove and defend, such civil actions or proceedings by the United States Attorneys shall be subject to the instructions and supervision of the Assistant Attorney General in charge of the Civil Division.

(b) The Assistant Attorney General in charge of the Civil Division is authorized: (1) To make the certification provided for in 42 U.S.C. 247b(k)(5) with respect to civil actions or proceedings brought against program participants in various courts of law; (2) to withdraw that certification if further evaluation of the relevant facts or the consideration of new or additional evidence calls for such action; (3) to move to revoke such certification pursuant to 42 U.S.C. 247b(k)(6) should the facts warrant; and (4) to redelegate to subordinate division officials the authority delegated by this paragraph, provided that such redelegation shall be in writing and shall be approved by the Associate Attorney General before becoming effective.

Dated: March 14, 1977.

GRIFFIN B. BELL,
Attorney General.

[FR Doc.77-8474 Filed 3-21-77;8:45 am]

Title 29—Labor

CHAPTER I—NATIONAL LABOR RELATIONS BOARD

PART 102—RULES AND REGULATIONS, SERIES 8

Ex Parte Communications

AGENCY: National Labor Relations Board.

ACTION: Correction of error in sequence of published rules.

SUMMARY: On Wednesday March 9, 1977 the National Labor Relations Board published in the FEDERAL REGISTER, 42 FR 13113-13114 certain revisions to Subpart P of its rules, relating to ex parte communications. Through error, the subsection (b) and (c) of § 102.133 were there published as subsections of § 102.132, which has no such subsections. The published text of §§ 102.132 and 102.133 is hereby corrected to show the subsections in the proper sequence, as set forth below:

Subpart P—Ex Parte Communications

§ 102.132 Reporting of prohibited communications; penalties.

(a) Any Board agent of the categories defined in § 102.128 to whom a prohibited oral ex parte communication is attempted to be made shall refuse to listen to the communication, inform the communicator of this rule, and advise him that if he has anything to say it should be said in writing with copies to all parties. Any such board agent who receives, or who makes or knowingly causes to be made, an unauthorized ex parte communication shall place or cause to be placed on the public record of the proceeding (1) the communication, if it was written, (2) a memorandum stating the substance of the communication, if it was oral, (3) all written responses to the prohibited communication, and (4) memoranda stating the substance of all oral responses to the prohibited communication. The executive secretary, if the proceeding is then pending before the Board, the administrative law judge, if the proceeding is then pending before any such judge, or the regional director, if the proceeding is then pending before a hearing officer or the regional director, shall serve copies of all such materials placed on the public record of the proceeding on all other parties to the proceeding and on the attorneys of record for the parties. Within 10 days after the mailing of such copies, any party may file with the executive secretary, administrative law judge, or regional director serving the communication, and serve on all other parties, a statement setting forth facts or contentions to rebut those contained in the prohibited communication. All such responses shall be placed in the public record of the proceeding, and provision may be made for any further action, including reopening of the record, which may be required under the circumstances. No action taken pursuant to this provision shall constitute a waiver of the power of the Board to impose an appropriate penalty under § 102.133.

§ 102.133 Penalties and enforcement.

(a) Where the nature and circumstances of a prohibited communication made by or caused to be made by a party to the proceeding are such that the interests of justice and statutory policy may require remedial action, the Board, administrative law judge, or regional director, as the case may be, may issue to the party making the communication a notice to show cause, returnable before the Board within a stated period not less than 7 days from the date thereof, why the Board should not determine that the interests of justice and statutory policy require that the claim or interest in the proceeding of a party who knowingly makes a prohibited communication or knowingly causes a prohibited communication to be made, should be dismissed, denied, disregarded or otherwise adversely affected on account of such violation.

(b) Upon notice and hearing, the Board may censure, suspend, or revoke the privilege of practice before the agency of any person who knowingly and willfully makes or solicits the making of a prohibited ex parte communication. However, before the Board institutes formal proceedings under this subsection, it shall first advise the person or persons concerned in writing that it proposes to take such action and that they may show cause, within a period to be stated in such written advice, but not less than 7 days from the date thereof, why it should not take such action.

(c) The Board may censure, or, to the extent permitted by law, suspend, dismiss, or institute proceedings for the

dismissal of, any Board agent who knowingly and willfully violates the prohibitions and requirements of this rule.

Dated, Washington, D.C., March 17, 1977.

By direction of the Board.

JOHN C. TRUESDALE,
Executive Secretary.

[FR Doc.77-8526 Filed 3-21-77;8:45 am]

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1952—APPROVED STATE PLANS FOR ENFORCEMENT OF STATE STANDARDS

Michigan Plan; Level of Federal Enforcement

1. *Background.* Part 1954 of Title 29, Code of Federal Regulations, sets out procedures under section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (hereinafter referred to as the Act) for the evaluation and monitoring of State plans which have been approved under section 18(c) of the Act and 29 CFR Part 1902. Section 1954.3 of this chapter provides guidelines and procedures for the exercise of discretionary concurrent Federal enforcement authority under section 18(e) of the Act with regard to Federal standards in issues covered under an approved State plan. In accordance with § 1954.3(b) of this chapter, Federal enforcement authority will not be exercised as to occupational safety and health issues covered under a State plan where a State is operational. A State is determined to be operational under § 1954.3(b) of this chapter when it meets the following requirements: enacted enabling legislation, approved State standards, a sufficient number of qualified enforcement personnel, and provisions for review of enforcement actions. In determining whether and to what extent a State plan meets the operational guidelines, the results of evaluations conducted under 29 CFR Part 1954 are taken into consideration. Once this determination has been made, under § 1954.3(f) of this chapter, a notice of the determination of the operational status of a State plan as described in an agreement setting forth the Federal-State responsibilities is to be published in the FEDERAL REGISTER.

2. *Notice of Michigan Operational Agreement.* (a) In accordance with the provisions of § 1954.3(f) of this chapter, notice is hereby given that it has been determined that Michigan has met the following conditions for operational status:

(1) Enactment of the Michigan Occupational Safety and Health Act (Act 154, Public Acts of 1974, MIOSHA) which became law and fully effective on January 1, 1975, and which was approved February 1, 1975 (41 FR 8555) as part of the Michigan Plan.

(2) The State has adopted and made effective occupational safety and health standards providing protection equal to those Federal standards contained in 29 CFR Part 1910, dated June 27, 1974, and in 29 CFR Part 1926, dated June 24, 1974.

(3) A sufficient number of qualified safety and health compliance personnel are employed by the State under an approved merit system to conduct MIOSHA inspections; namely, 55 safety and 37 health inspectors, as of January 6, 1977.

(4) Operations since January 1, 1975, under MIOSHA, provide a review and appeals system for employers and employees to contest enforcement actions and/or abatement periods.

(5) State enforcement since January 1, 1975, of the State standards described in (2) above has been monitored under Subpart C of 29 CFR Part 1954, including four semi-annual evaluations covering the period through April 1, 1976.

(b) In addition, the State has provided under its plan for:

(1) A State Occupational Safety and Health Poster, the display of which is required for compliance with Michigan's Occupational Safety and Health Act. The State has submitted the Poster as a developmental plan change in accordance with 29 CFR Part 1953 for which Federal approval was given September 22, 1975 (40 FR 44131).

(2) Occupational injury and illness recordkeeping and reporting by employers covered under the plan.

(3) Response to complaints filed with the Michigan Department of Labor for violation of the prohibition of employer discrimination against employees for exercising their rights under the Michigan Occupational Safety and Health Act.

(4) Assurances of the rights of employers and employees, and their representatives, consistent with the provisions of the Act and its implementing regulations.

Pursuant to this finding, an agreement effective January 6, 1977, and incorporated as part of the Michigan plan has been entered into among Keith Molin, Director, Michigan Department of Labor, Maurice S. Reizen, M.D., Director, Michigan Department of Public Health, and Barry J. White, Regional Administrator for Occupational Safety and Health of the U.S. Department of Labor, providing that Federal enforcement activity under section 18(e) of the Act will not be initiated with regard to Federal occupational safety and health standards in the issues covered under 29 CFR Part 1910 and Part 1926, where State standards are in effect and operational, except those areas listed below retained and/or exercised by the Federal Government under the Act.

Under the agreement, Federal responsibility under the Act will continue to be exercised, among other things, with regard to: complaints about violations of the discrimination provisions of section 11(c) of the Act (29 U.S.C. 660(c)); enforcement of standards promulgated under the Act subsequent to the agreement where necessary to protect employees as in the case of temporary emergency standards promulgated under section 6(c) of the Act (29 U.S.C. 655(c)), until such time as the State shall have adopted equivalent standards in accordance with Subpart C of 29 CFR Part 1953; enforcement of Federal standards contained in 29 CFR 1910.15 through 1910.19 in the U.S. navigable waters, which issues have been specifically excluded from coverage under the plan; and investigations and inspections for the purpose of evaluating the State plan under sections 18 (e) and (f) of the Act (29 U.S.C. 667 (e) and (f)). The agreement is subject to revision or termination by the Assistant Secretary of Labor for Occupational Safety and Health upon substantial failure by the State to comply with any of its provisions, or when the results of evaluation under 29 CFR Part 1954 reveal that State operations covered by the agreement fail in a substantial manner to be at least as effective as the Federal program.

In accordance with this agreement and effective as of January 6, 1977, Subpart T of Part 1952 is hereby amended as set forth below:

§ 1952.262 Level of Federal enforcement.

Pursuant to §§ 1902.20(b)(1)(iii) and 1954.3 of this chapter under which an agreement has been entered into with Michigan, effective January 6, 1977, and based on a determination that Michigan is operational in the issues covered by the Michigan occupational safety and health plan, discretionary Federal enforcement activity under section 18(e) of the Act (29 U.S.C. 667(e) will not be initiated with regard to Federal occupational safety and health standards in issues covered under 29 CFR Part 1910 and 29 CFR Part 1926. The U.S. Department of Labor will continue to exercise authority, among other things, with regard to: complaints filed with the U.S. Department of Labor about violations of the discrimination provisions of section 11(c) of the Act (29 U.S.C. 660(c)); Federal standards promulgated subsequent to the agreement where necessary to protect employees, as in the case of temporary emergency standards promulgated under section 6(c) of the Act (29 U.S.C. 655(c)), in the issues covered under the plan and the agreement until such time as Michigan shall have adopted equivalent standards in accordance with Subpart C of 29 CFR Part 1953; standards contained in 29 CFR 1910.15 through 1910.19, which issues have been specifically excluded from coverage under the Michigan plan; and investigations and inspections for the purpose of the evaluation of the Michigan plan under sections 18(e) and (f) of the Act (29 U.S.C. 667(e) and (f)). The Regional Administrator for Occupational Safety and Health will make a prompt recommendation for resumption of the exercise of Federal enforcement authority under section 18(e) of the Act (29 U.S.C. 667(e)) whenever, and to the degree, necessary to assure occupational safety and health protection to employees in the State of Michigan.

(Secs. 8(g)(2), 18, Pub. L. 91-596, 84 Stat. 1600, 1608 (29 U.S.C. 657(g)(2), 667).)

Signed at Washington, D.C., this 15th day of March 1976.

B. M. CONCKLIN,
Deputy Assistant Secretary of Labor.

[FR Doc.77-8508 Filed 3-21-77;8:45 am]

CHAPTER XX—OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

PART 2201—REGULATIONS IMPLEMENTING THE FREEDOM OF INFORMATION ACT

PART 2300—REGULATIONS IMPLEMENTING THE FREEDOM OF INFORMATION ACT

Changes in: (1) Method of Publishing Commission Decisions; (2) Delegation of Authority; and (3) Procedures for Requesting Documents and Information

On December 3, 1976, the Commission published (41 FR 53069) proposed amendments to its regulations implementing the Freedom of Information Act, 5 U.S.C. 552, as amended November 21, 1974 (Pub. L. 93-502). That publication also proposed that the present regulations, published in Part 2300, be redesignated Part 2201. Only one comment was received on the proposed amendment, and the comment was given due consideration as explained further below. However, no changes were made in the proposed amendments as a result of the comment received.

Minor editorial changes were made in the proposal in § 2201.4(e), those changes being made to correct incorrect addresses and phone numbers of Commission offices.

The one comment received contained a suggestion that the official citation for Commission decisions, discussed in § 2201.4(c) of the proposal, be changed to adopt a continuous page-numbering system for all decisions issued during any one year. Although the described citation method is not being changed presently, the suggestion is under study and may be acted upon at a later date.

Additionally, the Commission reemphasizes that the microfiche publishing medium has been adopted on an experimental basis and that its continued usage will be examined after adequate time has passed in which to judge its usability.

In consideration of the foregoing, Part 2300 of Title 29 is hereby vacated and new Part 2201 is hereby adopted as set forth below.

Effective date: The new Part 2201 will become effective on March 22, 1977.

Adopted by the Occupational Safety and Health Review Commission at its office in Washington, D.C., on the 16th day of March, 1977.

For the Commission,

WILLIAM S. MCLAUGHLIN,
Executive Secretary.

Sec.
2201.1 Purpose and scope
2201.2 Description of agency
2201.3 Delegation of authority
2201.4 Information policy
2201.5 Copies of records
2201.6 Procedure for obtaining information
2201.7 Processing requests
2201.8 Maintenance of statistics

AUTHORITY: Sec. 12(g), Pub. L. No. 91-596, 84 Stat. 1604 (29 U.S.C. 661(f)), 5 U.S.C. 552 as amended, 1974 (Pub. L. No. 83-502).

§ 2201.1 Purpose and scope.

The purpose of the provisions of the Part is to provide procedures to implement the Freedom of Information Act, 5 U.S.C. section 552, as amended November 21, 1974 (Pub. L. 93-502). The following provisions are applicable only to such items of information as relate to the agency or are items within its custody. They are not applicable to the rights of parties appearing in adversary proceedings before the Commission to obtain discovery from an adverse party. Such matters are governed by the Commission's Rules of Procedure which are published at Part 2200 of this chapter.

§ 2201.2 Description of agency.

The Occupational Safety and Health Review Commission (OSHRC) adjudicates contested enforcement actions under the Occupational Safety and Health Act of 1970 (84 Stat. 1590, 29 U.S.C. 651-77). Decisions of the Commission on such actions are issued only after the parties to the case are afforded an opportunity for a hearing in accordance with section 554 of Title 5, United States Code. All such hearings are conducted by an OSHRC Administrative Law Judge at a place convenient to the parties and are open to the public.

§ 2201.3 Delegation of authority.

The Director of Information and Publications is delegated the exclusive authority to act upon all requests for information, documents and records which are received from any person or organization. However, copies of individual Commission decisions are available without restriction (see §§ 2201.4(e) and 2201.6(a)).

§ 2201.4 Information policy.

(a) Except for matters specifically excluded by section 553(b) of Title 5, United States Code or other applicable statute, all documents and records maintained by this agency or within the custody thereof shall be available to the public upon request filed in accordance with this part.

(b) Any person may examine and copy any such document or record of this agency (or within the custody thereof), under conditions prescribed by the Director of Information and Publications, between the hours of 10:00 a.m. and 3:00 p.m. on any business day so long as it does not interfere with the trial or disposition of a pending case.

(c) All final OSHRC decisions (including decisions of the Commission and of its administrative law judges) of general applicability (including concurring and dissenting opinions) are published by the Superintendent of Documents, U.S. Government Printing Office, in a series of bound volumes known as OSAHRC Reports Volumes 1 through 20, for decisions and reports from April 28, 1971 to October 31, 1975. After Volume 20, OSAHRC Reports are published in a series of microfiche. An example of the official method of citation of Commission decisions printed on microfiche is as follows:

SAMPLE—Secretary v. J. W. Black Lumber Co., 75 OSAHRC 1/B9, p. 2

Year decision issued	The official reporter	The serial No. of Fiche where decision is printed	Coordinates on the Fiche for 1st page of cited decision	Cite to specific page of cited decision
1975....	OSAHRC	1/	B9	2

Copies of individual decisions will also be available from the Commission (see § § 2201.4(e) and 2201.6(a)).

(d) The Commission maintains an index to all decisions in OSAHRC Reports. This index is published and is available from the Superintendent of Documents, U.S. Government Printing Office. The index shall be updated, at least quarterly.

(e) Copies of individual Commission decisions (including administrative law judge decisions) may be obtained free of charge from the following offices:

NATIONAL OFFICE

Director of Information and Publications, 1825 K Street, N.W., Washington, D.C. 20006. 202-634-7943.

REGIONAL OFFICES

Atlanta, Georgia: 1365 Peachtree Street, N.E., Room 400, Atlanta, Georgia 30309. 404-881-4086.

Boston, Massachusetts: 100 Summer Street, Suite 1521, Boston, Massachusetts 02110. 617-223-3757.

Chicago, Illinois: 55 East Monroe Street, Room 1530, Chicago, Illinois 60603. 213-353-2564.

Dallas, Texas: 1507 Pacific Avenue, Fidelity Union Tower, Suite 400, Dallas, Texas 75201. 214-749-7171.

Denver, Colorado: 1050 Seventeenth Street, Prudential Building, Suite 1718, Denver, Colorado 80265. 303-837-2281.

San Francisco, California:
211 Main Street, Room 240, San Francisco, California 94105. 415-556-8558.

New York, New York:
1515 Broadway, Room 3800, New York, New York 10036. 212-399-5985.

St. Louis, Missouri:
1114 Market Street, Room 608, St. Louis, Missouri 63101. 314-425-5071.

Washington, D.C.:
6525 Belcrest Road, Suite 1005, Hyattsville, Maryland 20782. 301-436-8870.

(f) Disclosure of information contained in the official personnel folder of any OSHRC employee or former employee shall be governed by the regulations published by the United States Civil Service Commission in 5 CFR Part 294, Subpart G.

§ 2201.5 Copies of records.

(a) Copies of documents or records of this agency, or within the custody thereof, or information respecting the time and place of hearings will be furnished to any person or organization requesting the same in accordance with this part, except for OSAHRC Reports and Commission index, which are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (See § 2201.4(c) and (d)). See § 2201.4(e) for instructions for obtaining copies of individual Commission decisions.

(b) The Director of Information and Publications shall charge a fee for searching for and copying such documents or records.

(1) The fee per copy of each page up to 8½" x 14" shall be $.10 per copy per page. However, when the fee so computed would be less than $3.00, no fee shall be charged.

(2) The search charge shall be $5.00 per hour of clerical time and $10.00 per hour of professional time, except that no search charge shall be made for copies of decisions.

(3) Copies of individual decisions of the Commission shall be available from the Director of Information and Publications and from the several Commission offices without charge (see §§ 2201.4(e) and 2201.6(a)).

(4) Searches for computerized records shall be charged at the actual charge to the government not to exceed $200 per hour. This fee includes machine time and that of the operator and clerical personnel. The fee for computer printouts shall be 20 cents per page for the original and carbon copies concurrently printed.

(5) The fee for certification or authentication shall be $3.00 per document.

(c) All charges may be waived or reduced by the Director of Information and Publications whenever it is determined that it is in the public interest to do so because furnishing the information can be considered as primarily benefiting the general public.

(d) Copies of documents (including the hearing transcript) which have been filed in an OSHRC case which, at the time of the request therefor, is pending in any United States Court should be directed to such Court.

(e) Requests for transcripts of OSHRC hearing shall be made in accordance with the procedure set out in § 2201.6(d).

§ 2201.6 Procedure for obtaining information.

(a) Persons or organizations wishing to obtain copies of individual Commission decisions (including administrative law judge decisions) may call, write or visit either the Director of Information and Publications at the national office or any of the field offices of the Commission. See § 2201.4(e) for addresses and telephone numbers of those offices. These copies are available free of charge.

(b) Persons or organizations wishing to obtain copies of numerous decisions or an index of decisions are advised to contact the U.S. Government Printing Office to secure copies of OSAHRC Reports and of the OSAHRC Reports Index. See § 2201.4(c) for information on OSAHRC Reports. See § 2201.4(d) for information on the Commission index.

(c) Persons or organizations wishing to obtain copies of the Commission's press releases, rules of procedure or any other published material (other than the index and decisions), information concerning the date, time and place of hearings or other information of a general nature concerning operations of the Commission may call, write or visit the Director of Information and Publications at the national office of the Commission. These documents and items of information are available free of charge.

(d) All persons or organizations requesting any information from the Commission or any record or document (other than the information, records and documents specified in subsections (a), (b) and (c) of this section (§ 2201.6)) of the Commission or in its custody shall submit such request in writing to the Director of Information and Publications, OSHRC, 1825 K Street, N.W., Washington, D.C. 20006. All such requests for information should be clearly identified as a request for information under the Freedom of Information Act, and if submitted by mail or otherwise submitted in an envelope or other cover, should carry the phrase "INFORMATION REQUEST" in capital letters on the front of the envelope or cover.

(e) If a request does not comply with the provisions of the preceding paragraph, it shall not be deemed received by the Commission until the time it is actually received by the Director of Information and Publications.

§ 2201.7 Processing requests.

(a) The Director of Information and Publications shall respond promptly to all requests for information or for copies of records or documents which are submitted in accordance with this regulation but in no event shall such response be furnished later than ten (10) working days following receipt of such request.

(b) A request that is expected to involve assessed fees in excess of $50.00 will not be deemed to have been received until the requester is advised of the anticipated cost and agrees to bear it.

(c) In the event any request for information or for a copy of any document or record is denied, the Director of Information and Publications shall, within 10 working days of the receipt of the request, notify the requester of the denial. Such denial shall specify the reason therefor and also advise that the denial may be appealed as specified hereinafter.

(d) Whenever any request for information or for a copy of any document or record is denied by the Director of Information and Publications, an appeal may be filed with the Chairman of the Commission within 30 working days after the requester receives notification that the request has been denied. The appeal shall be in writing and the Chairman shall respond ot the same in accordance with section 552(a)(6) of Title 5, United States Code, and within the time period set forth therein.

§ 2201.8 Maintenance of statistics.

(a) The Director of Information and Publications shall maintain records of

(1) The total amount of fees collected by this agency pursuant to this part;

(2) The number of denials of requests for records or information made pursuant to this part and the reason for each;

(3) The number of appeals from such denials, together with the results of such appeals, and the reason(s) for the action upon each appeal that results in a denial of information or documents;

(4) The name(s) and title(s) or position(s) of each person responsible for each denial of records requested and the number of instances of participation for each;

(5) The results of each proceeding conducted pursuant to sect ion 552(a)(4)(F) of Title 5, United States Code, including a report of the disciplinary action against the official or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(6) A copy of every rule made by this agency affecting or in implementation of section 552 of Title 5, United States Code;

(7) A copy of the fee schedule for copies of records and documents requested pursuant to this regulation; and

(8) All other information which indicates efforts to administer fully the letter and spirit of the Freedom of Information Act and the above rules.

(b) The Director of Information and Publications shall annually, within 60 days following the close of each calendar year, prepare a report covering each of the categories of records to be maintained in accordance with the foregoing and submit the same to the Speaker of the House of Representatives and the President of the Senate for referral to the appropriate committees of the Congress.

[FR Doc.77-8417 Filed 3-21-77;8:45 am]

PART 2203—REGULATIONS IMPLEMENTING THE GOVERNMENT IN THE SUNSHINE ACT

Public Attendance at Meetings of the Commission

On February 11, 1977, the Commission published (42 FR 8680) proposed regulations implementing sections (b) through (f) of the Government in the Sunshine Act, 5 U.S.C. 552b ((b) through (f)), (the "Act"). Two comments were received, and both were given careful consideration as further explained below; however, no changes were made in the proposal.

One commentator stated that the exemption to open meetings contained in proposed § 2203.2(b), for meetings to discuss matters relating "solely to internal personnel rules and practices," was broader than the Act allows. The Commission feels that such is not the

case and that the exemption as stated is proper under the Act. The same commentator suggested that the regulations should require an annual report to Congress such as required in section (j) of the Act, 5 U.S.C. 552b(j). The Commission is required to submit such report in any event, and it is felt that a regulation on that subject is not essential.

Another commentator expressed concern that the definition of the term "meeting" in § 2203.2 of the proposal specifically excludes "the consideration by Commissioners individually of business which is circulated sequentially in writing . . ." The Commission feels that the proposed section meets both the spirit and the letter of the law as expressed in the Conference Report accompanying the bill. However, the Commissioners do not intend purposely to use this exemption to any extraordinary extent so as to avoid compliance with the Act.

In consideration of the foregoing, new Part 2203 is hereby adopted as set forth below.

Effective date: New Part 2203 will become effective immediately.

Adopted by the Occupational Safety and Health Review Commission at its office in Washington, D.C., on the 16th day of March, 1977.

For the Commission,

WILLIAM S. MCLAUGHLIN,
Executive Secretary.

Sec.
2203.1 Purpose and scope
2203.2 Meeting defined
2203.3 Public attendance at Commission meetings

AUTHORITY: 29 U.S.C. 661(f), Pub. L. No. 91-596, 84 Stat. 1604 (5 U.S.C. 552b(g), Pub. L. No. 94-409, 90 Stat. 1241.)

§ 2203.1 Purpose and scope.

Consistent with the principle that the public is entitled to the fullest practicable information regarding the decision-making processes of the Federal Government, it is the purpose of the regulations in this Part to open the meetings of the Occupational Safety and Health Review Commission to public observation while preserving the Commission's ability to carry out its responsibilities and protecting the rights of individuals.

§ 2203.2 Meeting defined.

(a) For the purposes of this Part, the term "meeting" means the deliberations of at least a majority of the members of the Commission, where such deliberations determine or result in the joint conduct or disposition of official Commission business, but does not include the deliberations required or permitted under §§ 2203.3 (c) and (d).

(b) The consideration by Commissioners individually of business which is circulated sequentially in writing is not considered a meeting for purposes of this part.

(c) Conference telephone calls among the Commissioners are considered meetings under this Part if such calls otherwise qualify as meetings under paragraph (a) of this section.

§ 2203.3 Public attendance at Commission meetings.

(a) Commissioners shall not jointly conduct or dispose of Commission business in a meeting other than in accordance with this part. Except as provided in paragraph (b) of this section, every portion of every meeting of the Commission shall be open to public observation. The public shall not be allowed to participate in any of the discussions.

(b) *Closed Commission meetings.* Except in a case where the Commission finds that the public interest requires otherwise, the second sentence of paragraph (a) of this section shall not apply to any portion of a Commission meeting, and the requirements of paragraphs (c) and (d) of this section shall not apply to any information pertaining to such meeting otherwise required by this section to be disclosed to the public, where the Commission properly determines that such portion or portions of its meeting or the disclosure of such information is likely to:

(1) Disclose matters that are (i) specifically authorized under criteria established by an Executive order to be kept secret in the interests of national defense or foreign policy and (ii) in fact properly classified pursuant to such Executive order;

(2) Relate solely to the internal personnel rules and practices of the Commission;

(3) Disclose matters specifically exempted from disclosure by statute (other than section 552 of title 5), *Provided*, That such statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) Disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Involve accusing any person of a crime, or formally censuring any person;

(6) Disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;

(7) Disclose investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records, but only to the extent that the production of such records or information would (i) interfere with enforcement proceedings, (ii) deprive a person of a right to a fair trial or impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel;

(8) Disclose information contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions;

(9) Disclose information the premature disclosure of which would:

(i) Be likely to (a) lead to significant financial speculation in currencies, securities, or commodities, or (b) significantly endanger the stability of any financial institution, or

(ii) Be likely to significantly frustrate implementation of a proposed Commission action, except where the Commission has already disclosed to the public the content or nature of its proposed action, or where the Commission is required by law to make such disclosure on its own initiative prior to taking final agency action on such proposal; or

(10) Specifically concern the Commission's issuance of a subpoena or the Commission's participation in a civil action or proceeding, an action in a foreign court or international tribunal, or an arbitration, or the initiation, conduct or disposition by the Commission of a particular case of formal Commission adjudication pursuant to the procedures in section 554 of Title 5, U.S.C.

(c) (1) *Procedures for closing meetings.* Action under paragraph (b) of this section shall be taken only when two Commissioners vote to take such action. A separate vote of the Commissioners shall be taken with respect to each Commission meeting a portion or portions of which are proposed to be closed to the public pursuant to paragraph (b) of this section, or with respect to any information which is proposed to be withheld under paragraph (b) of this section. A single vote may be taken with respect to a series of meetings, a portion or portions of which are proposed to be closed to the public, or with respect to any information concerning such series of meetings, so long as each meeting in such series involves the same particular matters and is scheduled to be held no more than thirty days after the initial meeting in such series. The vote of each Commissioner participating in such vote shall be recorded and no proxies shall be allowed.

(2) Whenever any person whose interests may be directly affected by a portion of a meeting requests that the Commission close such portion to the public for any of the reasons referred to in paragraphs (b)(5), (b)(6), or (b)(7) of this section, the Commission, upon request of any one of its members, shall vote by recorded vote whether to close such meeting.

(3) Within one day of any vote taken pursuant to paragraph (c)(1) or (c)(2) of this section, the Commission shall make publicly available a written copy of such vote reflecting the vote of each member on the question. If a portion of a meeting is to be closed to the public, the Commission shall, within one day

of the vote taken pursuant to paragraph (c)(1) or (c)(2) of this section, make publicly available a full written explanation of its action closing the portion together with a list of all persons expected to attend the meeting and their affiliation.

(4) The Commission has determined that a majority of its meetings may be closed to the public pursuant to paragraph (b)(10) of this section. Therefore, pursuant to 5 U.S.C. 552(b)(d)(4), Commission meetings shall be closed to the public pursuant to paragraph (b)(10) of this section when two Commissioners vote by recorded vote at the beginning of such meeting, or portion thereof, to close the exempt portion or portions of the meeting, and a copy of such vote, reflecting the vote of each Commissioner on the question, is made available to the public. The provisions of paragraphs (c)(1), (c)(2), and (c)(3) of this section, and all of paragraph (d) of this section shall not apply to any portion of a meeting to which this paragraph applies: *Provided*, That the Commission shall, except to the extent that such information is exempt from disclosure under the provisions of paragraph (b) of this section, provide the public with public announcement of the time, place, and subject matter of the meeting and of each portion thereof at the earliest practicable time.

(d) *Scheduling and public announcement.* (1) In the case of each meeting, the Commission shall make public announcement, at least one week before the meeting, of the time, place, and subject matter of the meeting, whether it is to be open or closed to the public, and the name and phone number of the official designated by the Commission to respond to requests for information about the meeting. Such announcement shall be made unless two Commissioners determine by a recorded vote that Commission business requires that such meeting be called at an earlier date, in which case the Commission shall make public announcement of the time, place, and subject matter of such meeting, and whether open or closed to the public, at the earliest practicable time.

(2) The time or place of a meeting may be changed following the public announcement required by paragraph (d)(1) of this section only if the Commission publicly announces such change at the earliest practicable time. The subject matter of a meeting, or the determination of the Commission to open or close a meeting, or a portion of a meeting, to the public, may be changed following the public announcement required by paragraph (d)(1) only if (i) two Commissioners determine by a recorded vote that Commission business so requires and that no earlier announcement of the change was possible, and (ii) the Commission publicly announces such change and the vote of each Commissioner upon such change at the earliest practicable time.

(3) Immediately following each public announcement required by paragraph (d)(1) of this section, notice of the time, place, and subject matter of a meeting, whether the meeting is open or closed, any change in one of the preceding, and the name and phone number of the official designated by the Commission to respond to requests for information about the meeting, shall also be submitted for publication in the FEDERAL REGISTER.

(e) *Certification of closed meetings; transcripts, electronic recordings, and minutes.* (1) For every meeting closed pursuant to paragraphs (b)(1) through (b)(10) of this section, the Counsel to the Commission shall publicly certify that, in his or her opinion, the meeting may be closed to the public and shall state each relevant exemptive provision. A copy of such certification, together with a statement from the presiding officer of the meeting setting forth the time and place of the meeting, and the persons present, shall be retained by the Commission. The Commission shall maintain a complete transcript or electronic recording adequate to record fully the proceedings of each meeting, or portion of a meeting, closed to the public, except that in the case of a meeting, or portion of a meeting, closed to the public pursuant to paragraph (b)(8), (b)(9)(i), or (b)(10) of this section, the Commission shall maintain either such a transcript or recording, or a set of minutes. Such minutes shall fully and clearly describe all matters discussed and shall provide a full and accurate summary of any actions taken, and the reasons therefor, including a description of each of the views expressed on any item and the record of any roll call vote (reflecting the vote of each Commissioner on the question). All documents considered in connection with any action shall be identified in such minutes.

(2) The Commission shall make promptly available to the public, in a place easily accessible to the public, the transcript, electronic recording, or minutes [as required by paragraph (e)(1) of this section] of the discussion of any item on the agenda, or of any item of the testimony of any witness received at the meeting, except for such item or items of such discussion or testimony as the Commission determines by a vote of two members (i) contains information which may be withheld under paragraph (b) of this section, and (ii) is not required by the public interest to be made available. Copies of such transcript, or minutes, or a transcription of such recording disclosing the identity of each speaker, shall be furnished to any person at the actual cost of duplication or transcription. The Commission shall maintain a complete verbatim copy of the transcript, a complete copy of the minutes, or a complete electronic recording of each meeting, or portion of a meeting, closed to the public, for a period of at least two years after such meeting, or until one year after that conclusion of any Commission proceeding with respect to which the meeting or portion was held, whichever occurs later.

[FR Doc.77-8418 Filed 3-21-77;8:45 am]

Title 47—Telecommunication

CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

[FCC 77-178]

PART 76—CABLE TELEVISION SERVICES

Network Program Nonduplication Protection Requirement of § 76.92

Adopted: March 8, 1977.

Released: March 18, 1977.

In re: Amendment of Part 76, Subpart F of the Commission's Rules and Regulations Concerning the Network Program Nonduplication Protection Requirement of § 76.92.

1. In Newport Cablevision, Inc. (Newport, Vermont), FCC 76-1140, ____ FCC 2d ____ (1976), the Commission clarified Section 76.92(d) of the Rules by stating that a television translator must be carried on a cable television system in order for the licensee or permittee of the translator to claim network program nonduplication protection. We have today denied a "Petition for Reconsideration" of our decision in the above-cited Newport Cablevision (FCC 77-179) case in which we have reiterated our determination that carriage of a translator by a cable system is a condition precedent to the assertion of nonduplication rights.

2. So as to avoid further confusion on the question of nonduplication rights of television translators, we are hereby amending § 76.92(d) of the Rules, as set forth below.

The amendment of our Rules, contained in the attachment is an interpretive rule and is therefore exempt from the prior notice requirements of the Administrative Procedure Act under 5 U.S.C. 553(A).

Authority for the rule amendment adopted herein is contained in Sections 4(i) and 303 of the Communications Act of 1934, as amended.

Accordingly, it is ordered, That effective March 23, 1977, § 76.92(d) of the Commission's Rules and Regulations is amended as set forth below.

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

FEDERAL COMMUNICATIONS COMMISSION,
VINCENT J. MULLINS,
Secretary.

Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

1. Section 76.92(d) is amended, as follows:

§ 76.92 Stations entitled to network program nonduplication protection.

* * * * *

(d) Any cable television system operating in a community to which a 100-watt or higher power translator station is licensed, which translator is located within the predicted Grade B signal contour of the television broadcast station that the translator station retransmits, and which translator is carried by the

cable system, shall, upon the request of such translator station licensee or permittee, delete the duplicating network programming of any television broadcast station whose reference point (See § 76.53) is more than 55 miles from the community of the system.

* * * * *

[FR Doc.77-8478 Filed 3-21-77;8:45 am]

[FCC 77-172]

PART 97—AMATEUR RADIO SERVICE

Deregulating Application Procedures Concerning Station Location of an Amateur Licensee

Adopted: March 8, 1977.

Released: March 17, 1977.

In the matter of amendment of Part 97 to deregulate application procedures concerning the station location of an Amateur licensee.

1. As part of its effort to eliminate those rules and regulations which are not absolutely essential to the proper administration of the Amateur Radio Service, the Commission has under consideration § 97.95(a)(2) of the Commission's Rules which requires a licensee to timely file a formal application when changing the fixed location of the licensee's amateur radio station.

2. At present when an authorized fixed station location is changed, formal application must be submitted to the Commission prior to any operation and within four months of the move. By this Order we are deleting the requirement that the application be filed within four months of the change of location. The rule has proved impractical to enforce and serves only a marginal purpose in the administration of the Amateur Radio Service.

3. Authority for this amendment appears in sections 4(i) and 303 of the Communications Act of 1934, as amended. The prior notice and public procedure provisions of the Administrative Procedure Act, 5 U.S.C. 553 are unnecessary because the Commission believes the minor amendment adopted herein will have an insignificant impact on Amateur licensees and the public at large and that no objection to such an amendment will be received. No present or future licensees in the Amateur Radio Service will be adversely affected by the removal of this restriction. Since the amendment relieves a rule restriction, the effective date of the rule change may be immediate, pursuant to the Administrative Procedure Act.

4. *Accordingly, it is ordered,* That Part 97 of the Commission's Rules is amended as set forth in the attachment below, effective March 23, 1977.

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

FEDERAL COMMUNICATIONS COMMISSION,
VINCENT J. MULLINS,
Secretary.

Part 97 of Chapter 1 of Title 47 of the Code of Federal Regulations is amended, as follows:

Section 97.95(a)(2) is revised to read as follows:

§ 97.95 Operation away from the authorized fixed operation station location.

(a) Operation within the United States, its territories, or possessions is permitted as follows:

* * * * *

(2) When the authorized fixed station operation location is changed, an application must be filed prior to any operation in accordance with § 97.47.

* * * * *

[FR Doc.77-8479 Filed 3-21-77;8:45 am]

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER D—TARIFFS AND SCHEDULES

[No. 35867][1]

PART 1307—FREIGHT RATE TARIFFS, SCHEDULES, AND CLASSIFICATIONS OF MOTOR CARRIERS

PART 1310—FREIGHT RATE TARIFFS AND CLASSIFICATIONS OF MOTOR COMMON CARRIERS

Construction, Filing, and Posting of Tariffs of Common Carriers of Property by Motor Vehicle and Tariffs of Certain Common Carriers by Water

Upon consideration of the record in the above-entitled proceeding, including the petition (1) of Sea-Land Service, Inc., filed August 30, 1976, (2) of Corley Companies, filed October 25, 1976, (3) of the Department of Defense, filed October 29, 1976, (4) of Aerospace Industries Association of America, Inc., filed October 29, 1976, (5) of Central and Southern Motor Freight Tariff Association, Inc., et al., filed October 29, 1976, (6) of Bulk Carrier Conference, Inc., filed October 29, 1976, and (7) of Motor Carriers Traffic Association, filed October 29, 1976, for reconsideration of the report and order (352 I.C.C. 46), and the reply to the petitions in (3) and (4) above, filed November 18, 1976, by Central and Southern Motor Freight Tariff Association, Inc., et al.; and

It appearing, that in the aforesaid report the Commission prescribed new regulations to govern the construction, filing, and posting of tariffs of common carriers of property by motor vehicle and tariffs of common carriers by water which contain joint motor-water rates or provisions governing such rates, designated as Tariff Circular MF No. 5 (49 CFR 1310); and that it was ordered that the Code of Federal Regulations be amended to reflect the addition of the new rules and the revocation of the old ones (Tariff Circular MF No. 3 (49 CFR 1307 B)), effective April 15, 1977;

And it further appearing, that in order to permit the Commission to consider the petitions filed, and in order that possible premature compliance with prescribed regulations may be forestalled, it is necessary that the effective date of the order be postponed until further notice by the Commission;

Wherefore, and good cause appearing therefore:

It is ordered, That on the Commission's own motion the effective date of the order entered in this proceeding on April 15, 1976, be, and it is hereby, stayed pending further order of the Commission.

And it is further ordered, That notice of this order be given to the general public by mailing a copy to each party of record in dockets Nos. 35867 and 35867 (Sub-No. 1) and by depositing a copy in the Office of the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, for public inspection, and by delivering a copy to the Director, Office of the Federal Register, for publication in the FEDERAL REGISTER as notice to all interested persons.

Dated at Washington, D.C., this 14th day of March 1977.

By the Commission, Commissioner Hardin.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8497 Filed 3-21-77;8:45 am]

[1] This proceeding is consolidated with docket No. 35867 (Sub-No. 1), Standard Headings and Standard Item Numbers for Commonly Published Rules in Tariffs of Class I Motor Common Carriers of Property and of Agents.

proposed rules

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

CIVIL SERVICE COMMISSION

[5 CFR Part 302]

EMPLOYMENT IN THE EXCEPTED SERVICE

Revised Basis for Disqualification and Dismissal

AGENCY: Civil Service Commission.

ACTION: Proposed rule.

SUMMARY: The Civil Service Commission proposes to amend § 302.203 of 5 CFR to revise the disqualifying factors for the excepted civil service. The Civil Service Commission published rules in the FEDERAL REGISTER on July 3, 1975 (40 FR 28047), for revision of the standards used to disqualify applicants for employment and for dismissing Federal employees as not suitable for Federal employment in the competitive civil service Through oversight at that time, 5 CFR Part 302 was not amended to revise the suitability standards for the excepted civil service.

DATES: Comments must be received on or before April 21, 1977.

ADDRESS: Written comments on this proposal may be sent to the Director, Bureau of Personnel Investigations, U.S. Civil Service Commission, 1900 E Street NW., Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT:

Joseph Durant, 202–632–6152

Accordingly, it is proposed to amend 5 CFR 302.203 as follows:

§ 302.203 Disqualifying factors.

The qualification standards established by an agency or by an administrative level or subdivision of an agency may provide that certain reasons disqualify an applicant for appointment. The following, among others, may be included as disqualifying reasons:

(a) Delinquency or misconduct in prior employment;

(b) Criminal, dishonest, infamous or notoriously disgraceful conduct;

(c) Intentional false statement or deception or fraud in examination or appointment;

(d) Habitual use of intoxicating beverages to excess;

(e) Abuse of narcotics, drugs, or other controlled substances;

(f) Reasonable doubt as to the loyalty of the person involved to the Government of the United States; or

(g) Any statutory disqualification which makes the individual unfit for the service.

An agency may not disqualify an applicant solely because of his or her retired status.

(5 U.S.C. 1302, 3301, 3302, 8151; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218.).

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77-8351 Filed 3-21-77;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 1006]

[Docket No. AO-356-A15]

MILK IN THE UPPER FLORIDA MARKETING AREA

Notice of Recommended Decision and Opportunity to File Written Exceptions on Proposed Amendments to Tentative Marketing Agreement and to Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This recommended decision would amend the Upper Florida Federal milk order. It provides interested parties with the opportunity to file written exceptions concerning the recommendations made herein.

The proposed amendment would provide regulated status for a milk plant located in the marketing area, which is operated by a cooperative association as a balancing plant for the market if during the month at least 50 percent of the producer milk of members of the cooperative association is delivered from farms to pool distributing plants or is transferred to such plants from the cooperative association's balancing plant(s).

The order change proposed in this decision would facilitate the efficient handling of the market's day-to-day milk supply needs.

DATE: Written exceptions to this recommended decision may be filed on or before the 7th day after publication of this decision in the FEDERAL REGISTER. Allowing 7 days for filing exceptions is adequate because: (1) this proceeding involves a limited issue; (2) the proposed action was not opposed at the hearing; and (3) the customary 15-day period for filing exceptions could unnecessarily delay timely final action to amend the order.

ADDRESS: Written exceptions should be filed in quadruplicate with the Hearing Clerk, Room 1077—South Building, United States Department of Agriculture, Washington, D.C. 20250. All written submissions will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT:

Martin J. Dunn, Marketing Specialist, Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, D.C. 20250 (202–447–7311).

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of Hearing—Issued February 3, 1977; published February 8, 1977 (42 FR 7962).

PRELIMINARY STATEMENT

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to proposed amendments to the tentative marketing agreement and order regulating the handling of milk in the Upper Florida marketing area, and of the opportunity to file written exceptions thereto.

This notice is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900).

The hearing on the record of which the proposed amendments, as hereinafter set forth, to the tentative marketing agreement and to the order, as amended, were formulated, was conducted at Orlando, Florida, on February 17, 1977, pursuant to notice thereof.

The material issue on the record of the hearing relates to whether the order should accord pool status to cooperative association balancing plants.

FINDINGS AND CONCLUSIONS

The following findings and conclusions on the material issue are based on evidence presented at the hearing and the record thereof:

Cooperative association balancing plants. The order should provide for the pooling of any non-distributing plant located in the marketing area and operated by a cooperative association as a balancing plant for the regulated market if during the month at least 50 percent of the producer mill of members of the cooperative association is delivered from the farms to pool distributing plants or is transferred to such plants from the cooperative association's balancing plant(s). Such pool status should be lim-

ited to plants approved by a duly constituted health authority to handle milk for fluid consumption. The plant should not be accorded pool balancing plant status if it meets the pooling standards for a supply plant under any Federal order.

The proposal for pooling a cooperative association balancing plant was made by the major cooperative association in the market. The requirements adopted herein are essentially those proposed by the association, and there was no opposition testimony presented at the hearing.

A spokesman for the cooperative testified that the association, since its formation, has assumed the responsibility of furnishing most of the fluid milk requirements of handlers regulated by the Upper Florida milk order. Also, the association handles practically all of the milk in excess of the fluid handlers' requirements.

The witness stated that as handlers have reduced the number of bottling days, the demand pattern for fluid milk has changed. Currently, one fluid handler bottles six days a week, six handlers bottle five days a week, and three handlers bottle four days a week. This development has tended to concentrate the number of days in the week that the association is called upon to dispose of reserve supplies not needed for fluid use. As there are no butter-nonfat dry milk or cheese plants located in Florida, a large proportion of the milk in excess of fluid requirements must be shipped out of State. About 67 percent of such milk was shipped out of State in 1976.

What has occurred, however, is that the reserve milk that must be handled by proponent association is heaviest on weekends, precisely when relatively nearby manufacturing plants in Tennessee and Louisiana are running at near capacity. Milk must then be hauled greater distances and, on occasion, has had to be taken to Minnesota for disposition. To improve this situation, the association is building a milk receiving and balancing station which is expected to be operative in May 1977.

The operation of a cooperative association balancing plant in the Upper Florida market will provide an efficient means whereby a cooperative association can assemble milk not needed at pool distributing plants. Such milk would be assembled for storage and subsequent disposition to manufacturing outlets, or transferred to pool distributing plants as needed. This method of operation will provide an efficient means whereby handlers buying milk from the cooperative may adjust their receipts from day to day to fit their bottling needs and at the same time have assurance through arrangements with the cooperative association that milk will always be available for fluid use as needed. Milk not needed for fluid use can then be disposed of by the association in an orderly and efficient manner.

To achieve this objective the order should provide for the pooling of any cooperative association balancing plant located in the marketing area if during the month at least 50 percent of the producer milk of members of the cooperative association is delivered from the farms to pool distributing plants or is transferred to such plants from the cooperative association's balancing plant(s). This is the same qualifying percentage that now applies to supply plants.

Without the in-area requirement for a cooperative association balancing plant, there would always be the threat that a multi-market cooperative could use the balancing plant provisions as a means of pooling unneeded milk supplies under the order by requesting the pooling of a plant basically associated with another market. This could be to the detriment of nonmember producers and other cooperatives associated with the Upper Florida market. To maintain the integrity of regulation, it is necessary to insure that only milk which by location or performance is reasonably a part of the market's milk supply be pooled under the Upper Florida order.

There is always the potential that a balancing plant could meet the shipping requirements for pooling either in this market or another Federal order market. In such event, it is intended that the plant be qualified as a pool supply plant under the appropriate order rather than as a pool balancing plant under this order. Testimony of proponent indicated that the balancing plant being constructed for the market will be used primarily for the disposition of milk not needed at pool distributing plants. There would be few if any shipments of milk from the balancing plant to pool distributing plants. If, in fact, the balancing plant should begin functioning as a supply plant it would be reasonable to expect the plant to qualify for pooling under the supply plant provisions already provided in the order.

As a further condition for pooling status, a cooperative balancing plant must be approved by a duly constituted health authority to handle milk for fluid consumption. Such a provision is necessary to assure that the plant can be depended upon for supplemental milk supplies when needed by distributors. Since the provision adopted herein would not require a minimum shipment to the market from a cooperative balancing plant, it is conceivable that the plant could neglect to maintain its health approval, in which case it would be inappropriate to pool the milk supply since it could not be made available to distributing plants for Class I use. Under such circumstances there would be no justification for such milk to share in the pool proceeds.

As a further requirement for pooling a cooperative balancing plant, the cooperative must make a request of the market administrator for pooling status. Only by this means can the cooperative's intention be known to the market administrator. Under certain circumstances, a cooperative might find it feasible not to pool a plant in this market, notwithstanding the fact that the plant was eligible for pooling. If the plant does not meet the shipping requirements for a pool supply plant, there is no necessity that it be pooled against the cooperative's wishes.

Rulings on Proposed Findings and Conclusions

An interested party filed a brief and proposed findings and conclusions. The brief, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by the interested party are inconsistent with the findings and conclusions set forth herein, the request to make such findings or reach such conclusions is denied for the reasons previously stated in this decision.

General Findings

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) The tentative marketing agreement and the order, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

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

(c) The tentative marketing agreement and the order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes if industrial and commercial activity specified in, a marketing agreement upon which a hearing has been held.

Recommended Marketing Agreement and Order Amending the Order

The recommended marketing agreement is not included in this decision because the regulatory provisions thereof would be the same as those contained in the order, as hereby proposed to be amended. The following order amending the order, as amended, regulating the handling of milk in the Upper Florida marketing area is recommended as the detailed and appropriate means by which the foregoing conclusions may be carried out:

1. In § 1006.7, the introductory text is revised by changing the reference to paragraph (c) to paragraph (d), paragraph (c) is redesignated as paragraph

(d), paragraph (b) is amended by replacing the period with a semicolon and adding the word "or," and a new paragraph (c) is added to read as follows:

§ 1006.7 Pool plant.

* * * * *

(c) A plant, other than a distributing plant, that is located in the marketing area and is operated by a cooperative association if pool plant status under this paragraph is requested for such plant by the cooperative association and 50 percent or more of the producer milk of members of the cooperative association is received at pool distributing plants either directly from farms or by transfer from plants of the cooperative association for which pool plant status under this paragraph has been requested, subject to the following conditions:

(1) The plant is approved by a duly constituted health authority for the disposition of Grade A milk in the marketing area; and

(2) The plant does not qualify as a pool plant under paragraph (b) of this section or under the provisions of another Federal order applicable to a supply plant.

* * * * *

Signed at Washington, D.C., on March 17, 1977.

WILLIAM T. MANLEY,
Deputy Administrator,
Program Operations.

[FR Doc.77-8496 Filed 3-21-77;8:45 am]

FEDERAL ENERGY ADMINISTRATION

[10 CFR Parts 211 and 212]

REDUCTION OF ENTITLEMENT OBLIGATIONS FOR LOWER TIER CRUDE OIL PRODUCED IN CALIFORNIA AND ALASKA

Proposed Amendments and Public Hearing

The Federal Energy Administration ("FEA") hereby proposes amendments to the domestic crude oil allocation program (the "entitlements program") which are intended to compensate for certain aspects to the program that appear to provide refiners with economic disincentives to pay the full current ceiling prices for certain lower quality domestic crude oils, and would tend to result in producers of heavy gravity lower tier crude oil in California receiving the current ceiling prices for such crude oil. The ceiling prices of most lower tier crude oil produced in California and Alaska were recently increased pursuant to the provisions of the Energy Conservation and Production Act (the "ECPA"). FEA will hold public hearings in San Francisco, California, and Washington, D.C. and will receive written comments on this proposal.

The increase in refiners' overall crude oil costs that is expected to result from these amendments is proposed to be limited to refineries located in Petroleum Administration for Defense District V, which for these purposes includes the States of Alaska, Arizona, California, Nevada, Oregon and Washington, but excludes Hawaii (hereinafter referred to as "PADD V"). The proposal therefore would not result in any change in the current inter-regional transfers under the entitlements program.

Under the proposed amendments, refiners with refineries located in PADD V would be issued 54 cents per barrel additional entitlement value for each barrel of lower tier crude oil produced in that District and included in the inventory receipts of those refineries. Concomitantly, the number of entitlements issued to all refiners for imported crude oil receipts for refineries located in PADD V would be decreased by an aggregate amount equal to the total increase in entitlement issuances for all PADD V refineries for lower tier PADD V production received in the particular month.

FEA is proposing these amendments for public comment, together with several other alternative courses of action described below, to receive information and views from the public and the industry specifically as to the anticipated effects and benefits that would flow from adoption of the proposed entitlement program amendments and, more generally, as to whether any one or both of the alternatives would constitute a more effective long-term means of enhancing domestic production, particularly in PADD V. Thus, FEA wishes to receive comment on the extent to which production of lower tier California heavy crude oil would be enhanced by adoption of the proposed entitlement changes, from both the short-term and long-term perspectives. FEA is also seeking comment on the extent to which consumer prices for petroleum products in PADD V would be increased by adoption of these entitlement amendments. FEA's preliminary estimates indicate that, if refiners passed through the entire amount of the projected increase in crude oil costs, consumer prices in PADD V could increase by $100 to $200 million per year. Thus, such a change in the regulatory programs will not be adopted in the absence of a clear showing of the benefits that would be realized under the changed regulations in the short and/or long term. This proposal is issued for the primary purpose of receiving data adequate to enable FEA to make a determination on the merits of the entitlements program proposal, in comparison with the other alternatives outlined below, both of which represent longer range actions. This proposal is therefore not intended to represent any commitment as to either the timing or nature of any action to be taken to address the problems of producers of low gravity crude oil in PADD V. It should also be noted in this regard that the information received in this proceeding will assist FEA in evaluating the problems associated with the pricing and entitlements treatment of Alaskan North Slope production, scheduled to come on stream in August or September of this year. (See 42 FR 13116, March 9, 1977.)

I. BACKGROUND

On October 29, 1976 FEA amended the Mandatory Petroleum Price Regulations to modify the lower tier ceiling prices for crude oil produced in California and Alaska (41 FR 48324, November 3, 1976). Those amendments were designed to allow the gravity price differentials with respect to heavy California and Alaska crude oil to more accurately reflect current market conditions. As was fully explained in the Further Notice of Proposed Rulemaking issued in that proceeding (41 FR 39331, September 15, 1976), on May 15, 1973 (the reference date for lower tier crude oil ceiling prices), gravity price differentials for crude oil averaged between 2 and 2.5 cents per degree API gravity per barrel nationally, while gravity price differentials in California averaged 6.2 cents per degree API gravity per barrel. Subsequent to May 15, 1973 (but prior to the imposition of price controls on "upper tier" crude oil on February 1, 1976), the California average differential for "upper tier" crude oil decreased to approximately 4.6 cents per degree API gravity. However, until the enactment of the ECPA on August 14, 1976, FEA was unable to make the necessary findings under section 8(b)(2) of the Emergency Petroleum Allocation Act of 1973 (Pub. L. 93-159, "EPAA") to permit any increase in the price of lower tier crude oil to reflect such market changes. The ECPA, however, specifically required in section 122 that amendments be promulgated to adjust differentials in ceiling prices which are the result of gravity price differentials which fail substantially to reflect current relative market valuations of such differentials.

Accordingly, the October 29 amendments provided that the ceiling price for lower tier California and Alaska crude oil could increase by 2 cents per barrel for each degree API gravity between 34 degrees API and 40 degrees API that it falls below 40 degrees API gravity and by 3 cents per barrel for each degree API gravity that it falls below 34 degrees API gravity.

FEA recognized that to the extent market conditions were continuing to change, actual gravity differentials might not decrease when ceiling prices were raised. FEA at that time stated:

> If the current market does determine that gravity differentials should be greater than used in calculating the revised ceiling price rules issued today, such increased gravity price differentials could result in producers' not being able to obtain the full amount of the revised ceiling prices, due to the operation of the entitlements program in conjunction with the lower relative value ascribed to such heavy gravity crude oil by the market. FEA will, therefore, continue to monitor the market situation with respect to changes in gravity price differentials for heavy gravity California crude oil and the relationship of the entitlements program to prices offered for such lower tier crude oil. To the extent that the adjustments made today fail to provide adequate production incentives to maintain maximum feasible rates of production for any California heavy crude oils, FEA will consider and take what-

ever further steps may be appropriate within its statutory authority to assure that such domestic crude oil production continues at maximum levels (41 FR at 48325, November 3, 1976).

Since the implementation of the October gravity differential adjustment amendments, FEA data indicate that PADD V producers of lower tier crude oil have generally not obtained the revised ceiling prices for their crude oil. Although PADD V upper tier crude oil producers have been receiving close to ceiling prices, 20 degrees API gravity lower tier crude oil, a representative low gravity crude oil, has been selling at approximately 54 cents per barrel below current ceiling prices. In fact, the adoption of revised ceiling prices for lower tier crude oil production does not appear to have had any appreciable effect on lower tier prices generally in California. Comments on current price levels for lower tier crude oil are requested.

The entitlements program was designed to distribute on a proportionate basis the benefits of access to supplies of price-controlled domestic crude oils among all domestic refiners, and is based on national average prices for each pricing category (i.e., lower tier, upper tier, and exempt domestic and imports). If the entitlements program were not in effect, all grades of price-controlled domestic crude oil would, at ceiling prices, be more valuable to domestic refiners than even the highest quality imported crude oil at world market prices. Currently under the program, however, certain low gravity domestic crude oils, which are not well suited for meeting the local demand for light refined products or for low sulphur residual fuel oil, are selling at less than lower tier ceiling prices because the receipt of such crude oil by a refiner results in a full entitlement obligation, the cost of which is based on the average acquisition costs for all domestic refiners of all their crude oil supplies. Thus, if sold above a certain price, these low gravity lower tier crude oils are uncompetitive with upper tier and exempt domestic and imported crude oils, as to which there is either no entitlement obligation or only a partial entitlement obligation. These effects of the entitlements program are especially pronounced in PADD V and particularly in California. FEA estimates that California alone accounts for approximately 75% of the total national production of low gravity crude oil (25 degrees API gravity, or less).

Therefore, for producers of low gravity lower tier crude oil in PADD V to receive ceiling prices, further purchase incentives for refiners, either through changes in market conditions or in FEA's regulations, appear to be needed. FEA has concluded that one possible change in this regard would be to modify, as described below, the entitlement treatment of lower tier crude oil receipts in PADD V, by reducing refiners' entitlement obligations associated therewith.

II. Proposed Amendments

Under the monthly entitlement program calculations, each refiner is issued a number of entitlements equivalent to the result of application of the domestic crude oil supply ratio to the volume (in barrels) of that refiner's crude oil runs for that month. Each refiner that has been issued fewer entitlements for that month than the number of barrels of deemed old oil (as defined in § 211.67(b)(2)) included in its adjusted crude oil receipts is required to purchase a number of entitlements effective for that month equal to the difference between the number of barrels of deemed old oil included in its adjusted crude oil receipts for that month and the number of entitlements issued to and retained by that refiner.

FEA is proposing in this notice that refiners that include in their adjusted crude oil receipts for a PADD V refinery lower tier crude oil produced in PADD V would receive an additional entitlement value of 54 cents for each such barrel so included. This is the amount that is estimated to be necessary to permit the selling price of 20 degree API gravity PADD V lower tier crude oil to rise to its ceiling price. Lower tier crude oil produced in Alaska is also proposed to be included for purposes of this adjustment because it is marketed primarily in PADD V, its volumes are not substantial, and to do otherwise could impact upon its market demand.

Under the proposed amendments, a new subparagraph (4) would be added to 10 CFR 211.67(a), providing that for each barrel of PADD V lower tier crude oil included in a refiner's adjusted crude oil receipts and attributable to a refinery located in that District, that refiner would receive an additional fraction of an entitlement equal to 54 cents divided by the entitlement price for that month.

FEA recognizes that its proposed 54 cent per barrel adjustment represents only its tentative conclusion as to the proper amount for the purposes of this rulemaking, since any value chosen will tend to benefit refiners or producers of one type of crude oil relatively more than refiners or producers of other types. The 54 cent per barrel adjustment should result in the selling price of 20 degrees API gravity lower tier PADD V crude oil rising to ceiling levels, and should have the same effect for crude oils above 20 and up to 25 degrees API gravity (which crude oils account for about 40% of PADD V heavy crude oil production), without overcompensating refiners to any significant extent. Although PADD V lower tier crude oils of less than 20 degrees API gravity might in certain cases not sell at ceiling prices with the 54 cent per barrel adjustment, prices for these heavier grades would also be raised significantly.

FEA is proposing that the entitlement benefits given to the PADD V refiners as to their purchases of lower tier PADD V crude oil be accounted for by a compensating adjustment in the entitlement benefits for imported crude oil in that District. This would be accomplished under the proposed § 211.67(a)(4)(ii), by reducing the number of entitlements issued to refiners receiving imported crude oil at PADD V refineries in an aggregate amount which would offset the total increase in entitlements issuances deriving from the benefits given to receipts of PADD V lower tier production. For every barrel of imported crude oil a refiner received at such a refinery in a month, it would lose a fraction of an entitlement equal to the total number of additional entitlements issued pursuant to § 211.67(a)(4)(i) in that month, divided by the total number of barrels of imported crude oil received in that month at all PADD V refineries. The per barrel penalty on imported crude oil vary greatly from month to month depending on actual receipts of import shipments and on the relative volumes of imported crude oil and lower tier domestic crude oil. To the extent that purchasers of imported crude oil in PADD V are able to pass through these higher crude oil costs, the proposed amendments, if adopted, would have the effect of increasing refined product prices in PADD V.

Comments are requested as to the probable effects of these proposed adjustments on incentives to import crude oil into PADD V and on whether the offsetting costs of the entitlement adjustment for lower tier crude oil should be accounted for by an adjustment in the entitlement benefits for uncontrolled domestic crude oil, in addition to imported crude oil, received into PADD V refineries. Comments are also requested on whether it is likely that Northern Slope Alaskan crude oil marketed in PADD V will so affect market conditions for PADD V production, that delay or modification of these proposed adjustments would be appropriate.

Reporting Requirements

To implement these amendments, FEA is proposing modifications to the monthly reporting requirements contained in 10 CFR 211.66(h), to provide FEA with information as to volumes of PADD V lower tier production and imported crude oil received into PADD V refineries.

Certified Requirements

FEA is further proposing additional certification requirements for §§ 212.131 and 211.67(l) to enable refiners to identify receipts from producers, resellers and nonrefiners of lower tier crude oil which was produced in PADD V. FEA is also proposing a modification of the certification requirements for resellers to change the provision under which an entire blended volume of covered products mixed with crude oil could be certified as crude oil. The proposed amendment would allow only the actual volumes of crude oil in the mixture to be so certified.

Exchanges and Buy/Sell Program Transactions

With respect to exchanges or matching purchases and sales of crude oil to which the provisions of 10 CFR 211.67

(g) would apply, FEA is proposing a conforming adjustment. In any such exchange or matching sale and purchase transaction where a refiner actually receives imported crude oil in a PADD V refinery, such imported crude oil would give rise to a reduction in entitlement issuances under proposed 10 CFR 211.67 (a)(4)(ii) at the time when such crude oil would constitute a crude oil receipt attributable to a PADD V refinery, notwithstanding that such crude oil would also be deemed to be domestic crude oil under § 211.67(g) and would incur the applicable entitlement obligation. FEA requests comments on whether any similar adjustments are necessary with respect to exchanges of lower tier PADD V production.

FEA is not proposing any special adjustments for volumes of crude oil sold in PADD V under 10 CFR 211.65. However, FEA does invite comments as to whether volumes of lower tier PADD V production included under 10 CFR 211.67 (f) in the seller's crude oil receipts should be attributable to the seller's PADD V refineries.

III. Other Alternatives for Consideration

The proposed entitlement amendments would tend to enable producers of lower tier crude oil in PADD V to receive their ceiling prices. As pointed out above, FEA believes that this proposal should be evaluated taking into account its long range implications for enhancing PADD V crude oil production. Therefore, FEA is also requesting comments on several other alternative courses of action which may be more appropriate to effectuate a longer term regulatory solution to the problems associated with marketing low gravity crude oil produced in PADD V.

The first alternative would be to amend the Mandatory Petroleum Price Regulations to permit refiners to pass through in increased product prices amounts to represent a return on investment on the capital costs of refinery modifications that would enable them to process additional low gravity high sulphur crude oil. If refiners were to undertake such investments, the demand for PADD V lower tier crude oil would be increased, with a related increase in the prices that refiners could economically afford to pay for that production. Although increased depreciation costs may be passed through pursuant to recently adopted amendments to 10 CFR 212.83(c)(2)(iii)(E) (42 FR 5023, January 27, 1977), these amendments may have not provided the incentives needed for further investments by refiners in this regard.

A second alternative involves changes in the Department of Commerce's export restrictions and removal of the entitlement program disincentives for exports, to permit exports of high sulphur residual fuel oil from PADD V without any entitlement loss and/or to allow exports of lower tier heavy gravity crude oil on a barrel for barrel exchange basis for imported crude oil. In this connection, FEA has removed the provisions for an entitlement loss for exports of bunker fuels (41 FR 49476, November 9, 1976), which FEA believes has materially assisted West Coast refiners in marketing high sulphur residual fuel oil. As to this second alternative FEA is particularly interested in receiving comments that address the likelihood of windfalls to refiners or producers if these export restrictions were changed, and as to how FEA could structure any modifications in this regard to assure that no such windfalls would take place.

IV. Written Comment and Public Hearing Procedures

Interested persons are invited to participate in this rulemaking by submitting their views with respect to the proposals set forth in this notice to Executive Communications, Room 3309, Federal Administration, Box LD, Washington, D.C. 20461.

Comments should be identified on the outside envelope and on documents submitted to FEA Executive Communications with the designation "Entitlement Adjustments for California Crude Oil". Fifteen copies should be submitted. All comments received before 4:30 p.m., e.s.t. April 12, 1977 will be considered by the Federal Energy Administration before final action is taken on the proposed regulations.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The FEA reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

Public hearings in this proceeding will be held in Washington, D.C. and in San Francisco, California.

The Washington, D.C. hearing (the "National hearing") will be held beginning at 9:30 a.m., e.s.t., on April 14, 1977, in Room 2105, 2000 M Street, N.W., Washington, D.C. 20036, in order to receive comments from interested persons on the matters set forth herein. The San Francisco, California hearing (the "California hearing") will be held at 9:30 a.m., local time, April 15, 1977 at the location specified below. Any person who has an interest in the proposals issued today, or who is a representative of a group or class of persons that has an interest in today's proposals may make a written request for an opportunity to make an oral presentation.

For the National hearing, such a request should be directed to Executive Communications, FEA, and must be received before 4:30 p.m., e.s.t., on April 5, 1977. Such a request may be hand delivered to Room 3309, Federal Building, 1200 Pennsylvania Avenue, N.W., Washington, D.C., between the hours of 8:00 and 4:30 p.m., Monday through Friday. For the California hearing, such a request should be received before 4:30 p.m., local time, on April 5, 1977 and should be directed to FEA at the address given below.

Submit requests to testify to:

Mr. Robert Laffel, Federal Energy Administration, Region IX, 111 Pine Street, San Francisco, California 94111.

Hearing Location:

Wells Fargo Building, Room 2575, 525 Market Street, San Francisco, California 94105.

Persons requesting an opportunity to make an oral presentation should submit their written requests to the appropriate address for the hearing in which they wish to appear. Requests should be labeled both on the document and on the envelope with the designation "Entitlement Adjustments for California Crude Oil".

The person making the request should be prepared to describe the interest concerned, if appropriate, to state why he or she is proper representative of a group or class of persons that has such an interest, and to give a concise summary of the proposed oral presentation and a phone number where he may be contacted through April 13, 1977. Each person selected to be heard will be so notified by the FEA before 4:30 p.m., April 7, 1977, and must submit 100 copies of this statement to Regulations Management, Room 2214, 2000 M Street, N.W., Washington, D.C. 20036, before 4 p.m., e.s.t., on April 13, 1977, for the National Hearing, and to FEA at the location of the hearing on the day the statement is scheduled to be presented, for the California Hearing.

The FEA reserves the right to select the persons to be heard at these hearings, to schedule their respective presentations, and to establish the procedures governing the conduct of the hearings. The length of each presentation may be limited, based on the number of persons requesting to be heard.

A FEA official will be designated to preside at the hearings. These will not be judicial or evidentiary-type hearings. Questions may be asked only by those conducting the hearings, and there will be no cross-examination of persons presenting statements. Any decision made by the FEA with respect to the subject matter of the hearings will be based on all information available to the FEA. At the conclusion of all initial oral statements each person who has made an oral statement will be given the opportunity, if he or she so desires, to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations.

Any person who wishes to ask a question at the National or California hearing may submit the question, in writing, to the presiding officer. The presiding officer will determine whether the question is relevant and whether the time limitations permit it to be presented for answer.

Any further procedural rules needed for the proper conduct of the hearings will be announced by the presiding officer.

A transcript of the hearings will be made and the entire record of the hearings, including the transcript, will be retained by the FEA and made available for inspection at the Freedom of Infor-

mation Office, Room 2107, Federal Building, 1200 Pennsylvania Avenue, N.W., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

As required by section 7(c)(1) of the Federal Energy Administration Act of 1974, Pub. L. 93-275, a copy of this notice of proposed rulemaking was submitted to the Administrator of the Environmental Protection Agency for his comments concerning the impact of this proposal on the quality of the environment. The Administrator had no comments.

NOTE.—This proposal is being reviewed in accordance with Executive Order 11821 and OMB Circular A-107 to determine whether it is of a nature to require the preparation of an inflationary impact statement.

(Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159, as amended, Pub. L. 93-511, Pub. L. 94-99, Pub. L. 94-133, Pub. L. 93-163, and Pub. L. 94-385; Federal Energy Administration Act of 1974, Pub. L. 93-275, as amended, Pub. L. 94-385; Energy Policy and Conservation Act, Pub. L. 94-163, as amended, Pub. L. 94-385; E.O. 11790, 39 FR 23185).

In consideration of the foregoing, Parts 211 and 212 of Chapter II Title 10 of the Code of Federal Regulations are proposed to be amended as set forth below.

Issued in Washington, D.C., March 17, 1977.

ERIC J. FYGI,
Acting General Counsel.

1. Section 211.62 is amended by adding a new definition of "PAD District V" in appropriate alphabetical order to read as follows:

§ 211.62 Definitions.

* * * * *

"PAD District V" means the States of Alaska, Arizona, California, Nevada, Oregon and Washington.

* * * * *

2. Section 211.66 is amended by revising paragraph (h) to read as follows:

§ 211.66 Reporting requirements.

* * * * *

(h) *Monthly report.* On or prior to the fifth day of each month, commencing with the month of _____, 1977, each refiner shall file with the FEA a report certifying the following information as to the second month prior to the month in which the report is filed:

(1) The estimated volume (to the best of the knowledge of the certifying officer) of old oil included in the crude oil receipts of that refiner.

(2) The estimated volume (to the best of the knowledge of the certifying officer) of upper tier crude oil included in the crude oil receipts of that refiner.

(3) Any permitted or required adjustments to the estimated volumes of old and upper tier crude oil included in the crude oil receipts of that refiner.

(4) The volume of crude oil runs to stills of that refiner, taking into account, and specifying the amount of, the adjustments provided for in § 211.67(d).

(5) The weighted average costs for that refiner (including transportation costs to the refinery) of old oil, upper tier crude oil, stripper well crude oil (as defined in Part 212 of this chapter), other domestic crude oils the first sale of which is exempt from the provisions of Part 212 of this chapter, and imported crude oil included in that refiner's crude oil receipts. For refiners required to file transfer pricing report forms under § 212.84 of this chapter, the weighted average cost of imported crude oil reported under this subparagraph shall be derived from the landed costs set forth in such reports.

(6) The estimated volume (to the best knowledge of the certifying officer) of old oil produced in PAD District V included in the crude oil receipts of that refiner and attributable to refineries located in PAD District V.

(7) The estimated volume (to the best knowledge of the certifying officer) of imported crude oil included in the crude oil receipts of that refiner attributable to refineries located in PAD District V.

(8) Such other information as the FEA may request.

* * * * *

3. Section 211.67 is amended by revising paragraph (a)(1), adding a new paragraph (a)(4), adding a new paragraph (g)(6) and revising paragraph (l) to read as follows:

§ 211.67 Allocation of domestic crude oil.

(a) *Issuance of entitlements.* (1) For each month, commencing with the month of _____ 1977, each refiner shall be issued a number of entitlements by the FEA equal to the number of barrels of crude oil included in the total volume of that refiner's crude oil runs to stills for that month multiplied by the national domestic crude oil supply ratio for that month, subject to the entitlement adjustment for small refiners set forth in paragraph (e) of this section, and the entitlement adjustment in paragraph (a)(4) of this section for crude oil receipts in PAD District V.

* * * * *

(4) For each month, commencing with the month _____, 1977, the number of entitlements issued under paragraph (a)(1) of this section to each refiner operating refineries located in PAD District V shall (i) be increased by the number of barrels of old oil produced therein included in its adjusted crude oil receipts attributable to its refineries located therein in that month multiplied by a fraction equal to 54 cents divided by the entitlement price for that month; and

(ii) be decreased by a number of entitlements equal to the number of barrels of imported crude oil included in its adjusted crude oil receipts attributable to its refineries located in PAD District V in that month multiplied by the aggregate increase in entitlement issuances for all refiners calculated pursuant to paragraph (a)(4)(i) of this section and divided by the total number of barrels of imported crude oil included in the adjusted crude oil receipts for all refiners attributable to refineries located in PAD District V for that month.

* * * * *

(g) *Exchanges of crude oil* * * *

(6) Where a refiner acquires imported crude oil which would constitute a crude oil receipt under § 211.62 of this subpart attributable to a refinery located in PAD District V, the receipt of such imported oil shall result in a reduction in entitlement issuances under paragraph (a)(4)(ii) of this section, notwithstanding that such crude oil may be deemed to be retained as domestic crude oil for purposes of this paragraph (g) as a result of an exchange or matching purchase and sale transaction of the type described in paragraph (g)(1) of this section.

* * * * *

(l) *Certification by non-refiners.* Within twenty-eight (28) days following each month, commencing with the month of _____ 1977, each firm other than a refiner that has delivered crude oil to a refiner for processing agreement in that month shall certify to that refiner the respective volumes of and that firm's costs for old oil (separately identifying any such old oil produced in PAD District V), upper tier crude oil, stripper well crude oil (as defined in Part 212 of this chapter), other domestic crude oils the first sale of which is exempt from Part 212 of this chapter, and imported crude oil contained in the crude oil so delivered to that refiner.

* * * * *

4. Section 212.131 is amended by revising paragraph (a)(2)(i), paragraph (a)(3)(i), paragraph (b)(1), adding paragraph (b)(3) and revising paragraph (c) to read as follows:

§ 212.131 Certification of domestic crude oil sales.

* * * * *

(a) * * *

(2) *Non-stripper well properties.* (i) With respect to each sale of crude oil from a property which has not qualified as a stripper well property, the producer shall certify in writing to the purchaser the number of barrels of new crude oil and the number of barrels of old crude oil (separately identifying any such old crude oil as has been produced in PAD District V). With respect to any property which has not qualified as a stripper well property, and from which crude oil is only sold to one purchaser, the requirements of this paragraph (a)(2)(i) of this section may be complied with by a one-time certification to the purchaser of the property's monthly base production control level determined pursuant to 10 CFR 212.72, whether based upon production and sale of crude oil in 1972 or upon production and sale of old crude oil in 1975, and, if applicable, either the property's adjusted base production control

level determined pursuant to 10 CFR 212.76 or the information necessary to compute such adjusted base production control level pursuant to 10 CFR 212.76.

* * * * *

(3) *Unitized properties.* (i) With respect to each sale of crude oil from a unitized property for which the producer has determined a unit base production control level, the producer shall certify in writing to the purchaser the number of barrels of new crude oil (if any, and whether "actual new crude oil" or "imputed new crude oil" determined pursuant to 10 CFR 212.75(b)), the number of barrels of old crude oil (separately identifying any such old crude oil as has been produced in PAD District V), and the number of barrels of imputed stripper well crude oil (if any) determined pursuant to 10 CFR 212.75 (b). With respect to any unitized property for which the producer has determined a unit base production control level, and from which crude oil is only sold to one purchaser, the requirements of this paragraph (a)(3)(i) of this section may be complied with a one-time written certification to the purchaser of (A) the monthly unit base production control level determined pursuant to 10 CFR 212.75(b); (B) the amount of imputed new crude oil (if any, determined pursuant to 10 CFR 212.75(b)); and (C) the amount of imputed stripper well crude oil (if any, determined pursuant to 10 CFR 212.75(b)).

* * * * *

(b)(1) Each seller of domestic crude oil, other than a producer of domestic crude oil covered by paragraph (a) of this section, shall, with respect to each sale of domestic crude oil other than (i) an allocation sale pursuant to § 211.65 of Part 211, or (ii) a sale in which no volumes of domestic crude oil are deemed to have been transferred pursuant to § 211.67(g) of Part 211, certify in writing to the purchaser the respective volumes of and respective per barrel prices for the old crude oil (separately identifying any such old crude oil which was produced in PAD District V), new crude oil, stripper well crude oil, and other domestic crude oils the first sale of which is exempt from the provisions of this part included in the volume of domestic crude oil so sold. The certification shall also contain a statement that the price charged for the domestic crude oil is no greater than the maximum price permitted pursuant to this part.

* * * * *

(3) All certifications required by this paragraph shall relate only to the actual volumes of crude oil included in any mixed blend of crude oil and other refined petroleum products and residual fuel oil.

(c) With respect to each allocation sale under § 211.65 of Part 211, the seller shall certify in writing to the purchaser the amount of old crude oil deemed (under the provisions of § 211.67(f) of Part 211) to be included in the volume of crude oil so sold and separately identifying any such old crude oil as was produced in PAD District V. Such written certification shall be made within 25 days following the month in which the crude oil so sold is delivered to or for the account of the purchaser.

* * * * *

[FR Doc.77-8555 Filed 3-18-77;9:23 am]

[10 CFR Part 430]

ENERGY CONSERVATION PROGRAM FOR APPLIANCES

Proposed Rulemaking and Public Hearing Regarding Test Procedures for Dishwashers

The Federal Energy Administration (FEA) hereby proposes to amend Chapter II of Title 10, Code of Federal Regulation, in order to prescribe test procedures for dishwashers, pursuant to section 323 (42 U.S.C. 6393) of the Energy Policy and Conservation Act (Act) (Pub. L. 94-163). FEA will receive written comments and hold a public hearing with respect to this proposal.

Development of test procedures is one discrete part of the energy conservation program for appliances. Even when promulgated, final test procedures will not of themselves require testing to be conducted. They will merely establish standard methods for testing when testing is otherwise required by the Act itself or by regulations implementing other parts of the program. For example, the Federal Trade Commission (FTC), in exercising its appliance energy efficiency labeling authority regarding a particular appliance type, may well require the application of substantially less than all of the final test procedures applicable to that appliance type.

By notice issued May 10, 1976 (41 FR 19977, May 14, 1976), FEA proposed to establish Part 430, entitled "Energy Conservation Program for Appliances," in Chapter II of Title 10 of the Code of Federal Regulations. That notice proposed a Subpart A to Part 430, containing general provisions, and a Subjart C, containing proposed energy efficiency improvement targets. A further proposal of Subpart C will be necessary in order to meet the requirements of section 325 (a)(1) of the Act as amended by section 161 of the Energy Conservation and Production Act (Pub. L. 94-385).

By notice issued July 22, 1976 (41 FR 31237, July 27, 1976), FEA proposed an amendment to proposed Part 430 to add a Subpart B which would contain the appliance test procedures required to be prescribed by section 323 of the Act. The notice issued July 22 described the requirements of section 323, set forth proposed test procedures for room air conditioners and indicated that proposed test procedures for dishwashers and certain other types of appliances would be forthcoming as soon as practicable.

FEA is today proposing test procedures for dishwashers as § 430.22(c) of Subpart B. Subpart A (41 FR 19977, May 14, 1976), as proposed, contained definitions in proposed § 430.2, some of which are applicable to the test procedures for dishwashers. In addition, FEA is proposing to add to the definition in § 430.2 of "Basic model", a subparagraph (3) applying specifically to dishwashers and is proposing definitions of various fuels.

Section 323(a)(2) of the Act requires FEA to direct the National Bureau of Standards (NBS) to develop for 13 types of covered products test procedures for the determination of the estimated annual operating costs and at least one other useful measure of energy consumption which FEA determines is likely to assist consumers in making purchasing decisions. Pursuant to the Act, FEA directed NBS to develop test procedures for FEA's use in prescribing test procedures under the Act. As part of this undertaking, NBS was requested to evaluate existing test procedures for measuring energy consumption of dishwashers.

NBS has transmitted to FEA a test procedure review document which reviewed existing test procedures for measuring energy consumption for dishwashers and recommended test procedures. Copies of this review document will be made available for inspection by interested persons as provided for later in this notice.

NBS, prior to the enactment of the Act, had begun preliminary studies of technical literature and had commenced discussions with the Association of Home Appliance Manufacturers (AHAM) with regard to test methods for measuring energy consumption of dishwashers. A test procedure was not developed under the Department of Commerce Voluntary Labeling Program due to the passage of the Act.

The existing AHAM Standard DW-1 for dishwashers does not specifically relate to energy consumption, but is concerned with other performance characteristics of dishwashers. The AHAM Dishwasher Engineering Committee has developed a draft supplement (DW-2EC) to the AHAM dishwasher standard that will contain a standard method of measuring energy consumption. The test procedures recommended by NBS incorporate the approach contained in the AHAM draft DW-2EC for measuring energy consumption for a normal cycle and, in addition, include procedures for determining the estimated annual operating cost and energy efficiency of dishwashers.

The Act requires FEA to prescribe test procedures for the determination of estimated annual operating costs and at least one other useful measure of energy consumption which the Administrator determines is likely to assist consumers in making purchasing decisions. Since the annual operating cost of a dishwasher could differ significantly depending upon whether the water utilized is heated by gas or oil, or by electricity, FEA is proposing to establish two alternate values for the estimated annual operating cost is the product of the representative average use cycle times the water is used and the other assuming that electrically-heated water is used. In each case, the estimated annual operating cost is the product of the representative average use cycle times the

cost of energy used per cycle for the normal cycle. The cost of energy used per normal cycle is, in turn, dependent upon the representative average unit energy costs as provided by the Administrator, the machine electrical energy consumption for the normal cycle, and the energy required to heat the water consumed in the normal cycle. The normal cycle would be defined as the cycle type (including the power-dry feature) recommended by the manufacturer for a full load of dishes, and, accordingly, is proposed as the cycle type upon which the estimated annual operating cost is based.

Also proposed § 430.22(c)(2)) as test procedures for the determination of other measures of energy consumption which are likely to assist consumers in making purchasing decisions are test procedures regarding the estimated annual operating cost for any specified cycle type other than the normal cycle. As with test procedures for the estimated annual operating cost, these test procedures could be used to provide consumers with useful cost information regarding dishwasher operation with both electrically-heated and gas-heated or oil-heated water. For example, if the estimated annual operating cost of the truncated cycle as defined in the proposed uniform test method (Appendix C), were presented to the consumer, it could encourage the consumer to purchase a dishwasher offering the truncated cycle as an optional feature. It is proposed that the estimated annual operating cost for any other specified cycle type be determined similarly to the determination of such cost for the normal cycle, except that any required tests would be run on the specified cycle and not on the normal cycle. The application of these test measures, however, is not required until an appropriate authority, such as FTC in exercising its authority pursuant to the appliance labeling provisions of Energy Policy and Conservation Act, has specified the cycle type(s) for which estimated annual operating costs are required to be measured.

An additional proposed measure that is likely to assist consumers in making purchasing decisions is the energy factor. For dishwashers that are not capable of being preset by consumers to eliminate the power-dry feature, this is defined as the reciprocal of the total per-cycle energy consumption for the normal cycle in kilowatt-hours per cycle. For dishwashers capable of being preset by consumers to eliminate the power-dry feature on the normal cycle, the energy factor is defined as the reciprocal of one-half the sum of the total per-cycle kilowatt-hour energy consumption for the normal cycle and the total per-cycle kilowatt-hour energy consumption for the normal cycle without the power-dry feature, *i.e.*, truncated cycle. Among other possible applications, the energy factor may be used by FEA to determine the efficiency of dishwashers for the purposes of the efficiency improvement program described by section 325 of the Act.

The procedure for measuring the contribution of a switch that disables the power-dry feature assumes a 50 percent usage for the switch, which is based on a survey conducted by the Kitchen Aid Division of Hobart Corporation. Kitchen Aid conducted a consumer usage survey which indicated that 39 percent of the participants used the switch disabling the power-dry feature all of the time and 29 percent used this switch part of the time. A 50 percent frequency of use basis was established under the Department of Commerce Voluntary Labeling Program for any feature that required consumer interaction and for which actual usage was unknown. Further, in public hearings held by FEA on the initial proposed energy efficiency targets, several appliance manufacturers recommended that a 50 percent figure for consumer usage be utilized for energy saving switches when actual usage is unknown. FEA is proposing a 50 percent frequency of use for computing the energy efficiency ratio because it believes that to be a reasonable estimate of actual consumer usage. FEA will modify the contribution of energy saving features, such as the switch for eliminating the power-dry feature, if additional usage information is developed that indicates that other frequency of use patterns exist.

FEA recognizes that there may be additional useful measures of energy consumption for dishwashers other than the measures described above. Accordingly, today's proposal, is proposed § 430.22(c)(4), provides for other useful measures which the Administrator determines are likely to assist consumers in making purchasing decisions. These measures, however, must be derived from the application of the uniform test method proposed today as Appendix C to Subpart B. Dishwasher manufacturers would, if required, only have to perform various computations while still applying the same test method contained in Appendix C. For example, if the Administrator determined that a per-cycle cost for a specified cycle type would aid consumers in making purchasing decision, this cost could be derived by applying the uniform test method for that cycle type and dividing by the annual usage to arrive at a per-cycle figure.

Section 430.23(c) would provide for sampling of each basic model to be tested when testing of dishwashers is required by the Act or by program regulations of agencies responsible for administering the Act. This provision is intended both to provide an acceptable level of assurance that test results are applicable to any entire basic model for which testing is required and to minimize the testing burden on manufacturers. FEA believes that the sampling approach proposed today will enable consumers to make meaningful comparisons of information appearing on appliance labels, and also will meet the requirements of section 323(b) of the Act that test procedures not be unduly burdensome to conduct.

Under proposed § 430.23(c), a sample of sufficient size of each basic model would be tested to assure that, for each measure of energy consumption described in § 430.22(c), there is a 95 percent probability that the mean of the values of these measures of the sample is within five percent of the true mean of these measures of the basic model. The size of the sample of a particular basic model will depend upon the following factors:

(a) the level of confidence required (set at 95 percent in the proposed regulations);

(b) the maximum allowable difference between the sample mean and the mean of the basic model (expressed in the proposal as a percent of the true mean and set at five percent); and

(c) the relationship of the mean and standard deviation of the basic model.

The relationship of the mean and standard deviation of the basic model can be determined from data available to manufacturers. With this information and using standard statistical techniques, manufacturers can determine the number of units required to be tested. In any case, no fewer than three units of each model must be tested. Sample units would be selected randomly from the production stream.

Manufacturers and other interested persons are encouraged to comment on the sampling approach. Manufacturers are specially encouraged to submit any data which relates to the size of the samples which the provisions would require to be tested. Comments alleging that the sampling provision is burdensome should include a full discussion of the facts upon which such allegation is based.

Proposed Appendix C to Subpart B provides for a controlled laboratory environment for measuring energy consumption for the various dishwashers (and their various cycle types) which are available to the consumer. The proposed test method in Appendix C measures energy consumption for heating dishwasher water in kilowatt-hours or British thermal units (Btu's) per cycle, depending on whether gas, oil or electricity is used to heat the water, and electrical energy consumption needed to perform any specified cycle on a dishwasher under test in kilowatt-hours per cycle. From these standard measures of energy consumption, using the proposed dishwasher test procedures (which include the values of the representative average-use cycle and the representative average unit costs of energy), various determinations of dishwasher energy costs and energy consumption can be derived in a standard fashion.

The nominal gas and oil water heater efficiency proposed in 4.2 of Appendix C to Subpart B for the calculation of per-cycle water energy consumption using gas-heated or oil-heated water is 75 percent. This number represents an average recovery efficiency for new gas- and oil-fueled water heaters. The water heater industry has established 70 percent as the minimum acceptable recovery efficiency through a self-certification program. According to an NBS review of industry data, energy conserving oil- and gas-fueled water heaters have recovery efficiencies as high as 78 percent. NBS

has recommended to FEA that 75 percent be used as the typical recovery efficiency of gas- and oil-fueled water heaters. The 75 percent value for recovery efficiency is recommended by AHAM in their draft test standard DW-2EC, which is designed to measure the energy consumption of dishwashers. Therefore, FEA believes that 75 percent is a reasonable estimate of recovery efficiency for gas- and oil-fueled water heaters.

The nominal water heater temperature rise proposed in 4.1 of Appendix C to Subpart B and incorporated by reference in 4.2 of Appendix C for the calculation of per-cycle water energy consumption is 90° F. NBS has determined that the average temperature rise for heated water is 90°F. The 90° F temperature rise represents the national average based on a median inlet water temperature for the United States of 55° F and a normal factory-set thermostat adjustment of 145° F. The 90° F temperature rise is also recommended by AHAM in their draft test standard DW-2EC, which is designed to measure the energy consumption of dishwashers. Therefore, FEA believes that a 90° F temperature rise for heated water is a reasonable estimate for residential water heater usage.

Section 323(b)(2) (42 U.S.C. 6293(b)(2) of the Act provides that test procedures for determining estimated annual operating costs of any covered product shall be calculated from measurements of energy use in a representative average-use cycle (as determined by the Administrator) and from representative average unit costs (as provided by the Administrator) needed to operate such product during such cycle. FEA has determined that the representative average use cycle for dishwashers is 416 cycles per year. This determination is based upon NBS' recommendation to FEA which, in turn, is based upon a Procter and Gamble field study on dishwasher use. NBS' recommendation and the Procter and Gamble field study are available for inspection as provided for later in this notice.

FEA intends to develop representative average unit costs of energy needed to calculate the annual operating cost for the representative average-use cycle and to provide this information to manufacturers and FTC on or before the effective date of test procedures for dishwashers.

While FEA is soliciting comments on all aspects of the proposed test procedures for dishwashers, FEA is particularly interested in receiving comments on any other useful measures of energy consumption or data on typical consumer usage of dishwashers in addition to those proposed today. In addition, FEA is interested in receiving comments on any definitions described in previously proposed section 430.2, as these provisions might affect the testing of dishwashers. Comments with respect to dishwashers regarding provisions in previously proposed § 430.2 are timely until the close of the written record, as specified below. For the convenience of the reviewer, the proposed definition of "dishwasher" (41 FR 19979, May 14, 1976) is as follows:

§ 430.2 *Definitions.*

"Dishwasher" means a cabinet-like appliance which with the aid of water and detergent, washes, rinses, and dries (when a drying process is included) dishware, glassware, eating utensils, and most cooking utensils by chemical, mechanical and/or electrical means and discharges to the plumbing drainage system.

Public Comment and Hearing Procedures

Interested persons are invited to participate in this rulemaking by submitting data, views, or arguments with respect to the proposed test procedures for dishwashers set forth in this notice to Executive Communications, Room 3309, Federal Energy Administration, Box LH, Washington, D.C. 20461.

Comments should be identified on the outside of the envelope and on documents submitted to FEA with the designation "Dishwashers—Proposed Test Procedures." Fifteen copies should be submitted. All comments received by May 9, 1977, before 4:30 p.m., e.s.t., and all other relevant information will be considered by FEA before final action is taken on the proposed regulations.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. FEA reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

A public hearing in this proceeding will be held at 9:30 a.m., on May 9, 1977 at Room 2105, 2000 M Street, N.W., Washington, D.C. 20461 in order to receive comments from interested persons on the proposed test procedure for dishwashers.

Any person who has an interest in the proposed rulemaking issued today, or who is a representative of a group or class of persons that has an interest in today's proposed rulemaking, must make a written request for an opportunity to make an oral presentation. Such a request should be directed to Executive Communications, FEA, and must be received before 4:30 p.m., e.s.t., on April 29, 1977. Such a request may be hand delivered to Room 3309, Federal Building, 12th and Pennsylvania Avenue, N.W., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. The person making the request should be prepared to describe the interest concerned, if appropriate, to state why she or he is a proper representative of a group or class of persons that has such an interest, and to give a concise summary of the proposed oral presentation and a telephone number where he or she may be contacted through May 2, 1977. Each person selected to be heard will be so notified by FEA before 4:30 p.m., e.s.t., May 2, 1977, and must submit 50 copies of his or her statement to Regulations Management, FEA, Room 2214, 2000 M Street, N.W., Washington, D.C. 20461, before 4:30 p.m., e.s.t., May 6, 1977. In the event any person wishing to testify cannot meet the 50 copy requirement, alternative arrangements can be made with the Office of Regulations Management in advance of the hearing by so indicating in the letter requesting an oral presentation or by calling the Office of Regulations Management at (202) 254-3345.

FEA reserves the right to select the persons to be heard at this hearing, to schedule their respective presentations and to establish the procedures governing the conduct of the hearing. The length of each presentation may be limited, based on the number of persons requesting to be heard.

An FEA official will be designated to preside at the hearing. This will not be a judicial or evidentiary-type hearing. Questions may be asked only by those conducting the hearing, and there will be no cross-examination of persons presenting statements. Any decision made by FEA with respect to the subject matter of the hearing will be based on all information available to FEA. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity, if he or she so desires, to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations.

Any interested person may submit questions to be asked of any person making a statement at the hearing to Executive Communications, FEA, before 4:30 p.m., e.s.t., May 2, 1977. FEA will determine whether the question is relevant and whether the time limitations permit it to be presented for answer.

Any person who makes an oral statement and who wishes to ask a question at the hearing may submit the question, in writing, to the presiding officer. The presiding officer will determine whether the question is relevant and whether the time limitations permit it to be presented for answer.

Any further procedural rules needed for the proper conduct of the hearing will be announced by the presiding officer.

A transcript of the hearing will be made and the entire record of the hearing, including the transcript, will be retained by FEA and made available for inspection at the FEA Freedom of Information Office, Room 2107, Federal Building, 12th and Pennsylvania Avenue, N.W., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter. A copy of NBS' recommendations concerning test procedures for dishwashers along with a related Procter and Gamble field study will also be made available for inspection at the FEA Freedom of Information Office.

As required by section 7(c)(2) of the Federal Energy Administration Act of 1974 (Pub. L. 93-275), a copy of this notice has been submitted to the Administrator of the Environmental Protection Agency for his comments concerning the impact of this proposal on the quality

of the environment. The Administrator had no comments.

The National Environmental Policy Act of 1969 requires FEA to assess the environmental impacts of any proposal by the Agency for "major Federal actions significantly affecting the quality of the human environment." Since test procedures under the energy conservation program for appliances will be used only to standardize certain measurements related to the energy efficiency and consumption of appliances covered by the program and will not affect energy production or usage, FEA has determined that the action of prescribing test procedures, by itself, will not result in any environmental impacts. On this basis, FEA has determined that, with respect to prescribing test procedures under the conservation program for appliances, no environmental impact statement is required.

The proposal has been reviewed in accordance with Executive Order 11821 as amended by Executive Order 11949, and OMB Circular No. A-107 and has been determined not to require evaluation of its economic impact as provided for therein.

(Energy Policy and Conservation Act, Pub. L. 94-163, as amended by Pub. L. 94-385; Federal Energy Administration Act of 1974, Pub. L. 93-275, as amended by Pub. L. 94-385; EO 11790, 39 FR 23185.)

In consideration of the foregoing, it is proposed to amend Chapter II of Title 10, Code of Federal Regulations, as set forth below.

Issued in Washington, D.C., March 17, 1977.

ERIC J. FYGI,
Acting General Counsel,
Federal Energy Administration.

1. Section 430.2 is amended by adding paragraph (3) as part of the definition of "Basic model", and by adding definitions of "gas," "natural gas," "oil" and "propane" to read as follows:

§ 430.2 Definitions.

* * * * *

"Basic model" means all units of a given type of covered product manufactured by one manufacturer and—

* * * * *

(3) with respect to dishwashers, having identical cycle types and essentially identical functional physical and electrical characteristics.

* * * * *

"Gas" means either natural gas or propane.

* * * * *

"Natural gas" means natural gas as defined by the Federal Power Commission.

"Oil" means heating oil grade No. 2 as defined in American Society for Testing and Materials (ASTM) D396-71.

"Propane" means a hydrocarbon whose chemical composition is predominantly C_3H_8, whether recovered from natural gas or crude oil.

2. Section 430.22 is amended by adding a paragraph (c), to read as follows:

§ 430.22 Test procedures for measures of energy consumption.

* * * * *

(c) *Dishwashers.* (1) The estimated annual operating cost for dishwashers shall be—

(i) When electrically-heated water is used, the product of the following three factors: (A) the representative average-use cycle of 416 cycles per year, (B) the total per-cycle energy consumption for the normal cycle in kilowatt-hours per cycle, determined according to 4.4 of Appendix C of this subpart, and (C) the representative average unit cost in dollars per kilowatt-hour as provided by the Administrator, the resulting product then being rounded off to the nearest dollar per year, and

(ii) When gas-heated or oil-heated water is used, the product of: the representative average use cycle of 416 cycles per year times the sum of (A) the product of the per-cycle machine electrical energy consumption for the normal cycle in kilowatt-hours per cycle, determined according to 4.3 of Appendix C to this subpart, times the representative average unit cost in dollars per kilowatt-hour as provided by the Administrator plus (B) the product of the per-cycle water energy consumption for gas-heated or oil-heated water for the normal cycle, in Btu's per cycle, determined according to 4.2 of Appendix C to this subpart, times the representative average unit cost in dollars per Btu for oil or gas, as appropriate, as provided by the Administrator, the resulting product then being rounded off to the nearest dollar per year.

(2) The estimated annual operating cost for any other specified cycle type for dishwasters shall be—

(i) when electrically-heated water is used, the product of the following three factors: (A) The representative average-use cycle of 416 cycles per year, (B) the total per-cycle energy consumption for the specified cycle type in kilowatt-hours per cycle, determined according to 4.4 of Appendix C to this subpart, and (C) the representative average unit cost in dollars per kilowatt-hour as provided by the Administrator, the resulting product then being rounded off to the nearest dollar per year; and

(ii) when gas-heated or oil-heated water is used, the product of: The representative average-use cycle of 416 cycles per year times the sum of (A) the product of the per-cycle machine electrical energy consumption for the specified cycle type in kilowatt-hours per cycle, determined according to 4.3 of Appendix C to this subpart, times the representative average unit cost in dollars per kilowatt-hour as provided by the Administrator plus (B) the product of the per-cycle water energy consumption for gas-heated or oil-heated water for the specified cycle type, in Btu's per cycle, determined according to 4.2 of Appendix C of this subpart, times the representative average unit cost in dollars per Btu for oil or gas, as appropriate, as provided by the Administrator, the resulting product then being rounded off to the nearest dollar per year.

(3) The energy factor for dishwashers, expressed in cycles per kilowatt-hour, shall be—

(i) For dishwashers not having a truncated normal cycle, as defined in 1.5 of Appendix C of this subpart, capable of being preset, the reciprocal of the total per-cycle energy consumption for the normal cycle in kilowatt-hours per cycle, determined according to 4.4 of Appendix C of this subpart, and

(ii) For dishwashers having a truncated normal cycle, as defined in 1.5 of Appendix C of this subpart, capable of being preset, the reciprocal of one-half the sum of (A) the total per-cycle energy consumption for the normal cycle plus (B) the total per-cycle energy consumption for the preset cycle type closest to the truncated normal cycle, each in kilowatt-hours per cycle and determined according to 4.4 of Appendix C of this subpart.

(4) Other useful measures of energy consumption for dishwashers shall be those measures of energy consumption for dishwashers which the Administrator determines are likely to assist consumers in making purchasing decisions and which are derived from the application of Appendix C of this subpart.

* * * * *

3. Section 430.23 is amended by adding a paragraph (c), to read as follows:

§ 430.23 Units to be tested.

* * * * *

(c) *Dishwashers.*

(1) When testing of dishwashers is required for a measure or measures of energy consumption described in § 430.22(c) of this subpart, a sample of sufficient size of each basic model shall be tested to ensure that, for each such measure of energy consumption, there is a 95 percent probability that the mean of the sample is within five percent of the true mean of such measures of the basic model, except that no fewer than three units of each basic model shall be tested.

(2) The sample selected for paragraph (c)(1) of this section shall be a simple random sample drawn from the production stream of the basic model being tested.

(3) A basic model having dual voltage ratings shall be separately tested at each design voltage such that the requirements of paragraph (c)(1) of this section are satisfied at each rating.

* * * * *

4. Subpart B of Part 430 is amended to add an Appendix C, to read as follows:

APPENDIX C—UNIFORM TEST METHOD FOR MEASURING THE ENERGY CONSUMPTION OF DISHWASHERS

1. DEFINITIONS

1.1 "Cycle" means a sequence of operations of a dishwasher which performs a complete dishwashing operation, and may include variations or combinations of the functions of washing, rinsing and drying.

1.2 "Cycle type" means either any complete sequence of operations capable of being preset on the dishwasher prior to the initiation of machine operation or the truncated normal cycle.

1.3 "Normal cycle" means the cycle type recommended by the manufacturer for a full load of dishes, including the power-dry feature, and typically characterized by six water changes.

1.4 "Power-dry feature" means that function in a cycle in which electrically-generated heat is introduced into the washing chamber for the purpose of improving the drying performance of the dishwasher.

1.5 "Truncated normal cycle" means the normal cycle interrupted to eliminate the power-dry feature after the termination of the last rinse operation.

2. TESTING CONDITIONS

2.1 *Installation.* Install the dishwasher in accordance with the manufacturer's instructions, except that undercounter dishwashers need not be installed under a counter.

2.2 *Electrical supply.* Maintain the electrical supply to the dishwasher within two percent of 120 volts and within one percent of its nameplate frequency as specified by the manufacturer.

2.3 *Water temperature.* Maintain the water supply temperature between 138° F and 142° F.

2.4 *Water pressure.* Maintain the pressure of the water supply between 32.5 and 37.5 pounds per square inch.

2.5 *Ambient and machine temperature.* Maintain the room ambient air temperature between 70° F and 85° F, and assure that the dishwasher and its load, if any, are at room ambient temperature at the start of each test cycle.

2.6 *Load.* Use an eight place setting test load of dishes. One place setting consists of the following:

One glass—12 oz., straight sides, made of glass.
One cup—Corning "Centura" No. C-308.
One saucer—Corning "Centura" No. C-506.
One dinner plate—Corning "Centura" No. C-110.
One bread and butter plate—Corning "Centura" No. C-106.
One fruit bowl—Corning "Centura" No. C-409.
One dinner fork—Stainless steel.
One salad fork—Stainless steel.
One knife—Stainless steel.
Two teaspoons—Stainless steel.

3. TEST CYCLE AND MEASUREMENTS

3.1 *Test cycle.* Perform a test cycle by establishing the testing conditions set forth in 2 of this Appendix, setting the dishwasher to the cycle type to be tested, initiating the cycle and allowing the cycle to proceed to completion.

3.2 *Machine electrical energy consumption.* Measure the machine electrical energy consumption, specified as the number of kilowatt-hours of electrical energy consumed during the entire test cycle, using a kilowatt-hour meter having a resolution no larger than 0.001 kilowatt-hours and a maximum error no greater than one percent.

3.3 *Water consumption.* Measure the water consumption, specified as the number of gallons delivered to the dishwasher during the entire test cycle, using a water meter having a resolution no larger than 0.1 gallon and a maximum error no greater than 1.5 percent for all water flow rates from one to five gallons per minute and for all water temperatures encountered in the test cycle.

3.4 *Reported values.* State the reported values of machine electrical energy consumption and water consumption as the average of these respective values measured in three identical consecutive test cycles for the cycle type under test.

4. CALCULATION OF DERIVED RESULTS FROM TEST MEASUREMENTS

4.1 *Per-cycle water energy consumption using electrically heated water.* Calculate for the cycle type under test the per-cycle water energy consumption using electrically heated water, W_e, expressed in kilowatt-hours per-cycle and defined as:

$$W_e = V \times T \times K,$$

where

V = reported water consumption in gallons per cycle for the cycle type under test.
T = nominal water heater temperature rise = 90° F.
K = water specific heat in kilowatt-hours per gallon per degree F = 0.00244.

4.2 *Per-cycle water energy consumption using gas-heated or oil-heated water.* Calculate for the cycle type under test the per-cycle water energy consumption using gas-heated or oil-heated water, W_g, expressed in Btu's per cycle and defined as:

$$W_g = \frac{V \times T \times C}{e}$$

where

V and T are defined in 4.1 of this Appendix, and
C = water specific heat in Btu's per gallon per degree F = 8.34.
e = nominal gas or oil water heater efficiency = 0.75.

4.3 *Per-cycle machine electrical energy consumption.* Calculate for the cycle type under test the per-cycle machine electrical energy consumption, M_e, expressed in kilowatt-hours per cycle, and defined as the reported value of the machine electrical energy consumption for the cycle type under test.

4.4 *Total per-cycle energy consumption when electrically heated water is used.* Calculate for the cycle type under test the total per-cycle energy consumption, E_t, expressed in kilowatt-hours per cycle, and defined as the sum of the per-cycle machine electrical energy consumption, M_e, and the per-cycle water energy consumption using electrically-heated water, W_e, calculated for that cycle type, determined according to 4.3 and 4.1, respectively.

[FR Doc.77-8460 Filed 3-17-77;1:53 pm]

NATIONAL CREDIT UNION ADMINISTRATION

[12 CFR Part 701]

ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

Share Draft Programs; Hearings

AGENCY: National Credit Union Administration.

ACTION: Notice of Hearing on Proposed Rule.

SUMMARY: This notice sets forth the dates, time and place of a hearing to be held on the proposed rule for share draft programs. It also provides for the notification of intent to make oral presentation.

DATES: The hearing will convene at 9:00 a.m. on Tuesday, April 19, 1977, and, if necessary, will reconvene at 9:00 a.m. on Wednesday, April 20, 1977.

ADDRESSES: Send copies of written statements and notification of intent to present oral testimony to Joseph Bellenghi, Assistant Administrator for Examination and Insurance, National Credit Union Administration, 2025 M Street, NW, Washington, DC 20456. The hearing will be conducted in Room 400 at 1111 18th Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Joseph Bellenghi, Assistant Administrator for Examination and Insurance, National Credit Union Administration, 2025 M Street, NW, Washington, DC 20456. Telephone: (202) 254-8760.

SUPPLEMENTARY INFORMATION: On February 28, 1977, the Administrator of the National Credit Union Administration published a proposed rule (42 FR 11247) which prescribes the requirements for the establishment and implementation of share draft programs by Federal credit unions. In order to give interested parties an additional opportunity to participate in the rulemaking process through oral presentation, the Administrator has scheduled a hearing for that purpose. The hearing is to be held at 9:00 a.m., Tuesday, April 19, 1977, at 1111 18th Street, NW, Room 400, Washington, D.C. If necessary the hearing will be carried over to Wednesday, April 20, 1977.

All persons desiring to make oral presentation at the hearing must notify Joseph Bellenghi at the above address of their intention to do so no later than April 5, 1977. Such persons must submit 25 copies of their written testimony to Joseph Bellenghi no later than April 15, 1977.

Persons appearing at the hearing will be allotted 15 minutes to make their oral presentation. Interested persons may request additional time in their notice of intent to appear. However, the granting of additional time will be within the discretion of the Administrator, taking into consideration the number of other

persons who have filed notices of appearance and the availability of time.

C. AUSTIN MONTGOMERY,
Administrator.

MARCH 17, 1977.

(Sec. 120, 73 Stat. 635 (12 U.S.C. 1766) and sec. 209, 84 Stat. 1014 (12 U.S.C. 1789).)

[FR Doc.77-8477 Filed 3-21-77;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 940]

[Docket No. 76N-0504]

FOOD SERVICE SANITATION

Withdrawal of Proposal and Termination of Rule Making Proceeding

The Commissioner of Food and Drugs is withdrawing the proposed food service sanitation regulation published in the FEDERAL REGISTER of October 1, 1974 (39 FR 35438) and terminating the rule making proceeding.

The October 1, 1974 proposal set forth a regulation and model ordinance to provide State and local governments with a comprehensive model law for the regulation of food service sanitation. The proposal had, as one of its primary purposes, the establishment of criteria for the Federal regulation of food service operations on interstate conveyances and food sources for interstate conveyances, and it would have superseded Subpart B of Part 1250 of Title 21 (21 CFR § 1250.20 through § 1250.39).

A number of comments received in response to the proposal opposed the concept of a Federal regulation that established sanitation standards for all food service operations. The primary objections to the proposal were that it abridged a long-term understanding between the States and the Federal government regarding the regulation of the food service industry, and that the proposal inadequately addressed the special circumstances involved in the operation of interstate conveyances and their sources of food.

The Commissioner has concluded that the proposal should be withdrawn and the rule making proceeding terminated because it was never his intention to supersede State and local regulation of food service sanitation or to fail to account for the special circumstances involved in the operation of interstate conveyances and their sources of food. At a future date, the Commissioner will issue a new notice of proposed rule making to supersede Subpart B of Part 1250 for the purpose of establishing criteria for the approval of food service operations on interstate conveyances and for food sources for interstate conveyances.

In the interest of establishing uniform sanitation requirements and enforcement practices, the 1976 revision of the Food Service Sanitation Manual (which includes an updated Model Food Service Sanitation Ordinance) has been prepared and submitted to the Government Printing Office. All of the technical comments received in response to the October 1, 1974 proposal were carefully considered and appropriate changes made in the model ordinance.

A notice will be published in the FEDERAL REGISTER announcing the availability of the manual and model ordinance and the procedure for obtaining a copy from the Food and Drug Administration. Draft copies of the manual are currently being sent to Federal and State offices so that they may familiarize themselves with the model ordinance. A draft copy may be reviewed in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

(Public Health Service Act (secs. 301, 311, 361, 58 Stat. 691, 693, 703 as amended (42 U.S.C. 241, 243, 264)) and the Federal Food, Drug, and Cosmetic Act (secs. 402, 701, 52 Stat. 1046-1047, 1055-1056 as amended (21 U.S.C. 342, 371)) and under authority delegated to him (21 CFR § 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262).)

The Commissioner hereby withdraws the proposed Part 940, published in the FEDERAL REGISTER of October 1, 1974 (39 FR 35438) and terminates the rule making proceeding begun by that proposal.

Dated: January 27, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-8409 Filed 3-21-77;8:45 am]

[21 CFR Parts 1000 and 1020]

[Docket No. 77N-0031]

IONIZING RADIATION THERAPY EQUIPMENT

Notice of Intent to Propose Rules and Develop Guidelines

AGENCY: Food and Drug Administration.

ACTION: Notice of Intent.

SUMMARY: The Food and Drug Administration is considering a control program for radiation therapy equipment. The agency asks for further information before beginning such a program.

DATES: Comments and data by July 20, 1977.

ADDRESSES: Written comments to the Office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvyn R. Altman, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857. (301) 443-3426.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration may develop standards or guidelines for ionizing radiation equipment used primarily for treating cancer. One or more actions could follow: regulatory performance standards, recommended user procedures, recommended training criteria for personnel, and recommended manufacturing or testing procedures. The Food and Drug Administration, through the Bureau of Radiological Health and under the authority of the Radiation Control for Health Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), administers an electronic product radiation control program. This authority provides for development and administration of radiation safety performance standards and development of recommendations for controlling electronic product radiation. The Food and Drug Administration also has authority under the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Devices Amendments of 1976 (Pub. L. 94-295; 90 Stat. 539-583 (21 U.S.C. 379)) regarding safety and effectiveness of medical radiation therapy equipment.

A contract overview study was recently conducted for FDA. This study on electron linear accelerators in medical radiation therapy produced four overview reports: (1) physical characteristics; (2) market and use characteristics; (3) accident history; and (4) regulations, standards, and guidelines. The reports are available from the National Technical Information Service, Springfield, VA 22161. (Some copies of the physical characteristics overview report are available from the Bureau of Radiological Health (HFX-28), 5600 Fishers Lane, Rockville, MD 20857.) The overview study identifies several types of equipment problems that can cause radiation accidents involving incorrect or unintentional exposure of patients or operators. Copies of the study are available for public examination at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Through an interagency agreement with the National Bureau of Standards, a survey of cobalt teletherapy equipment has been instituted. This program, which is nearing completion, is designed to assess the capability of a teletherapy facility to deliver a specified radiation dose, under specified conditions, to a set of dosimeters. The dose and conditions were chosen to simulate typical radiation therapy use. When completed, the survey should cover approximately 60 to 70 percent of the cobalt teletherapy units in the United States. Preliminary results indicate that although most facilities can deliver an adequately precise dose (within ±5 percent), unnecessary errors in dose calculation and dose delivery are common in some facilities. An assistance program is being considered to attempt to identify problems at facilities where the dose delivered was significantly different from that specified. A similar dose evaluation program for radiation therapy facilities using particle accelerators in now being planned. Such surveys help FDA identify problems with radiation therapy services (equipment and user procedures) and help develop appropri-

ate control programs. More information, however, is needed before a specific control program can be started.

The Commissioner of Food and Drugs will consult one or more of the advisory committees concerned with the safety and effectiveness of radiation therapy devices—the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), the Medical Radiation Advisory Committee (MRAC), and the Panel on Review of Radiology Devices—concerning the proposed action and the comments received in response to this advance notice of proposed rule making. The Technical Electronic Product Radiation Safety Standards Committee is a permanent statutory advisory committee to the Secretary of Health, Education, and Welfare; TEPRSSC must be consulted before the establishment of standards under the Radiation Control for Health and Safety Act of 1968. The Medical Radiation Advisory Committee advises and consults with the Bureau of Radiological Health in formulating policy and developing a coordinated program related to use of ionizing radiation in the healing arts. The Panel on Review of Radiology Devices reviews and evaluates data concerning the safety, effectiveness, and reliability of radiology devices; and it advises the Commissioner on the classification of those devices and the need for standards. Other panels will become involved in the development of standards when appropriate.

Interested persons are invited to participate in the development of the control program for radiation therapy equipment by submitting written comments, views, and data on the subject. Communications should reference the docket number appearing in the heading of this document and should be sent to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857, before July 20, 1977. Timely comments will be considered in formulating the control program. Comments received after July 20, 1977 may be considered, depending on the stage of development of any standards or recommendations.

To assist the Commissioner in the development of useful standards and/or recommendations, detailed scientific and technical data, as well as comments or suggestions supported by detailed rationale and justification, are specifically invited on the following questions:

1. Are performance standards or recommended criteria needed for radiation therapy equipment? If so, what types of equipment should be covered, for example, low energy (5 to 50 kilovolts) x-ray generators, neutron generators, electron linear accelerators, cobalt and cesium teletherapy equipment, brachytherapy sources, and betatrons?

2. What types of performance criteria are needed in a performance standard or recommendation? For example, should the criteria address interlock systems, isodose curves, calibration of dosimeter system, leakage radiation, shielding, electrical and mechanical safety, and effectiveness?

3. Is there a significant hazard associated with the neutron contamination of high energy ($E > 12$ megavolts) photon beams? If so, what standards or recommendations are needed? Do such high-energy photon beams have a significantly increased therapeutic effectiveness compared with lower-energy photon beams?

4. What types of performance criteria related to accessory devices should be included, for example, patient-positioning equipment, electronic interference, isodose plotting devices, electronic data processing, and calibration devices?

5. What types of information should be supplied by manufacturers, for example, isodose curves, calibration procedures, and shielding information?

6. Are guidelines (recommendations) related to the operation of radiation therapy equipment needed? If so, should they address, for example, training and experience for personnel (therapists, physicists, technologists), current shortages in radiation therapy personnel, and minimum staffing for various types of facilities?

7. Are guidelines needed for routine maintenance, operator and patient protection, and recordkeeping?

8. For questions 1 through 7, what are the costs and environmental impacts of the suggested actions; and what are the bases for determining these impacts? Also, what are the priorities for the various actions and types of equipment?

9. What existing codes, recommendations, and standards are applicable to the various types of radiation therapy equipment?

10. Are there documented cases of accidents or incidents related to radiation therapy equipment, which resulted in actual or potential injuries to patients or therapy personnel? What were the associated equipment and/or dose-delivery problems?

Persons or organizations wishing further information made public on the development of the control program for radiation therapy equipment and its use may write to the Division of Compliance, Bureau of Radiological Health (HFX–440), 5600 Fishers Lane, Rockville, MD 20857.

This issuance is made under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (secs. 356 and 358, 82 Stat. 1174–1179 (42 U.S.C. 263d and 263f)); the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 301 et seq.); and authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)).

Written comments or data should be sent to the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and should be identified by referring to the docket number appearing in the heading of this document.

Dated: March 14, 1977.

JOSEPH P. HILO,
Associate Commissioner for Compliance.

[FR Doc.77-8289 Filed 3-21-77;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[25 CFR Part 11]

LAW ENFORCEMENT STANDARDS FOR POLICE AND DETENTION PROGRAMS

Proposed Changes to Training Requirements

This notice is published in exercise of authority delegated by the Secretary of the Interior to the Commissioner of Indian Affairs by 230 DM 2.

Notice is hereby given that it is proposed to revise §§ 11.304(g) and 11.305 (n) of Part 11, Subchapter B, Chapter I, of Title 25 of the Code of Federal Regulations. This revision is proposed under the authority contained in 5 U.S.C. 301, 25 U.S.C. § 2 and 25 U.S.C. § 450k.

Subparagraph (1) of § 11.304(g) is revised to include any training program that is approved by the Commissioner of Indian Affairs. The present regulation authorizes only training given by the Indian Police Academy or the state where the officer is employed. The change will give the officer a wider choice of training programs.

Subparagraphs (2), (3), and (4) of § 11.304(g) are revised to authorize training prior to entry on new duties. This change should improve the quality of service rendered by newly promoted or appointed personnel.

Paragarph (n) of 11.305 is revised to permit jailors to serve up to six months before completing training. This paragraph is also revised to include any training program approved by the Commissioner. The present regulation permits only training by the Indian Police Academy or by the State where the jailor is employed. These changes are needed because only limited training for jailors is available at the Indian Police Academy.

Each paragraph or subparagraph being revised will state that transfer may result in demotion. The present regulations require demotion or discharge when an employee fails to pass a required course. The change is designed to leave open the possibility of a transfer that does not require a demotion.

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions, or objections regarding the proposed revision to the Director, Office of Indian Services, Washington, D.C. 20245, on or before April 21, 1977.

It is proposed to amend §§ 11.304 and 11.305 of Subchapter B, Chapter I, Title

25 of the Code of Federal Regulations as follows:

1. By revising § 11.304(g) to read as follows:

§ 11.304 Minimum standards for police programs.

* * * * *

(g) (1) Newly-employed patrol officers shall successfully complete within their first year of service the approved Basic Police Training Course conducted at the Indian Police Academy or a similar course approved by the Commissioner of Indian Affairs. An officer who fails to complete the training required by this subparagraph shall be discharged or transferred to a position not involving law enforcement duties. Transfer may result in demotion.

(2) Prior to, or within one year after, promotion or appointment to a supervisory enforcement position, an employee shall complete the approved Supervisory Enforcement Officer Training Course conducted at the Indian Police Academy or a similar course approved by the Commissioner of Indian Affairs. An officer who is serving in a supervisory position and fails to complete the training required in this subparagraph shall be transferred to a nonsupervisory position. Transfer may result in demotion.

(3) Prior to, or within one year after, promotion or appointment to a criminal-investigator position, an officer shall successfully complete the Criminal-Investigator Training Course conducted at the Indian Police Academy or a similar course approved by the Commissioner of Indian Affairs. An officer who is serving in a criminal-investigator position and fails to complete the training required in this subparagraph shall be transferred to a noncriminal-investigator position. Transfer may result in demotion.

(4) Prior to, or within one year after, promotion or appointment to a supervisory criminal-investigator position, an officer shall successfully complete the Executive Management Course of Training conducted at the Indian Police Academy or a similar course approved by the Commissioner of Indian Affairs. An officer who is serving in a supervisory criminal-investigator position and fails to complete the training required in this subparagraph shall be transferred to a nonsupervisory criminal-investigator position. Transfer may result in demotion.

2. By revising § 11.305(n) to read as follows:

§ 11.305 Minimum standards for detention programs.

* * * * *

(n) Prior to, or within six months after, promotion or appointment to a position involving detention/jail duties, an employee shall successfully complete a Detention/Jail Operations and Management Training Course approved by the Commissioner of Indian Affairs. An employee who is serving in a position involving detention/jail duties and fails to complete the training required by this paragraph shall be transferred to a position not involving detention/jail or law enforcement duties or discharged. Transfer may result in demotion.

(Catalog of Federal Domestic Assistance Program No. 15.131, Indian Law Enforcement Services)

RAYMOND V. BUTLER,
Acting Commissioner of Indian Affairs.

[FR Doc.77-8473 Filed 3-21-77;8:45 am]

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1953]

CHANGES TO STATE PLANS FOR THE DEVELOPMENT AND ENFORCEMENT OF STATE STANDARDS

Notice of Proposed Amendment to Regulation

1. *Background.* In accordance with the provisions of sections 8(g)(2) and 18(c) of the Occupational Safety and Health Act of 1970 (hereinafter referred to as the Act) (29 U.S.C. 657(g)(2) and 667), it is proposed to amend § 1953.23 of Title 29, Code of Federal Regulations. Section 1953.23 pertains to the submission of change supplements to a State plan for the development and enforcement of occupational safety and health standards approved under section 18(c) of the Act whenever there is a change in the Federal program which could have an adverse impact on the "at least as effective as" status of the State program. Among other things, § 1953.23 provides procedures and requirements for the submission of State occupational safety and health standards or amendments to such standards whenever a new permanent Federal standard is promulgated or there is a more stringent amendment to an existing standard. The regulation currently provides that the Regional Administrator shall advise the State of any new Federal standards or any amendments to an existing Federal standard and that a State supplement is required in response to these changes. It is proposed to amend this regulation by deleting the requirement that the Regional Administrator notify the State designee of the promulgation of new Federal standards or amendments to existing Federal standards.

All new Federal standards and all amendments to existing Federal standards are published in the FEDERAL REGISTER. Each state agency designated to administer the State's program for the development and enforcement of such standards subscribes to the FEDERAL REGISTER. It is apparent that the notification to the State of all new standards and amendments by the Regional Administrator is superfluous since each State agency would have received the FEDERAL REGISTER by the time it is notified of the standards change by the Regional Administrator.

This proposal would have no effect on the requirement of 29 CFR 1953.23(a)(2) that the State promulgate a new permanent standard or more stringent amendment to an existing standard within six months of the promulgation of a new Federal permanent standard or more stringent amendment to an existing Federal permanent standard. The proposal merely changes the manner in which a State is officially notified of the standards changes and the pertinent response to such changes by the State.

It should be noted that the provisions of 29 CFR 1953.22 pertaining to notification to the States of the promulgation of emergency temporary standards by the Regional Administrator are not changed. Timeliness is a critical element in the promulgation or adoption of such emergency standards and it is appropriate that the States be notified of such standards by the Regional Administrator even though most designated agencies may have received the Federal Register document containing the emergency temporary standard before being notified by the Regional Administrator.

2. *Public participation.* Interested persons are given until April 21, 1977 to submit written comments, suggestions or objections regarding the proposed amendment of § 1953.23 to the Deputy Director of the Office of Federal Compliance and State Programs, Occupational Safety and Health Administration, Room N-3112, 200 Constitution Ave. NW., Washington, D.C. 20210.

Comments received will be available for public inspection and copying during normal business hours at the above address. The proposed rules may be revised prior to final publication to reflect suggestions made by the comments.

Section 1953.23 of Title 29 of the Code of Federal Regulations would be amended as follows:

§ 1953.23 Submission and consideration of Federal program changes.

(a) (1) Within a reasonable time after the occurrence of a Federal program change, other than promulgation of emergency temporary standards, new permanent standards or more stringent amendments to existing standards, the Regional Administrator, as directed by the Assistant Secretary, shall advise the States of the Federal program change and that a State supplement is required. The notification shall also contain a time period, generally not to exceed 30 days, for submission of the Federal program change supplement, or a schedule for the completion of such change.

(2) Where the Federal program change is a new permanent standard, or a more stringent amendment to an existing permanent standard, the State shall promulgate a State standard adopting such new Federal standard, or an at least as effective equivalent thereof, within six months of the date of promulgation of the new Federal standard or more stringent amendment. Publication of the adoption of the new permanent Federal standard or more stringent amendment to an existing permanent standard shall be the official notice to the States of the adoption of the new permanent Federal standard or more stringent amendment to an existing permanent standard and of the need to

submit a plan supplement incorporating the new Federal standard or amendment within six months. The Assistant Secretary may permit a longer time period if the State makes a timely demonstration that good cause exists for extending the time limitation.

* * * * *

(Secs. 8(g)(2) and 18(c), Pub. L. 91-596, 84 Stat. 1600, 1608 (29 U.S.C. 657(g)(2) 667 (c)).)

Signed at Washington, D.C., this 15th day of March 1977.

B. M. CONCKLIN,
Deputy Assistant Secretary of Labor.

[FR Doc.77-8507 Filed 3-21-77;8:45 am]

LIBRARY OF CONGRESS

Copyright Office

[37 CFR Part 201]

[Docket RM 77-2]

COMPULSORY LICENSE FOR CABLE SYSTEMS

Advance Notice of Proposed Rulemaking

AGENCY: Library of Congress, Copyright Office.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: This advance notice of proposed rulemaking is issued to advise the public that the Copyright Office of the Library of Congress is considering adoption of regulations to implement a section of Pub. L. 94-553 (90 Stat. 2541), the Act for General Revision of the Copyright Law, which provides a compulsory license for secondary transmissions of copyrighted works by cable systems. This notice announces and invites participation in a public hearing intended to elicit comment, views and information which will assist the Copyright Office in considering alternatives and formulating tentative regulations to be later issued as proposed rules for additional comment.

DATES: The hearing will be held on April 12 and 13, 1977, commencing at 9:30 a.m. on April 12.

Members of the public desiring to testify should submit written requests to present testimony before April 4, 1977, to the address set forth below. The request should clearly identify the individual or group requesting to testify and the amount of time desired.

ADDRESSES: The hearing will be held in Room 910, Crystal Mall Building No. 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

Requests to present testimony should be addressed to: *Office of the General Counsel*, U.S. Copyright Office, Library of Congress, Washington, D.C. 20559.

FOR FURTHER INFORMATION, CONTACT:

Jon Baumgarten, General Counsel, U.S. Copyright Office, Library of Congress, Washington, D.C. 20559, (703-557-8731).

SUPPLEMENTARY INFORMATION: Section 111(c) of the first section of Pub. L. 94-553 establishes a compulsory licensing system under which cable systems may make secondary transmissions of copyrighted works. The compulsory license is subject to, among other conditions, the requirement that the cable system comply with certain filing and accounting provisions. Under section 111(d)(1) of the Act:

(1) Any system that is in operation on April 17, 1977 must record the following information in the Copyright Office no later than April 18, 1977:

(a) "the identity and address of the person who owns or operates the secondary transmission service or has power to exercise primary control over it"; and

(b) "the name and location of the primary transmitter or primary transmitters whose signals are regularly carried by the cable system". (2) Any system that begins operation after April 17, 1977, must record the specified information (quoted in the preceding paragraph) at least one month before the date operations commence. (As a transitional exception, the recording deadline for any system that starts operating between April 18, 1977, and May 18, 1977, is April 18, 1977.)

(3) After making the initial record (described in the preceding two paragraphs), the cable system must then make supplemental records "within thirty days after each occasion on which the ownership or control or the signal carriage complement of the cable system changes."

(4) In addition to the initial and supplemental records (described in the preceding three paragraphs), the cable system must record "thereafter, from time to time, such further information as the Register of Copyrights, after consultation with the Copyright Royalty Tribunal (if and when the Tribunal has been constituted), shall prescribe by regulation to carry out the purpose of this clause."

In addition, section 111(d)(2)(A) of the Act requires that cable systems exercising the compulsory license file, semiannually and in accordance with Copyright Office regulations:

> a statement of account, covering the six months next preceding, specifying the number of channels on which the cable system made secondary transmissions to its subscribers, the names and locations of all primary transmitters whose transmissions were further transmitted by the cable system, the total number of subscribers, the gross amounts paid to the cable system for the basic service of providing secondary transmissions of primary broadcast transmitters, and such other data as the Register of Copyrights may, after consultation with the Copyright Royalty Tribunal (if and when the Tribunal has been constituted), from time to time prescribe by regulation. Such statement shall also include a special statement of account covering any nonnetwork television programming that was carried by the cable system in whole or in part beyond the local service area of the primary transmitter, under rules, regulations, or authorizations of the Federal Communications Commission permitting the substitution or addition of signals under certain circumstances, together with logs showing the times, dates, stations, and programs involved in such substituted or added carriage;

together with royalties computed as set forth in other paragraphs of the section. In discussing this requirement of "semiannual" accountings, the Report of the Judiciary Committee of the House of Representatives states (H.R. Rep. No. 94-1476, 94th Cong., 2d Sess. at 95): "The dates for filing such statements of account and the six-month period which they are to cover are to be determined by the Register of Copyrights after consultation with the Copyright Royalty [Tribunal]". Distribution of the royalties is to be made to specified classes of copyright owners who file claims with the Copyright Royalty Tribunal during the month of July in each year.

By notice published on March 18, 1977 (42 FR 15065), the Copyright Office adopted an interim regulation § 201.11 pertaining to the filing by cable systems of the information quoted above in numbered paragraphs (1), (2), and (3). With this notice we are now initiating our consideration of final regulations to implement the filing and accounting provisions of section 111(d) of the Act as a whole.

Testimony is invited on all considerations relevant to the formulation of regulations referred to in sections 111(d)(1) and 111(d)(2) of the Act. These considerations include, but are not limited to, the following questions:

(1) Should interim regulation § 201.11 be modified for cable systems commencing operations or undergoing ownership or signal carriage changes in the future?

(2) What relationship should be established between the "further information" clause of section 111(d)(1) and the accounting provisions of section 111(d)(2)? Should the Copyright Office implement the final clause of section 111(d)(1) by requiring the filing of information other than that required under interim regulation § 201.11 and/or the accounting provisions? If so, what information should be required, and with what frequency should it be filed?

(3) In order to assure adequate time for cable systems to prepare statements of account and for copyright owners to review the statements and prepare and file claims to royalties during the month of July, what dates should be established for the filing of accounts and what six-month periods should they cover?

(4) What "other data" should be included in statements of account and special statements of account under section 111(d)(2)? Are there special issues to be considered in connection with the terms "number of channels", "number of subscribers", "gross amount", and "basic service" as used in paragraph (A) of that section?

(5) Is the definition of "cable system" in section 111(f) of the Act adequate for purposes of the recording and accounting provisions? For example, where two or more cable systems in non-contiguous communities operate from one head-end, shall they be considered as one sytem

for these purposes? Where an operator maintains facilities in separately identifiable non-contiguous communities, what is "the cable system?" In the context of configurations or interconnections employing "central" and "local" or "hub" head-end, what is the "cable system" and "one head-end"?

(6) How should the reference to including the names and locations of "all primary transmitters whose transmissions were further transmitted by the cable system" in statements of account under section 111(d)(2)(A) be treated for systems carrying the entire FM band? Are there special issues to be considered (pertaining to both identification and classification of signals) in the event of cable system retransmission of signals received from translator or similar stations?

(7) Considering, among other factors, that section 111(d)(2) of the Act requires a special statement of account for substituted programming, what significance should be attributed to differences between the phrase "all primary transmitters whose transmissions were further transmitted by the cable system" appearing in the first clause of section 111(d)(2)(A) and the phrase "the primary transmitter or primary transmitters whose signals are regularly carried by the cable system" in section 111(d)(1)? What differences exist, if any (a) between the primary transmitters to be identified in statements of account and special statements of account, respectively, under section 111(d)(2); (b) between those primary transmitters and the primary transmitters to be identified under section 111(d)(1)?

(8) To what extent, if any, should the Copyright Office examine and enter into correspondence concerning the contents of statements of account with respect to (a) clerical and mathematical accuracy; (b) compliance on their face with the requirements of section 111(d)(2), including the appropriate computations required by subclauses (B), (C), or (D); (c) conformance between the statement of account and the total amount of the accompanying deposit of royalities; (d) conformance between the statement of account and the information already filed by the cable system under section 111(d)(1); and (e) any other matters?

(9) Should the Copyright Office impose a fee under section 708(a)(11) for the handling and recordation of notices and statements of account under paragraphs (1) and (2) of section 111(d)?

(10) Should the Copyright Office provide printed forms for the filing of statements of account? If so, should their use by cable systems be mandatory or optional? What records should the Copyright Office make and maintain on the basis of these statements?

WRITTEN STATEMENTS

All witnesses are requested to provide 10 copies of a written statement of their testimony to the Office of the General Counsel, at the address given above, by 4 p.m. on April 8, 1977.

The record of the proceedings will be kept open until May 13, 1977 for receipt of written supplemental statements. (17 U.S.C. § 207; and under the following sections of Title 17 of the United States Code as amended by Pub. L. 94-553: sections 111; 702).

Dated: March 18, 1977.

BARBARA RINGER,
Register of Copyrights.

Approved:

WILLIAM J. WELSH,
Acting Librarian of Congress.

[FR Doc.77-8580 Filed 3-21-77;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 701-2]

APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Missouri: Approval and Disapproval of Compliance Schedules

On May 31, 1972 (37 FR 10842), pursuant to Section 110 of the Clean Air Act and 40 CFR Part 51, the Administrator approved portions of State plans for implementation of the national ambient air quality standards.

On November 23, 1976, the State of Missouri submitted to the Environmental Protection Agency compliance schedules to be considered as proposed revisions to the approved plans pursuant to 40 CFR 51.6. 40 CFR 51.8 requires the Administrator to approve or disapprove compliance schedules submitted by the States. Therefore, the Administrator proposes the approval of the compliance schedules listed below.

The approvable schedules were adopted by the State and submitted to the Environmental Protection Agency after notice and public hearings in accordance with the procedural requirements of 40 CFR 51.4 and 51.6 and the substantive requirements of 40 CFR 51.15 pertaining to compliance schedules. The compliance schedules have been reviewed and determined to be consistent with the approved control strategies of Missouri. This determination is based on a finding that the compliance schedules will not interfere with attainment and maintenance of NAAQS.

Each approved revision establishes a new date by which the individual source must comply with the applicable emission limitation in the federally approved State Implementation Plan. This date is indicated in the table below under the heading "Final Compliance Date." In all cases, the schedules include incremental steps toward compliance with the applicable emission limitations. While the tables below do not include these interim dates, the actual compliance schedules do. The "Effective Date" column in the table indicates the date the compliance schedules become effective for purposes of federal enforcement.

In the indication of proposed approval of individual compliance schedules, the individual schedules are included by reference only. An evaluation report has been prepared for each individual compliance schedule. These evaluation reports are available for public inspection at the Environmental Protection Agency Regional Office, 1735 Baltimore, Kansas City, Missouri. The compliance schedules proposed to be approved and the State Implementation Plans are available for public inspection at the Environmental Protection Agency Regional Office; the Environmental Protection Agency, Public Information Reference Unit, Room 2922, 401 M Street SW., Washington, D.C. 20460; and the Missouri Department of Natural Resources, State Office Building, Jefferson City, Missouri.

Interested persons may participate in this rulemaking by submitting written comments in triplicate to the Region VII office at the above address. All comments submitted on or before April 21, 1977 will be considered. All comments received, as well as copies of the applicable implementation plans, will be available for inspection during normal business hours at the Regional Office.

(Sec. 110(a) of the Clean Air Act, as amended 42 U.S.C. 1857c-5.)

Dated: March 9, 1977.

CHARLES V. WRIGHT,
Acting Regional Administrator,
Region VII.

It is proposed to amend Part 52 of Chapter I, Title 40 of the Code of Federal Regulations as follows:

Subpart AA—Missouri

1. In § 52.1335, the table in subparagraph (a) is amended by adding the following:

§ 52.1335 Compliance schedules.

* * * * * *

(a) * * *

Missouri

Source	Location	Regulation involved[1]	Date adopted	Effective date	Final compliance date
*	*	*	*	*	*
Associated Electric Cooperative, Thomas Hill Unit No. 2	Moberly	10 CSR 10-3.060, 10 CSR 10-3.080	Nov. 17, 1976	Immediately.	June 1, 1979
Farmers Chemical Co., Inc., Ammoniator-Granulator Process	Joplin	10 CSR 10-3.050, 10 CSR 10-3.080	do	do	Jan. 15, 1978

[1] Effective July 1, 1976, the State of Missouri revised the numbering system for all air pollution control regulations throughout the State. The State air regulations are contained in title 10, division 10 of the Code of State Regulations designated 10 CSR 10. This designation will be used in all future FEDERAL REGISTER documents.

[FR Doc.77-8258 Filed 3-21-77;8:45 am]

[40 CFR Part 260]

[FRL 699-3]

ENVIRONMENTAL RADIATION PROTECTION CRITERIA AND STANDARDS FOR RADIOACTIVE WASTES

Public Workshop

Notice was given (41 FR 53363 Monday, Dec. 6, 1976) that the U.S. Environmental Protection Agency intends to develop environmental radiation protection standards for high-level radioactive waste to assure protection of the public health and the general environment. This development will focus initially on two major outputs: general environmental protection criteria for all radioactive waste and numerical standards for high-level radioactive waste. These criteria and standards will be developed under the broad authorities transferred to the Agency from the former Atomic Energy Commission and the former Federal Radiation Council by Reorganization Plan No. 3 of 1970.

ANNOUNCEMENT OF WORKSHOP ON ENVIRONMENTAL PROTECTION CRITERIA

In the course of developing the criteria, EPA plans to hold a second workshop entitled "Policy and Technical Issues Pertinent to the Development of Environmental Protection Criteria for Radioactive Wastes" on April 12-14, 1977, at the Albuquerque Inn/Convention Center, Albuquerque, New Mexico. This workshop is a sequel to the workshop held in Reston, Virginia, on February 3-5, 1977, in which public policy issues were discussed. Proceedings of the Reston Workshop will be available prior to the second workshop and will be used as background for interacting public and technical considerations basic to developing criteria for all forms of radioactive waste. No fee will be charged for attendance although advance registration is requested. Most of the first day will consist of a plenary session during which invited participants will provide their opinions on key issues in each of the topical areas. These invited participants have been selected to provide a well-balanced approach to the working sessions. Additionally, if any individual or member of an organization wishes to present a formal statement, the Agency will accept a written statement of no more than 1,000 words submitted no later than April 4, 1977. Limited time has been allotted for oral presentation of these formal statements on the afternoon of April 12, 1977. Selection for oral presentation (limited to 10 minutes) will be on a first-come basis; however, all submitted statements will be included in the published proceedings of the workshop. The remaining day and a half of the workshop will be devoted to smaller participative working sessions, each addressing a specific topic. Each working group will be expected to prepare a summary report on its topic, including minority or dissenting opinions, for inclusion in the record. The topical areas are:

Topic 1: Policy and Technical Considerations for High-Level Radioactive Waste: This session will focus on the public policy and technical aspects of risk and legacy associated with high-level and transuranic (TRU) waste. An effort will be made to delineate technical bases for the criteria development process.

Topic 2: Policy and Technical Considerations for Intermediate and Low-Level Radioactive Waste: This session will put into perspective the public policy and technical aspects associated with intermediate and low-level waste. Criteria development will be discussed in the context of present practice and experience with such sources as low- and intermediate-level commercial wastes, uranium mill tailings, and phosphate wastes.

Topic 3: Public Acceptance of the Risk Associated with Radioactive Waste: A major basis of the environmental protection criteria to be developed by EPA is public acceptance of the known and perceived risks associated with radioactive waste. This session will evaluate the social, moral, political, and technical issues bearing on such acceptance as it relates to criteria development.

ADDRESS

Advanced registration will be handled for EPA by Ecological Analysts, Inc., at the address below:

Registrar, EPA Workshop, Ecological Analysts, Inc., 275 Broad Hollow Road, Melville, New York 11746.

Statements, comments, information, or other requests should be addressed to: Manager, Waste Environmental Standards (AW-460), Office of Radiation Programs, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

Dated: March 10, 1977.

EDWARD F. TUERK,
Acting Assistant Administrator for Air and Waste Management.

[FR Doc.77-7979 Filed 3-18-77;9:36 am]

[40 CFR Part 700, 710]

[FRL 699-4]

CHEMICAL SUBSTANCE INVENTORY REPORTING REQUIREMENTS

Public Meeting

In order to provide interested persons an opportunity to comment publicly on the proposed regulations for compiling the chemical substance inventory required by section 8(b) of the Toxic Substances Control Act (TSCA) (Pub L. 94-469; 15 U.S.C. 2601, et seq.), the Agency will hold a public meeting on April 18, 1977 at the Jefferson Memorial Auditorium, Department of Agriculture, 14th and Independence Avenue, S.W., Washington, D.C., from 9 a.m. to 4:30 p.m.

On March 9, 1977, the Agency published proposed regulations and reporting forms in the FEDERAL REGISTER (42 FR 13130). The regulations would prescribe: (1) certain definitions applicable to rules under TSCA; (2) what chemical substances may be included on the inventory to be published in November 1977; (3) who should report and the procedures for reporting chemical substances for the inventory; (4) exemptions from such reporting requirements and certain prohibitions; and (5) procedures for handling claims of confidentiality.

For certain proposals, the Agency explicitly solicited comments in the preamble to the proposed regulations and would especially welcome comment on those issues.

EPA will record the proceedings and make a transcript available for public inspection by May 3, 1977 in the Office of Toxic Substances from 8:30 a.m. to 4:00 p.m. on normal business days.

Subject to time limitations, EPA will give anyone who wants to make an oral presentation an opportunity to do so. Such persons should notify, in writing or by telephone, Mrs. Vickie Briggs, Office of Toxic Substances (WH-557), Environmental Protection Agency, Room 715 East Tower, 401 M Street, S.W., Washington DC, 20460, telephone number (202) 426-9819 by April 11, 1977. Written requests should include the following document control number: OTS-081002.

Dated: March 14, 1977.

KENNETH L. JOHNSON,
Acting Assistant Administrator for Toxic Substances.

[FR Doc.77-7980 Filed 3-21-77;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

[42 CFR Parts 50-59a]

HEALTH MANPOWER PROGRAMS

Intent to Issue Proposed Rules

Notice is hereby given that the Secretary of Health, Education, and Welfare intends to propose regulations to implement the following sections of the Public Health Service Act:

332(b), 42 U.S.C. 254e(b)—Criteria for Designation of Health Manpower Shortage Areas.
701 (7) and (8), 42 U.S.C. 292a (7) and (8)—Programs for the Training of Physician Assistants and Programs for the Training of Expanded Function Dental Auxiliaries.
708, 42 U.S.C. 292h—Health Professions Data.
711, 42 U.S.C. 292k—Payment for Tuition and Other Educational Expenses.
720, 42 U.S.C. 293—Grants for Construction of Teaching Facilities.
726, 42 U.S.C. 2931—Loan Guarantees and Interest Subsidies to Assist in Construction of Teaching Facilities.
759, 42 U.S.C. 294aa—Lister Hill Scholarship Program.
782, 42 U.S.C. 295g-2—Education of Returning United States Students from Foreign Medical Schools.
783, 42 U.S.C. 295g-3—Programs for Physician Assistants and Expanded Function Dental Auxiliaries.
784, 42 U.S.C. 295g-4—Training, Traineeships, and Fellowships in General Internal Medicine and General Pediatrics.
788(f), 42 U.S.C. 295g-8(f)—Medical School Planning Costs.
788(g), 42 U.S.C. 295g-8(g)— New Medical Schools Emphasizing Family Medicine.
789(a), 42 U.S.C. 295f-6(a)—Training in Emergency Medicine.

Except for section 789(a), which was enacted by Pub. L. 94-573, the "Emergency Medical Services Amendments of 1976," these provisions were enacted by

Pub. L. 94-484, the "Health Professions Educational Assistance Act of 1976."

EXPLANATION OF THE PURPOSE OF THIS NOTICE

This notice presents a short description of the statutory provisions and the major issues raised by these provisions and discusses proposed approaches to resolving the issues and implementing the programs. The solutions discussed are intended to be illustrative of approaches which are to be taken. Their listing is not intended to be exhaustive of all possible alternatives.

All interested parties are invited to submit comments on the issues and proposals discussed below as well as on any other issues raised by the statutory provisions. Comments are invited which support or dispute issues which have been raised or the options which have been provided. Also invited are comments which identify issues or options which have not been included in this document.

Commenters should address only those issues which concern the implementation of these statutory provisions through regulations.

To enable the Department to meet the legislatively mandated dates for publication of regulations, comments on the provisions related to programs for Physician Assistants, Expanded Function Dental Auxiliaries and Criteria for Designation of Health Manpower Shortage Areas should be submitted on or before April 21, 1977. Comments on the remaining portions of this Notice will be received on or before May 6, 1977.

Because of the statutory publication deadlines, it is anticipated that after consideration of public comments received in response to this Notice, that provisions for Physician Assistants, Expanded Function Dental Auxiliaries and Criteria for Designation of Health Manpower Shortage Areas will next be issued as Interim Final Regulations effective upon publication in the FEDERAL REGISTER. Public comments will be received for a period of 45 days after publication of the Interim Final Regulations. After consideration of the public comments received in response to the publication of the Interim Final Regulations, the regulations will be republished in the FEDERAL REGISTER within 90 days after the expiration of the 45 day comment period.

All comments and suggestions should be submitted in writing to the Director, Bureau of Health Manpower, 9000 Rockville Pike, Room 5C-02, Building 31, Bethesda, Maryland 20014. Consideration will be given to all comments and suggestions received on or before April 21, 1977. Such comments and suggestions will be available for public inspection at the above address during regular business hours. Any comments or suggestions received after the close of the comment period will be considered along with the comments received in response to the publication of proposed regulations.

Additional Notices of Intent to Issue Proposed Rules relating to other sections of the Act will be published within the next several weeks.

Summaries of the provisions listed above, the issues raised, and proposed approaches to resolving them are as follows:

ASSISTANCE FOR CONSTRUCTION OF TEACHING FACILITIES; SUMMARY OF PROVISIONS OF LAW

REGIONAL PROGRAMS (FY 1977 ONLY)

For FY 1977 only, construction grant authority is amended to allow clinical facilities affiliated with a school of veterinary medicine, optometry, podiatry, or pharmacy to apply directly for a grant for construction of a facility having as its purpose the establishment or expansion of a regional health professions program. Also, the authority is amended to require the Secretary to give special consideration to applications for facilities for the establishment or expansion of regional health professions programs. Such regional programs are defined in the law as limited to schools of veterinary medicine, optometry, podiatry and pharmacy.

CONSTRUCTION GRANT AMENDMENTS EFFECTIVE IN FY 1978

Effective in FY 1978, existing construction grant authority is extended through 1980 and amended as follows:

Ambulatory primary care teaching facilities. New authority is added for grants to public and nonprofit private entities to assist in the construction of ambulatory primary care teaching facilities for the training of physicians and dentists. No such grant may exceed 50 percent of cost of facility or $1 million, whichever is less. In award of grants under this authority, special consideration shall be given to entities receiving aid under special project authorities relating to area health education centers, general internal medicine and general pediatrics, and family medicine and the general practice of dentistry.

Medical school projects in States without such schools. Existing construction authority is amended to require that special consideration be given, in the award of grants to medical or osteopathic schools under that authority, to projects for physician training facilities in States not now having such facilities.

Matching maximum. Construction authority for health professions teaching facilities is amended to provide a single maxmum share of 80 percent of costs in place of existing different maximums for different maximums for different types of projects.

Earmarking of appropriations. Of sums appropriated for construction grants, 50 percent shall be obligated for grants under existing construction grant authority and 50 percent shall be obligated for grants for ambulatory primary care teaching facilities.

Construction guaranteed loans and interest subsidies. Authority for loan guarantee and interest subsidies for construction of health professions teaching facilities is extended through FY 1980, with amendments to allow the Federal Government to pay full amount of losses in case of defaults on loans (previously limited to 90 percent of such losses); and to add authority for guarantees of loans made by a Federal Financing Bank. These amendments apply with respect to loans guaranteed after September 30, 1977.

Noninterference provision repealed. Section 726 prohibiting Federal interference with the administration of institutions receiving grants under the health professions teaching facilities construction program is repealed.

ISSUES

(1) The legislation requires that special consideration be given to:

(a) Applications from schools of medicine in States without such schools.

(b) Applications for facilities for the establishment or expansion of regional health professions (veterinary medicine, optometry, podiatry, or pharmacy) programs.

(c) Entities which have been awarded grants or received contracts under section 781, 784, or 786, of the PHS Act. In this context, how should "special consideration" be defined?

Alternative solutions. (a) "Special consideration" may be defined as awarding bonus points to the priority scores of approved applications which qualify for special consideration.

(b) "Special consideration" may be defined as funding all approved applications qualifying for special consideration before funds are allocated for other approved applications.

(2) Within the limited authorization levels for this program, little national impact could be realized if expensive inpatient facilities were supported with grant funds. Alternate financing mechanisms are available for hospitals, such as the Health Professions Loan Guaranteed and Interest Subsidy Program, the Health Resources Development Program (Title XVI, PHS Act) an reimbursement of capital expenditures through third party payers. In view of the above, should the regulations provide that construction of inpatient bed space for the teaching program will be supported by other available resources, and that grant funds will be allowed only in unusual circumstances on a case by case basis with complete justification as determined by the Secretary?

Alternative solutions. (a) Do not provide funds for inpatient bed space.

(b) Provide funding for inpatient bed space only when additional beds are required to support programs in family medicine, general internal medicine, and general pediatrics.

(3) Many potential applicants for construction grants will be eligible to apply for support under both section 720(a)(1) and 720(a)(2). Section 720(a)(1) has the most favorable matching provision and does not have an upper limit on the grant amount. Therefore it is expected that some applicants that are eligible under section 720(a)(2) will also wish to seek assistance under section 720(a)(1) for the same project. Should the regulations provide that an eligible institution may apply for support under both section 720(a)(1) (general teaching facilities) and section 720(a)(2) (ambulatory, primary care teaching facilities) but in no case would an applicant receive support under both sections for the same project?

(4) Applicants for grants for construction of ambulatory, primary care teaching facilities must assure that sufficient funds will be available for operaiton of the training programs when the facilities are constructed. Should the regulations require that, in additoin to the assurance, a financial feasibility study be submitted?

Alternative solutions. (a) Require each applicant to submit a financial feasibility report. This report prepared by a recognized consultant for expertise in this area would demonstrate to the satisfaction of the Secretary that the applicant will have sufficient financial resources to operate and maintain the facilities for which it is requesting construction funds.

(b) Do not place this burden on an applicant and require an assurance that sufficient funds will be available and provide sufficient data for the Secretary to make a feasibility determination.

(5) In instances where the legislation does not require an increase in or maintenance of student enrollement, should the regulations require the maintenance of student enrollment equal to the enrollment at the time of the application?

Alternative solutions. (a) Require each applicant under subsections 720(a)(1) (general teaching facilities) and 720(a)(2) (ambulatory, primary care facilities) to maintain its first-year student enrollment at the time of application for a specified number of years.

(b) Provide for such a requirement under subsection 720(a)(1) only. (Subsection 720(a)(2) provides for facilities to be used principally by third-year and fourth-year medical students.)

(c) Provide for no enrollment maintenance requirement.

(6) Effective in fiscal year 1978, the Government will guarantee payment when due of principal and interest on a loan in lieu of guaranteeing up to 90 percent of the loss. How should the Government's payment be made to lenders in the event of default?

Proposed solution. When the lender demands payment from the Department, give the Secretary the authority to (1) purchase the loan through the payment to the lender of the full unpaid principal plus any reasonable expense incurred by the lender in attempting to secure payment from the applicant; or (2) pay to the lender, on behalf of the applicant, the full amount of all overdue payments of principal, accrued interest, and reasonable late charges, and continue to make such payments when due until the applicant resumes the making of payments or the Secretary elects to purchase th loan in accordance with option (1).

(7) Should the Secretary establish award priorities among the various health professions schools, e.g., should medical school applications have a higher priority than all others?

Lister Hill Scholarship Program, Summary of Provisions of Law

Effective in FY 1977, the Secretary is required annually to award medical school scholarships of up to $8,000 a year for up to four years to at least 10 medical students who agree to enter family practice of medicine in a health manpower shortage area.

ISSUE

Inasmuch as few awards would be made each year, what kind of eligibility requirements should be established?

Education of Returning U.S. Students From Foreign Medical Schools, Summary of Provisions of Law

Effective in FY 1977, new categorical authority is added for grants to schools of medicine and osteopathy to plan, develop, and operate programs to assist U.S. citizens enrolled in foreign medical schools before the date of enactment of this Act, in transferring to U.S. medical or osteopathic schools with advanced standing. Secretary to submit to Congress before September 30, 1979, an analysis and evaluation of information on deficiencies (if any) identified by schools in the foreign medical education of students trained by them under this program.

ISSUE

(1) Section 771(b)(3) requires that in order to be eligible for a capitation grant, a school of medicine shall assure that it will reserve positions in the school year beginning immediately before the fiscal year for which a grant is applied for, for an equitable number of U.S. citizens who have successfully completed two years in a foreign medical school and have successfully completed Part I of the National Board of Medical Examiners' examination. Should Education of Returning U.S. Citizens grant funds be used only for the educaton of students the grantee institution accepts over and above the capitation requirement?

Training, Traineeships, and Fellowships in General Internal Medicine and General Pediatrics; Summary of Provisions of Law

Effective in FY 1977, new categorical authority is established for grants and contracts to schools of medicine and osteopathy to plan, develop, and operate approved medical residency programs in internal medicine or pediatrics that emphasize training for practice in general internal medicine or general pediatrics; and to provide traineeships and fellowships to residents participating in these programs.

ISSUES

(1) How are the terms "general internal medicine" and "general pediatrics" to be defined?

Proposed elements of a definition. "Practice of general internal medicine or general pediatrics" includes:

(a) Serving as physician of first contact with the ambulatory patient and providing a means of entry into the health care system.

(b) Evaluating the patient's total health care needs, providing personal medical care within one or more fields of medicine, and referring the patient, when indicated, to appropriate sources of care while preserving the continuity of care.

(c) Assuming responsibility for the patient's comprehensive and continuous health care and acting as leader or coordinator of the provision of health services.

(d) Accepting responsibility for the patient's total health care within the context of his environment, including the community and family or comparable social unit.

(e) Where applicable, the planned sharing of the above functions with other physicians.

(2) How is the term "approved residency training programs" to be defined?

Proposed definition. An approved program is defined as one which is fully or provisionally accredited by the Liaison Committee on Graduate Medical Education. Also approval is defined as meaning recommendation by the American Osteopathic Association that the general internal medicine or general pediatrics program in osteopathy is endorsed.

(3) What assurances are necessary to indicate that recipients of traineeships (stipends) under section 784 will practice general internal medicine or general pediatrics?

Medical School Planning Costs Summary of Provisions of Law

For FY 1977 only, authority is provided for grants to meet planning costs of medical schools providing the last two years of training in offsite clinical facilities located in a health manpower shortage area as opposed to the principal teaching facilities of the school.

ISSUES

(1) How is the term "principal teaching faciilties of the school" to be defined?

Proposed definition. All facilities that are owned and/or operated by the school's parent institution and other clinical facilities in which the applicant has conducted training programs sponsored by more than one department or in which more than one-half of the undergraduates receive training.

New Medical Schools Emphasizing Family Medicine Summary of Provisions of Law

For fiscal years 1977 and 1978 only, authority is provided for grants to institutions of higher education and health care delivery facilities to assist in the early stages of development of new medical schools emphasizing training in family medicine.

ISSUES

(1) Should applicants for assistance under section 788(g) be required to assure that a minimum number of students will be enrolled in the first year of operation?

Proposed solution. In the development of the school, plans should be made to enroll at least 24 students in the first year of operation, given the goal of the program to attain eligibility for Start-Up Grants.

(2) How is the statutory requirement that grant applications contain assurances that there is a "reasonable indication" of non-Federal financial resources for the development and operation of a school to be met?

Proposed solution. Require that at least 50 percent of eligible project costs be supported by non-Federal funds.

(3) What documentation shall be required for applicants to meet the eligibility requirement that they be engaged in the development of a new school of medicine?

Proposed solution. Require the applicant to (1) have formal support of a sponsoring body, (2) have a dean or executive officer appointed, and (3) provide reasonable assurance of adequate financial support to start a new medical school.

(4) How is the term "emphasizing training programs in family medicine" to be defined?

Proposed definition. Applicants shall be determined to be "emphasizing training programs in family medicine" if they plan to have an administrative unit devoted to family medicine training and to require experiences in such unit as a prerequisite for graduation for every student.

(5) What shall be considered assurances satisfactory to the Secretary that the school of medicine will improve access to health care for residents of the area in which the school is to be located?

(6) What shall be considered a reasonable acceleration of the opening date for a new school?

PHYSICIAN ASSISTANTS SUMMARY OF PROVISIONS OF LAW

Within 180 days of enactment of this Act, the Secretary is required, after consultation with appropriate professional organizations, to prescribe regulations for programs to train physician assistants. Regulations must require as a minimum that programs (1) extend for at least one academic year and consist of supervised clinical practice and at least four months of classroom instruction directed toward preparing students to deliver health care; and (2) have a minimum enrollment of eight students. Effective in FY 1978, new categorical authority is provided for grants or contracts to schools of medicine and osteopathy and other public or nonprofit private entities to meet cost of projects to plan, develop, and operate or maintain existing programs for the training of physician assistants. The school must have appropriate mechanisms for placing graduates of training programs. The cost for training faculty for PA programs is allowable.

ISSUES

(1) Shall the term "program for the training of physician assistants" be defined to mean one which trains primary care assistants to the physician?

Proposed definition. The term "program for the training of physician assistants" shall be defined exclusively as one which trains primary care assistants to the physician. This definition is in accordance with the aim of the Act to train more primary care providers.

(2) On making awards, should special consideration be given to programs:

(a) Whose graduates locate in large proportion in underserved geographic areas?

(b) Whose graduates score high on the PA Certification Examination?

(c) Which have a large proportion of students with substantial prior health care experience?

(d) Whose graduates practice in physicians' offices rather than in inpatient institutions?

EXPANDED FUNCTION DENTAL AUXILIARIES SUMMARY OF PROVISIONS OF LAW

Within 180 days of enactment of this Act, the Secretary is required, after consultation with appropriate professional organizations, to prescribe regulations for programs to train dental auxiliaries. Regulations must require as a minimum that programs (i) extend for at least one academic year and consist of supervised clinical practice and at least four months of classroom instruction, directed toward preparing students to assist in provision of dental eare; and (ii) have a minimum enrollment of eight students. Effective in FY 1978, new categorical authority is provided for grants or contracts to schools of dentistry and other public or nonprofit private entities to meet costs of projects to plan, develop, and operate or maintain existing programs for the training of expanded function dental auxiliaries. The school must have appropriate mechanisms for placing graduates of training programs. Costs may include costs of training faculty for EFDA programs.

ISSUE

Should the Secretary specify the functions that are to be taught in an EFDA program?

Alternative solutions. (a) Specify the functions that shall be taught in an EFDA program.

(b) Require only those functions to be taught which are compatible with the practice law of the State in which the grantee institution is located.

(c) Permit functions not compatible with appropriate State law to be taught if permitted in writing by the State board of dentistry.

(d) Permit functions not compatible with State law to be taught if the functions are allowed in a specified number of other States.

HEALTH MANPOWER SHORTAGE AREA CRITERIA SUMMARY OF PROVISIONS OF LAW

Effective on the date of enactment of Pub. L. 94-484, the previous authority for designation of "critical health manpower shortage areas" (section 329(b) of the Public Health Service Act) is replaced by a new section 332 providing for designation of "health manpower shortage areas." Such an area is defined as:

(a) a rational area for the delivery of health services, in an urban or rural area, determined by the Secretary to have a health manpower shortage;

(b) a population group determined by the Secretary to have such a shortage; or

(c) a public or nonprofit private medical facility or other public facility determined by the Secretary to have such a shortage.

Criteria for designation of such areas are required to be established, by regulation, no later than May 1, 1977. Certain factors are listed that must be taken into consideration in establishing such Health Systems Agencies (HSA's), State Health Planning and Development Agencies (SHPDA's), and Governors are required to be considered. A list of designated areas is required to be developed by November 1, 1977, with review of these designations at least annually thereafter.

The health manpower shortage areas designated under this section are to be the areas eligible to receive health services provided by National Health Service Corp (NHSC) personnel (section 333(a)). They are also to be the areas in which recipients of National Health Service Corps Scholarship support must serve periods of obligated service (section 751(f)). Effective October 1, 1977, section 741(f) is revised so that these areas will also be the areas where health professionals must serve to receive loan repayment benefits under section 741(f). In addition, service in these areas may qualify a health professional for repayment of loans insured under the new Federal Program of Insured Loans to Graduate Students in Health Professions Schools (section 735(c)).

ISSUES

(1) The categories of health manpower currently used by the National Health Service Corps are predominantly physicians (primary care physicians and psychiatrists), dentists, nurse practitioners, physician assistants, and nurses. The manpower categories supported with NHSC Scholarships will include physicians, dentists, and nurses. Manpower categories eligible for Loan Repayment under section 741(f) include physicians, dentists, optometrists, podiatrists, pharmacists, and veterinarians. How can the criteria for health manpower shortage areas take into account shortages of these different categories of health manpower?

Proposed solution. Have separate sets of criteria for each of the following:

(a) Primary medical care manpower including primary care physicians (physicians in general or family practice, pediatrics, internal medicine, or obstetrics and gynecology), nurse practitioners, and physician's assistants;

(b) Psychiatric manpower shortage areas, i.e., areas with shortages of psychiatrists and other practitioners providing mental health and related services (including alcohol and drug abuse);

(c) Dental manpower shortage areas, i.e., areas with shortages of dentists and dental auxiliaries;

(d) Vision care manpower shortage areas, i.e., areas with shortages of optometrists or other practitioners providing vision care services;

(e) Foot care manpower shortage areas, i.e., areas with shortages of podiatrists or other practitioners providing foot care services;

(f) Pharmaceutic manpower shortage areas, i.e., areas with shortages of pharmacists;

(g) Veterinary manpower shortage areas, i.e., areas with shortages of veterinarians; and

(h) Nursing manpower shortage areas, i.e., areas with shortages of nurses. These nursing criteria would be identical to those defined under section 836(h) for Nursing Loan Repayment.

(2) How best can the factors mentioned in section 332(b) (1) and (2) (manpower-to-population ratios, indicators of need, including access, infant mortality, and health status) be taken into consideration in identifying shortages of each of these manpower types?

Proposed solution. For each type of care, computer for each area a modified population-to-practitioner ratio. Adjust the population to reflect the varying care needs and utilization of different population components; adjust the number of practitioners where appropriate to reflect differential productivity based on such factors as age and type of practice, and, where possible, take into account the effect of auxiliaries. Compare this modified population-to-practitioner ratio thus obtained with a "shortage" level developed either (a) by examining the distribution of population-to-practitioner ratios by county for the whole U.S. and choosing a level which selects the "worst" end of the distribution; or (b) by identifying adequately-served counties and choosing the shortage level by comparison with the level prevailing in the adequately-served areas.

Designate those counties or other service areas where the modified population-to-practitioner ratio is greater than the shortage level.

In the case of primary medical care, reduce the "shortage" level of the ratio for those areas with high fertility rates and/or high infant mortality rates and/or other high-need indicators. In considering contiguous area resources, allow these resources to be discounted if there are significant barriers to their being accessed by the population in need in the candidate area.

Similarly, for other types of care, take into account need factors analogous to those considered in the medical case.

For veterinary care, use a combination of the ratio of food animal population to veterinarians treating food animals (with various weights for different types of animals) and the ratio of human population to veterinarians treating companion animals.

(3) In what manner should the percentage of hospital-employed graduates of foreign medical schools (FMG's) be taken into account?

Alternative solutions. (a) In counting physicians available to an area, population, or facility, exclude all FMG's who are not fully licensed, and those fully licensed FMG's who are on temporary visas. (Thus, only fully licensed U.S. citizens and foreign nationals on permanent visas would be counted);

(b) Count FMG's as in (a), but consider the excluded FMG's as an available resource to be taken into account in evaluating cases where ratio criteria indicate that the area is on the borderline between shortage and non-shortage; and

(c) Count all FMG's as being equal to U.S. trained physicians in computing ratios, but consider the presence of a high percentage of unlicensed FMG's or licensed FMG's on temporary visas as a factor which could indicate a probable future shortage.

(4) How should population groups with a health manpower shortage be identified? (Section 332(a)(1)(B))

Alternative solutions. (a) Identify Indians as a population group for whom the Federal Government has a special responsibility and which has special health care problems. On this basis give a blanket shortage designation to all reservations and to all facilities serving predominately Indian populations.

(b) Identify migrant workers as a population group for whom the Federal Government has a special responsibility and which has special access problems. On this basis allow deignation of any migrant health center which demonstrates a staffing shortage and give increased priority to any ambulatory care facility which demonstrates a staffing shortage and which serves a significant number of migrant workers.

(c) For these and other identifiable population groups with special problems, such as language, cultural, or other barriers, there are at least two other options:

(1) Designate the portion of the population which has a problem, within a particular city or other area, as a population group with a health manpower shortage. This would presumably enable the NHSC to accept applications for practitioners to serve such a specific population.

(2) Based on the fact that such a population is present in a particular area, decrease the population-to-practitioner ratio required for designation of the area and/or increase the priority for placement of a professional in the area if it is designatable by the area criteria.

(5) How should public or nonprofit private medical facilities (or other public facilities) with a health manpower shortage be identified?

Alternative solutions. (a) Designate only those medical facilities identified as providing medical services to designated shortage areas or shortage populations and identified as having a staffing shortage based on staffing ratios, (e.g., inpatient days-to-staff and/or outpatient visits-to-staff ratios).

(b) Proceed as in alternative (a), but determine staffing shortages by computing staffing ratios not only for the facility itself but jointly for all similar types of facilities serving a given area.

(6) Section 333(c)(1) requires that priority be given to applications for NHSC personnel from areas, population groups, or facilities "with the greatest health manpower shortage, as determined under criteria implemented; i.e., how should the areas, groups, or facilities with the greatest shortage be identified, and how should decisions be made about relative priorities among different types of shortage "areas," e.g., urban areas, rural areas, Indian populations, community health centers, community mental health centers, Federal prisons, etc.?

Alternative solution. A variety of factors and measures exist which could be used for assigning priorities among designated areas. Among the alternatives, which could be used singly or in some combination, are:

(a) Modified population-to-practitioner ratio;

(b) Sensitivity of ratio to increase in health manpower;

(c) Size of population in shortage area;

(d) Number of health manpower necessary to remove area from shortage list;

(e) Length of time area has had shortage; and

(f) Distance to alternative care sources.

One or more of these measures could be used to rank all areas from most severe shortage to least severe shortage, and then cut-off points could be chosen to establish two or three groups (e.g., "critically short," "severely short," and "short").

(7) What procedures should be instituted for individuals or groups to follow in making recommendations to the Secretary regarding possible designations under section 332(g)?

Alternative solutions. (a) Individuals may submit designation requests directly to the Bureau of Health Manpower. Such requests would then be referred by BHM to the appropriate health systems agency (and/or State health planning and development agency) to verify the data and to make recommendations for final consideration by BHM.

(b) Individual requests could be submitted through the appropriate HSA (and/or SHPDA), with their verification of the data and their recommendations.

Payment for Tuition and Other Educational Costs Summary of Provisions of Law

The Secretary shall by regulation establish criteria for determining allowable increases in tuition and other educational costs for which he shall be responsible under any provision of Title VIII after the date of enactment of this Act.

Issues

(1) What costs should be included in and excluded from the definition of the term "tuition and other educational costs?"

(2) What should the criteria be for determining allowable increases?

Health Professions Data Summary of Provisions of Law

The Secretary shall establish a program to collect, compile, and analyze health professions data which shall initially include data on physicians and dentists but may be expanded as needed, at discretion of the Secretary, to cover other health personnel. Grants or contracts to States (or appropriate nonprofit private entity in a State) authorized for establishing a uniform health professions data reporting system. The Secretary may give technical assistance to State and local governments in the development of systems (including model laws) concerning confidentiality and comparability of data collected. Restrictions imposed on release of individually identifiable personal data. Report to President and Congress required September 1 of each year. No appropriation authorizations.

ISSUE

What types of data in addition to data respecting the training, licensure status, place of practice, professional specialty, practice characteristics, place and date of birth, sex, and socio-economic background of health professions personnel should be collected and about which types of other health personnel in addition to dentists and physicians?

TRAINING IN EMERGENCY MEDICINE
SUMMARY OF PROVISIONS OF LAW

The Secretary is authorized to award grants and contracts to schools of medicine, dentistry, osteopathy, and nursing, hospitals, allied health professions training centers, and other educational entities for training programs in the techniques and methods of providing emergency medical services.

ISSUE

No major issues have been identified.

SCHEDULE FOR COMMENTS

To meet legislatively mandated publication dates for final regulations, comments are due on or before April 21, 1977 for the following three programs:

(1) Physician Assistants.
(2) Expanded Function Dental Auxiliaries.
(3) Health Manpower Shortage Area Criteria.

For the remaining programs listed below, comments are due within 45 days following publication of this Notice.

(1) Assistance for Construction of Teaching Facilities.
(2) Lister Hill Scholarship Program.
(3) Education of Returning U.S. Students from Foreign Medical Schools.
(4) General Internal Medicine and Pediatrics.
(5) Medical School Planning Costs.
(6) New Medical Schools Emphasizing Family Medicine.
(7) Payment for Tuition and Other Educational Costs.
(8) Health Professions Data.
(9) Training in Emergency Medicine.

Dated: March 11, 1977.

JOSEPH A. CALIFANO, Jr.,
Secretary.

[FR Doc.77-8340 Filed 3-21-77;8:45 am]

[42 CFR Part 72]

[Docket No. 76N-0504]

LAND AND AIR CONVEYANCES, AND VESSELS: FOOD

Withdrawal of Proposal and Termination of Rule Making Proceedings

Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs is withdrawing the proposed food service sanitation regulation published in the FEDERAL REGISTER of October 1, 1974 (39 FR 35438). In that same issue of the FEDERAL REGISTER (39 FR 35438), the Commissioner proposed that Subpart H of Part 72 (42 CFR Part 72, Subpart H) be superseded by Part 940 of Subchapter I—Federal/State Cooperative Programs.

Since the publication of the original proposal, the text of the affected §§ 72.161 through 72.174 were transferred to 21 CFR Part 1250 as part of a recodification published in the FEDERAL REGISTER of February 6, 1975 (40 FR 5624). Termination of the food service sanitation rule making proceedings has resulted in the termination of the proposed action to supersede Subpart H of Part 72, and these regulations remain in force as recodified under Part 1250.

Dated: February 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-8410 Filed 3-21-77;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[43 CFR Part 2400]

ALASKA

Proposed Amendment of Principles and Procedures for Land Classifications in Alaska; Extension of Time for Comments

In a proposed rulemaking notice published in the FEDERAL REGISTER on January 19, 1977 (42 FR 3657), the Department of the Interior published proposed regulations providing rules to add the authority for classification and reclassification of lands in Alaska contained in section 17(d)(1) of the Alaska Native Claims Settlement Act (43 U.S.C. 1616 (d)(1)), and to place all classification criteria and procedures relating to lands in Alaska under the proposed subpart (2480).

In that notice, comments were requested by February 22, 1977. It has been decided to extend the comment period an additional 90 days. Comments received on or before May 23, 1977, will be considered before final action is taken on the proposed regulations. Interested parties may submit written comments, suggestions, or objections with respect to the proposed rules to the Director (210), Bureau of Land Management, Department of the Interior, Washington, D.C.

Copies of comments, suggestions, or objections made pursuant to this notice will be available for public inspection at the foregoing address during regular working hours (7:45 a.m. to 4:15 p.m.)

CHRIS FARRAND,
Acting Assistant Secretary of the Interior.

MARCH 15, 1977.

[FR Doc.77-8421 Filed 3-21-77;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Parts 1, 97]

[Docket No. 21135; FCC 77-156]

SIMPLIFICATION OF THE LICENSING AND CALL SIGN ASSIGNMENT SYSTEMS FOR STATIONS IN THE AMATEUR RADIO SERVICE

Notice of Proposed Rulemaking

Adopted: March 2, 1977.

Released: March 11, 1977.

In the matter of the simplification of the licensing and call sign assignment systems for stations in the Amateur Radio Service.[1]

1. In accordance with the Administrative Procedure Act, 5 U.S.C. 553, and § 1.412 of the Commission's Rules, 47 CFR 1.412, the Commission hereby gives Notice of Proposed Rule Making in the above-captioned matter.

2. During the past two years there has been an unprecedented explosion in interest in personal radio communications in the United States. The popularity of the CB Radio Service has mushroomed to the point that there are now 8.5 million CB licensees, representing an estimated 20 million users of the CB Service. As recently as February 1975 there were only 1.1 million CB licensees. The Amateur Radio Service has also grown substantially. Although the population of the Amateur Service had remained fundamentally static for several years, the number of licensees has begun to rise, and the number of newcomers to the Service, those obtaining Novice Class operator licenses, has shown particular growth. In December 1976, for example, there were 36,000 Novice Class licenses outstanding, while in December 1974, 21,000 operators held Novice Class licenses. The overall population of the Amateur Service is now approximately 293,000. Two years ago it was 255,000.

3. This surge in interest in personal radio communications has placed a heavy burden on those members of the Commission's staff engaged in the processing and issuance of licenses for personal radio communications. Although the workload imposed upon the Commission's staff at our Gettysburg, Pennsylvania license processing facility has increased approximately 1000 per cent over the past two years, the number of permanent staff employees at Gettysburg has increased by only 50%. This has led, in turn, to an increase in the length of time necessary to process and issue Amateur Radio Service and CB Radio Service licenses. Although temporary permit procedures in the Amateur and CB Services allow, in some instances, operation pending issuance of a license, we are very much aware that many ama-

[1] Chairman Wiley concurring in the result.

teur radio licensees are dissatisfied with the speed with which their regular licenses are processed and issued, and we are investigating methods by which, assuming no new resources to be forthcoming, service to our amateur licensees might be further improved.

4. The Rules governing the Amateur Radio Service contain licensing and call sign assignment systems of some complexity. At the time these rules were adopted, the size and workload of our Gettysburg staff were such that routine and special amateur application processing could be accomplished without undue delay. As we indicated in the preceding paragraph, however, our resources have not kept pace with the increased demand for personal radio communications. Given these limited resources, we have been forced to assign priorities to our current licensing activities. We believe our most important task in the Amateur Radio Service to be the processing and issuance of amateur operator and primary station licenses. We have reached the point at which our lack of resources simply precludes all but the most basic licensing functions. Our regulatory obligations have outstripped our current capabilities. See paragraph 8, *infra*.

5. During most of the boom in personal radio communications, the Commission has been engaged in a program to deregulate the Amateur Radio Service. The proposals and amendments adopted during this period have been intended largely to simplify the licensing and operation of stations in the Amateur Service, and to that extent they complement our desire to improve our procedures in processing and issuing amateur licenses. They have also been intended, at least in part, to reduce the Commission's workload, whenever such a reduction is consistent with the Commission's regulatory obligations. For example, in a Notice of Inquiry and Notice of Proposed Rule Making in Docket 21033, released January 6, 1977 (42 FR 2089), we proposed, *inter alia*, to eliminate from Part 97 of the Rules repeater stations, auxiliary link stations, and control stations. Under the terms of our proposal in Docket 21033, the functions of such stations could be conducted by other amateur radio stations without prior Commission authorization. If adopted, our proposals in that proceeding would afford amateur licensees much greater flexibility in their operations and would also result in a considerable reduction in the workload of the Commission's amateur radio processing staff. Such a workload reduction would, in turn, enable us to redistribute our resources and provide our amateur licensees with better service in other, more vital, areas.

6. We believe the concepts underlying the proposals in Docket 21033 are sound and may logically be extended to several other aspects of station licensing and operation in the Amateur Radio Service. We are by this Notice proposing revisions of Part 97 of the Rules which, if adopted, would result in a significant simplification of the licensing structure of the Amateur Service and of Part 97 itself.

7. Under the existing amateur radio licensing system, a licensee must obtain both an operator license and a station license. A licensee holds only one operator license and is required by Section 97.40 of the Rules to have, at a minimum, a primary station license, as well. There are several other station licenses available, however, including military recreation, club, special event, Radio Amateur Civil Emergency Service (RACES), and secondary station licenses, and many amateur operators have obtained one or more (occasionally, many more) such licenses. Additionally, many amateur radio operators are eligible for specific station call signs or call signs based on particular "preferred" formats.

8. We do not believe that the continuation of the issuance of the various station licenses, other than primary station licenses, listed above or the existence of the current call sign assignment system to be essential to the Amateur Service. The entire system has become extraordinarily burdensome and difficult to administer properly: a disproportionate percentage of our resources must, because of existing rules, be devoted to the processing of special call sign requests and non-primary station license applications. Processing of primary station license applications and operator license applications suffers as a result. For example, as of January 31, 1977 approximately 308,000 stations were licensed in the Amateur Radio Service. Of these, about 95% were primary stations. The other 5% were secondary stations, club stations, Military recreation stations, and RACES stations. Yet processing applications for these non-primary stations required resources nearly equal to the resources needed to process primary station license applications. Similarly, Amateur Extra Class licensees comprise only 6% of the amateur population, but processing specific call sign requests from such licensees requires as much (if not more) time as issuing call signs to the remaining 94%. Clearly, our resources are not allocated in the most effective manner.

9. In this proceeding we are proposing to simplify the basic licensing structure of the Amateur Service by discontinuing the issuance of all amateur station licenses, other than primary station licenses and space station licenses. (Space stations are under consideration in Docket 19852, Notice of Inquiry adopted October 25, 1973, and we are not proposing their deletion.) All amateur radio operators would be limited to one station license. Specifically, we propose to delete from Part 97 of the Rules military recreation stations, club stations, RACES stations (but not RACES itself), and all additional stations, including secondary stations and special event stations. (As we indicated above, we have already proposed in Docket 21033 to eliminate repeater, auxiliary link, and control stations.) Licensees holding the types of station licenses listed above would be permitted to retain them until expiration of the licenses but would not be permitted to renew them.

10. We recognize that the proposals contained in the preceding paragraph would, if adopted, have an impact on certain groups and individuals. We believe, however, that any such impact would be relatively minor and that the Commission and its licensees would realize significant benefits in the long run from the deletion of the station types in question, including the more efficient issuance of operator and primary station licenses. With respect to the specific station types we are proposing to eliminate and the probable effects of their elimination, we would make the following observations:

a. *Repeater stations, auxiliary link stations, and control stations.* Our proposals concerning these stations are fully explained in our Notice of Inquiry and Notice of Proposed Rule Making in Docket 21033, FCC 76-1198, 42 FR 2089 (1977). Basically, the functions now conducted by such stations would be permitted all remaining amateur stations without separate Commission authorization. No one would appear to be adversely affected by adoption of this proposal.

b. *Military recreation stations.* At the end of 1976 there were only 425 licensed military recreation stations, which are amateur stations licensed to the person-in-charge, often a non-amateur, of a land location at which an amateur station has been provided for the use of operators under the auspices of the United States armed forces. We are aware of no need for continuing the separate licensing of such stations. Those amateur operators wishing to operate such stations may do so by operating portable under their own individual station authorizations. (We note that one possible disadvantage to portable operation, the requirement that transmissions form stations in portable operation be distinctively identified, was eliminated by the Commission's Report and Order in Docket 20686, 61 F.C.C. 2d 337 (1976).

c. *Club stations.* There are presently 4,500 licensed club stations. Although the elimination of separate club station licenses would have an impact on certain amateur operating programs and traditions, we believe separate licensing of such stations, which may be held by a club comprised of as few as two persons, to be non-essential. Operations now conducted by club stations may be conducted either by club members operating their stations portable or by club members acting as control operators of another club member's station. We are, however, particularly interested in receiving comments concerning the continued usefulness to the amateur community of separately licensing club stations.

d. *Secondary stations.* A secondary station is a separate station licensed to an individual amateur operator for a location other than the primary station location. Typically, such stations have been licensed for vacation homes or offices. We believe there to be no need to continue to issue authorizations for secondary stations, because, as we noted in paragraph 10(b), supra, amateurs may, under the rule amendments adopted in Docket 20686, operate their primary sta-

tions at portable and mobile locations without the previous inconvenience of distinctively identifying their transmissions or providing the Commission with advance notification of extended portable or mobile operation. Further, since the suspension of all licensing fees by the Commission, effective January 1, 1977, we have been receiving multiple—and in many instances, frivolous—applications for secondary station licenses from individual amateurs. The applications for secondary station licenses we have received since January 1, 1977 are already beginning to burden our processing staff, and we anticipate a flood of new secondary station license applications as soon as this Notice of Proposed Rule Making is released to the public. For this reason, and to enable the continued efficient processing of other amateur radio license applications, we are hereby declaring, effective with the release of the News Release announcing adoption of this document, a "closed season" on the filing of applications for new secondary stations or special event stations (see below). All applications for new secondary stations or special event stations received on or after the effective date of the closed season will be returned. Applications for renewal or modification of existing secondary station licenses will continue to be accepted, however. The closed season on filing applications for special event and new secondary station licenses will continue until Commission policy in this area is determined.

e. *Special event stations.* Special event stations are licensed for temporary use in connection with the celebration of an event of either general interest to the public or of particular interest to amateur radio operators, and are intended to bring favorable public attention to the Amateur Radio Service. In 1976 approximately 100 special event stations were licensed. Special event stations are assigned distinctive, unusual call signs, and it frequently appears that such stations are used not so much to celebrate special events as to enable amateur operation with "exotic" call signs. We solicit comments concerning the continued usefulness, if any, of special event stations and wish to be provided with specific, concrete examples of special event stations that have brought favorable public attention to the Amateur Radio Service. For reasons outlined above, we are including special event stations in the closed season on the submission of station license applications.

f. *RACES stations.* Radio Amateur Civil Emergency Service stations are stations licensed to civil defense organizations to provide the facilities for amateur radio operators to conduct communications in RACES. Such stations are assigned distinctive call signs prefixed by the letters "WC". Such stations must in all instances be operated by licensed amateur radio operators, and for this reason we believe such operation can be conducted by amateur operators under their individual station licenses. Functions now conducted by RACES stations and amateur stations participating in RACES would be combined in a form of amateur operation known as "RACES operation". Under this proposal, there would be no change in the basis and purpose of RACES itself, and we believe RACES operations would not be seriously affected if our proposal is ultimately adopted. We do wish to receive comments addressing the utility of separately licensed RACES stations, however.

Deletion of the types of amateur stations listed above would have the added advantage of enabling us to delete the FCC Form 610–B, Application for Amateur Club, Military Recreation, or Radio Amateur Civil Emergency Service Station license.

11. We are also proposing in this proceeding to simplify drastically the system of amateur radio call sign assignment. Under Section 2.302 of the Rules, the Amateur Radio Service is allocated certain blocks of call signs. Sections 97.51 and 97.53 of the Rules contain rather complex regulations and policies governing amateur radio call sign assignment. Certain licensees are eligible for "1x2" call signs (call signs consisting of one letter, one digit, and two letters), others are eligible for certain nonspecific "preferred" call signs, while still others must take the call signs assigned them by the Commission. We believe there to be no compelling need to continue the complex system of call sign assignment that now exists, a system which, as we indicated heretofore, occupies an inordinate amount of our staff's time, and we are proposing, accordingly, to amend Section 97.51 of the Rules to state simply that amateur radio call signs will be assigned on a systematic basis. Section 97.53 of the Rules would be deleted entirely. Licensees holding Amateur Extra Class operator licenses would be afforded the opportunity to obtain 1x2 and 2x2 call signs, but such call signs would be assigned systematically by the Commission (Amateur Extra Class licensees would not be permitted, as they are now, to obtain specific 1x2 call signs of their choice.) Licensees moving from one call sign area to another and modifying their licenses to reflect the moves would not continue to be assigned new call signs of the same format as the call signs relinquished. Nor would we continue to issue specific call signs to former holders thereof. We would not issue any more distinctive call signs to stations in repeater or RACES operation.[2] Our proposal, if adopted, would result in a much simplier and fairer call sign assignment system and would permit us to concentrate our limited resources in areas more productive for the Amateur Radio Service.

12. The specific rule amendments we are proposing are set forth below. Authority for these proposals and for the "closed season" announced herein is contained in Sections 4(i), 5(e), and 303 of the Communications Act of 1934, as amended. We invite interested parties to submit comments concerning our proposals on or before June 2, 1977 and reply comments on or before June 30, 1977. An original and five copies of all comments and reply comments shall be furnished the Commission, pursuant to Section 1.419 of the Rules. Respondents wishing each Commissioner to have a personal copy of the comments may submit an additional six copies. Members of the public wishing to express interest in our proposals but unable to provide the required copies may participate informally by submitting one copy of their comments, without regard to form, provided the correct Docket number is specified in the heading of the comments. All comments and reply comments filed in this proceeding should be sent to the Secretary, Federal Communications Commission, Washington, D.C. 20554.

13. Individuals wishing to inspect the comments and reply comments filed in this proceeding may do so during regular business hours, 8:00 a.m. to 4:30 p.m., Monday through Friday, in the Commission's Public Reference Room, 1919 "M" Street, N.W., Washington, D.C. 20554.

FEDERAL COMMUNICATIONS COMMISSION,
VINCENT J. MULLINS,
Secretary.

Parts 1 and 97 of Chapter I of Title 47 of the Code of Federal Regulations are proposed to be amended, as follows:

§ 1.922 [Amended]

1. In § 1.922, FCC Form 610–B is deleted.

2. In § 1.926, paragraph (b)(4) is deleted and designated [Reserved], and paragraph (b)(1) is amended, as follows:

§ 1.926 Application for renewal of license.

* * * * *

(b)(1) Applications for renewal of an amateur operator license, an amateur station license, or a combined amateur operator/station license, shall be filed on FCC Form 610.

* * * * *

(4) [Reserved].

* * * * *

3. Section 1.951(a) is amended to read as follows:

§ 1.951 How applications are distributed.

(a) Personal Radio Division: Amateur, Disaster, and Personal

* * * * *

4. Section 1.952 is amended to read, as follows:

§ 1.952 How file numbers are assigned.

* * * * *

(b) File number symbols and service or class of station designators:

AMATEUR AND DISASTER SERVICES

Y—Amateur
D—Disaster

* * * * *

[2] We are aware that in Docket 21033 we proposed to continue in certain instances to issue distinctive call signs to stations in repeater operation and that our proposal in this proceeding to eliminate such call signs entirely is, to that extent, inconsistent.

5. Section 1.1115 is amended to read, as follows:

§ 1.1115 Schedule of fees for the Safety and Special Radio Services.

(a) * * *

Amateur Service:	
Modification of license without renewal	$3

(c) * * *

(6) Application for Interim Amateur Permits or Novice Class licenses in the Amateur Radio Service.

6. In § 97.3, paragraphs (f), (g), (h), and (i) are deleted, paragraphs (j) through (y), inclusive, are redesignated paragraphs (f) through (u), respectively, and paragraphs (c) and (d) are amended to read, as follows:

§ 97.3 Definitions.

(c) *Amateur radio operator.* A person holding a valid license to operate an amateur radio station issued by the Federal Communications Commission.

(d) *Amateur radio license.* The instrument of authorization issued by the Federal Communications Commission consisting of a station license and an operator license.

Operator license. The instrument of authorization including the class of operator privileges.

Station license. The instrument of authorization for a radio station in the Amateur Radio Service.

Interim Amateur Permit. A temporary operator and station authorization issued to licensees successfully completing Commission supervised examinations for higher class operator licenses.

7. In § 97.37, the headnote and text are amended to read, as follows:

§ 97.37 Eligibility for station license.

(a) An amateur radio station license shall be issued only to a licensed amateur radio operator.

(b) An amateur radio station license shall not be issued to a school, club, company, corporation, association, or other organization.

(c) An amateur radio operator shall be issued no more than one amateur radio station license. (This paragraph does not apply to an amateur radio operator applying for a space radio station license.)

§ 97.39 [Deleted]

8. Section 97.39 is deleted.

9. Section 97.40 is deleted and redesignated § 97.39, paragraphs (c), (d), and (e) are deleted, and paragraph (b) is amended to read, as follows:

§ 97.39 Station license required.

(b) Every amateur radio operator shall have an amateur radio station license.

(c)–(e) [Deleted]

10. In § 97.41, paragraphs (b), (c), and (d) are deleted, paragraphs (e), (f), and (g) are redesignated paragraphs (b), (c), and (d), respectively, and paragraphs (a) and (b) are amended, as follows:

§ 97.41 Application for station license.

(a) Each application for an amateur radio station license shall be made on FCC Form 610.

(b) If the application is for a station license, only, it shall be submitted to the Federal Communications Commission, Box 1020, Gettysburg, Pennsylvania, 17325.

11. Section 97.47 is revised to read, as follows:

§ 97.47 Renewal and/or modification of amateur station license.

(a) Application for renewal and/or modification of a station license shall be submitted on FCC Form 610. In every case the application shall be accompanied by the applicant's license or a photocopy thereof. Applications for renewal of unexpired licenses must be made during the license term and should be filed not later than 90 days prior to the end of the license term. In any case in which the licensee has, in accordance with the provisions of this chapter, made timely and sufficient application for renewal of an unexpired license, no license with reference to any activity of a continuing nature shall expire until such application shall have been finally determined.

(b) If a license is allowed to expire, application for renewal may be made during a period of grace of one year after the expiration date of the license. During this one year period, a license is not valid. A license renewed during this one year period will be dated currently and will not be backdated to the date of expiration.

(c) When the name of a licensee is changed, or when the mailing address is changed (without changing the authorized location of the amateur radio station) a formal application for modification of license is not required. The licensee shall notify the Commission promptly of these changes, however. The notice, which may be in letter form, shall contain the name and address of the licensee as they appear in Commission records, the new name and/or address, as the case may be, and the call sign and class of operator license. The notice shall be sent to the Commission, Gettysburg, Pennsylvania 17325, and a copy shall be maintained with the license of each station until a new license is issued.

12. In § 97.51, paragraph (a) is amended, paragraph (b) is redesignated paragraph (d), and new paragraphs (b) and (c) are added, as follows:

§ 97.51 Assignment of call signs.

(a) The call sign of an amateur radio station shall be assigned by the Commission on a systematic basis.

(b) An Amateur Extra Class operator may obtain on request, subject to availability, a station call sign consisting of one letter followed by one digit followed by two letters, or a call sign consisting of two letters followed by one digit followed by two letters. Call signs assigned under this paragraph shall be assigned by the Commission on a systematic basis. No request for a specific call sign or call sign format shall be granted.

(c) No request for a specific call sign or call sign format shall be granted.

(d) * * *

§ 97.53 [Deleted]

13. Section 97.53 is deleted.

14. Section 97.87(b) is amended to read, as follows:

§ 97.87 Station identification.

(b) If the control operator of a station is not the station licensee, the station identification required by this section shall be the call sign assigned that station. If a station is operated on frequencies authorized by § 97.7 for use by the control operator but not authorized for use by the station licensee, the required station identification shall be the call sign of that station followed by the station call sign of the control operator (e.g. WB6XYZ/W6XY).

15. Section 97.95 (a)(1) and (a)(2) are amended to read as follows:

§ 97.95 Operation away from the authorized fixed operation station location.

(a) * * *

(1) When there is no change in the authorized fixed operation station location, an amateur radio station may be operated under its station license anywhere in the United States, its territories or possessions, as a portable or mobile operation, subject to § 97.61.

(2) When the authorized permanent station location is changed, formal application (FCC Form 610) must be submitted to the Commission prior to any operation and within 4 months of the move for the purpose of modifying the station license to show the new permanent station location. Operation at the new location is permitted under the license for the former station from the date the modification application is mailed until the applicant is advised of Commission action on that application.

16. Section 97.103(b)(1) is amended to read as follows:

§ 97.103 Station log requirements.

(b) * * *

(1) The date and time periods the duty control operator for the station was other than the station licensee, and the signature and station call sign of that duty control operator.

17. Section 97.112(b) is amended, as follows:

§ 97.112 No remuneration for use of station.

* * * * *

(b) Control operators of an amateur station may be compensated when the station is operated primarily for the purpose of conducting amateur radiocommunication to provide telegraphy practice transmissions for persons learning or improving proficiency in the international Morse code, or to disseminate information bulletins consisting solely of subject matter of direct interest to amateur radio operators, provided:

* * * * *

18. Section 97.163(b) is amended to read, as follows:

§ 97.163 Definitions.

* * * * *

(b) *RACES operation.* Amateur radiocommunication conducted by amateur radio stations in the Radio Amateur Civil Emergency Service.

19. Section 97.165 is amended to read, as follows:

§ 97.165 Applicability of rules.

In all cases not specifically covered by this Subpart, amateur radio stations engaging in RACES operation shall be governed by the provisions of the rules governing amateur radio stations and operators (Subparts A through E of this Part).

20. Section 97.169 is amended to read, as follows:

§ 97.169 Station license required.

No station shall engage in RACES operation unless the station is an amateur radio station licensed by the Federal Communications Commission and is certified by a responsible civil defense organization as being registered with that organization.

§ 97.171 [Deleted]

21. Section 97.171 is deleted.

§ 97.173 [Deleted]

22. Section 97.173 is deleted.

§ 97.175 [Deleted]

23. Section 97.175 is deleted.

24. Section 97.177 is amended to read, as follows:

§ 97.177 Operator requirements.

No person shall be the control operator of an amateur radio station engaging in RACES operation unless that person holds a valid amateur radio operator license issued by the Federal Communications Commission and is certified by a responsible civil defense organization as being registered with that organization.

25. Section 97.181 is deleted and a new § 97.181 added, as follows:

§ 97.181 Station identification.

In addition to the station identification requirements of § 97.87, each amateur radio station engaging in RACES operation shall transmit the following additional information: When identifying by radiotelephony, a station in RACES operation shall transmit the word "RACES" at the end of the station call sign. When identifying by radiotelegraphy, a station in RACES operation shall transmit the fraction bar DN followed by the letters "C" or "CD" at the end of the station call sign.

26. § 97.185(b) is amended to read, as follows:

§ 97.185 Frequencies available.

(b) In the event of any emergency which necessitates the invoking of the President's War Emergency Powers under the provisions of Section 606 of the Communications Act of 1934, as amended, unless modified or otherwise directed, amateur radio stations engaging in RACES operation will be limited in operation to the following frequencies: * * *

* * * * *

27. Section 97.189 is amended to read, as follows:

§ 97.189 Points of communication.

Amateur radio stations engaging in RACES operation may be used only to communicate with the following, upon authorization of the responsible civil defense official for the organization in which the amateur radio station is registered:

(a) Amateur radio stations registered with the same or another civil defense organization;

(b) Stations in the Disaster Communications Service;

(c) Stations of the United States government authorized by a responsible agency to exchange communications with stations engaging in RACES operation; and

(d) Any other station in any other service regulated by the Federal Communications Commission, whenever such station is authorized by the Commission to exchange communications with stations engaging in RACES operation.

28. In § 97.193, the headnote is revised and the text amended, as follows:

§ 97.193 Limitations on the use of stations operating in RACES.

All messages which are transmitted in connection with drills or tests in RACES shall be clearly identified as such by the use of the words "drill" or "test", as appropriate, in the body of the messages.

[FR Doc.77-8480 Filed 3-21-77;8:45 am]

[47 CFR Part 15]

[Docket No. 20990; IKM-1617, etc.]

RADIO FREQUENCY DEVICES

Remote Control and Security Devices; Further Order Extending Time for Filing Comments and Reply Comments

Adopted: March 14, 1977.

Released: March 15, 1977.

AGENCY: Federal Communications Commission.

ACTION: Extension of time.

SUMMARY: An extension of time to file comments and reply comments has been requested in Docket No. 20990. Because of the importance of this proceeding to both the manufacturers and consumers, the Commission is granting the request. No objections have been received.

DATES: Comments must be received by June 28, 1977, and Reply comments must be received on or before July 28, 1977.

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

FOR FURTHER INFORMATION CONTACT:

Leslie A. Wall, RF Devices & Experimental Branch, Office of Chief Engineer, Federal Communications Commission, Washington, D.C. 20554 (202-632-7095).

In the matter of amendment of Part 15 of FCC Rules to provide for remote control and security devices (Docket No. 20990, RM-1617, RM-2125, RM-2223).

1. The Door Operator and Remote Controls Manufacturers Association, The Security Equipment Industry Association and the Alliance Manufacturing Co., Inc. have requested a second extension of time within which comments and reply comments in the above captioned proceeding (41 FR 56677, Wednesday, Dec. 28, 1977) might be filed.

2. Because of the importance of this proceeding to both manufacturers and consumers; and because of the Commission's desire to have the most definitive responses possible, an extension of time to June 28, 1977, for filing of Comments and July 28, 1977, for the filing of Reply Comments IS ORDERED pursuant to Section 0.241(d) of the Commission's Rules.

RAYMOND E. SPENCE,
Chief Engineer.

[FR Doc.77-8481 Filed 3-21-77;8:45 am]

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ENVIRONMENTAL PROTECTION AGENCY

[FRL 702-4]

ENVIRONMENTAL IMPACT STATEMENTS

Availability of Comments and Other Actions Impacting the Environment

Pursuant to the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969, and section 309 of the Clean Air Act, as amended, the Environmental Protection Agency (EPA) has reviewed and commented in writing on Federal agency actions impacting the environment contained in the following appendices during the period of January 1, 1977 and January 31, 1977.

Appendix I contains a listing of draft environmental impact statements reviewed and commented upon in writing during this review period. The list includes the Federal agency responsible for the statement, the number and title of the statement, the classification of the nature of EPA's comments as defined in Appendix II, and the EPA source for copies of the comments as set forth in Appendix VI.

Appendix II contains the definitions of the classifications of EPA's comments on the draft environmental impact statements as set forth in Appendix I.

Appendix III contains a listing of final environmental impact statements reviewed and commented upon in writing during this review period. The listing includes the Federal agency responsible for the statement, the number and title of the statement, a summary of the nature of EPA's comments, and the EPA source for copies of the comments as set forth in Appendix VI.

Appendix IV contains a listing of final environmental impact statements reviewed but not commented upon by EPA during this review period. The listing includes the Federal agency responsible for the statement, the number and title of the statement, and the source of the EPA review as set forth in Appendix VI.

Appendix V contains a listing of proposed Federal agency regulations, legislation proposed by Federal agencies, and any other proposed actions reviewed and commented upon in writing pursuant to section 309(a) of the Clean Air Act, as amended, during the referenced reviewing period. The listing includes the Federal agency responsible for the proposed action, the title of the action, a summary of the nature of EPA's comments, and the source for copies of the comments as set forth in Appendix VI.

Appendix VI contains a listing of the names and addresses of the sources of EPA reviews and comments listed in Appendices I, III, IV, and V.

Copies of the EPA Manual setting forth the policies and procedures for EPA's review of agency actions may be obtained by writing the Public Information Reference Unit, Environmental Protection Agency, Room 2922, Waterside Mall SW., Washington, D.C. 20460, telephone 202-755-2808. Copies of the draft and final environmental impact statements referenced herein are available from the originating Federal department or agency.

Dated: March 10, 1977.

REBECCA W. HANMER,
Director,
Office of Federal Activities.

APPENDIX I.—*Draft environmental impact statements for which comments were issued between Jan. 1, 1977, and Jan. 31, 1977*

Identifying No.	Title	General nature of comments	Source for copies of comments
	CORPS OF ENGINEERS		
DS-COE-A32099-MN	South Fork Zumbro River Watershed, Olmstead County, Minn.	ER-2	F
DS-COE-A35118-MN	Duluth-Superior Harbor, operation and maintenance, Diked Disposal Facility, Minnesota.	LO-2	F
D-COE-E35030-NC	Bald Head Island Marina, Permit, Construction of Boat Marina and Access Facilities Adjacent Cape Fear River, Brunswick County, N.C.	LO-1	E
D-COE-E35040-NC	North Carolina Phosphate Corp., Dredging Permit, Aurora, Beaufort County, N.C.	EU-2	E
D-COE-E35041-00	Commercial Sand and Gravel Dredging Operations, Ohio River, Mile 438 to Mile 981, Permit Issuance, Kentucky, Ohio, and Illinois.	ER-2	E
D-COE-E35042-NC	Wanchese Harbor Development Project, Enlarging and Deepening Existing Boat Basin, Permit, Brunswick County, N.C.	ER-2	E
D-COE-E35043-TN	Additional Harbor Facilities, Improvement of the Mississippi River, Memphis, Tenn.	ER-2	E
D-COE-F36047-MN	Flood Control, Redwood River, Marshall, Minn.	ER-2	F
D-COE-G35002-OK	Tulsa Urban Renewal River Parks Project, Permit, Tulsa, Okla.	LO-1	G
D-COE-J39004-ND	Pembina River, Clearing and Snagging, North Dakota	ER-2	I
DS-COE-L36028-OR	Chetco River Jetty Extension, Brookings, Oreg.	LO-1	K
	DEPARTMENT OF AGRICULTURE		
D-AFS-D82003-00	Cooperative Gypsy Moth Suppression and Regulatory Program, 1977 Activities.	LO-1	D
D-AFS-E65015-AL	Conecuh National Forest, Unit No. 6, Covington, Escambia, and Coffee Counties, Ala.	LO-1	E
D-AFS-G65019-TX	Sabine Unit Plan, Sabine National Forest, Jasper, Newton Sabine, Shelby, and San Augustine Counties, Tex.	LO-1	G
D-AFS-G65020-NM	Algecide Treatment, Snow and Quemado Lakes, Gila National Forest, N. Mex.	LO-2	G
D-AFS-G65021-OK	Management of Tiak Unit, Ouachita National Forest, McCurtain County, Okla.	LO-1	G
D-AFS-J65054-MT	Mount Hebgen Management Alternatives, Gallatin National Forest, Gallatin County, Mont.	ER-3	I
D-AFS-K61012-CA	Little Kern Land Use Plan, Sequoia National Forest, Tulare County, Calif.	3	J
D-AFS-K61013-CA	Big Sur Coastal Planning Unit, Los Padres National Forest, Calif.	LO-1	J
D-AFS-L61084-ID	Lowell Planning Unit, Clearwater National Forest, Idaho County, Idaho (USDA-FS-R1-DES-ADM-77-3).	LO-2	K
D-REA-F07005-IN	Merom Generating Station, Associated Transmission, Hoosier Energy Division, Ind.	EU-3	F
D-SCS-F36046-MN	South Zumbro Watershed, Dodge and Olmstead Counties, Minn.	ER-2	F
	DEPARTMENT OF COMMERCE		
D-DOC-E69001-TN	Knoxville International Energy Exposition, Energy Expo 82, Knox County, Tenn.	LO-2	E
D-DOC-K69003-CA	Proposed Expo 1981, Los Angeles-Ontario Region of Southern California.	ER-2	J
	DEPARTMENT OF DEFENSE		
D-USA-J10000-UT	Transportation of Chemical Material, Tooele Army Depot, Operation DTS, Dugway Proving Ground, Tooele County, Utah.	LO-1	I
D-USA-J10001-UT	Transportation of Chemical Material, Operation TNS, North-South Tooele Depot, Tooele County, Utah.	LO-1	I

Identifying No.	Title	General nature of comments	Source for copies of comments
	DEPARTMENT OF INTERIOR		
D-BLM-A02109-00	Proposed 1977 Outer Continental Shelf (OCS) Oil and Gas Lease Sale, Gulf of Mexico, OCS Sale No. 47.	ER-2	A
D-BLM-A03067-00	Crude Oil Transportation System, Valdez, Alaska, to Midland, Tex., Sohio Transportation Co.	3	A
D-NPS-H61003-MO	Wilsons Creek National Battlefield, Greene and Christian Counties, Mo. (DES-76-48).	LO-1	H
	DEPARTMENT OF TRANSPORTATION		
RD-DOT-A52102-00	Average Fuel Economy Standard, Nonpassenger Automobiles, Model Year 1979.	LO-1	A
D-FHW-B40020-MA	MA-2, Greenfield, Gill, Erving, Wendell, Orange, and Franklin County, Mass. (MA-EIS-76-01-D).	ER-2	B
D-FHW-C40027-00	Southern Tier Expressway, Hinsdale, New York to Erie, Pa....	ER-2	C
DS-FHW-D40008-MD	City Boulevard from Eutaw St. to Russell St., Baltimore City, Md.	ER-2	D
DS-FHW-D40009-MD	I-395, Ostend to Russell and Conway St., City Boulevard Ring, Baltimore, Md.	ER-2	D
D-FHW-E40052-FL	Southeastern Extension of FL-9-A, Duval County, Fla. (FHWA-FLA-EIS-76-09-D).	ER-2	E
D-FHW-E40005-GA	I-175 Albany to I-75 South of Cordele Connector, Dougherty, Lee, Worth, and Crisp Counties, Ga.	ER-2	E
D-FHW-F40080-OH	OH-315, Ackerman Rd. to I-270, Franklin County, Ohio.....	ER-2	F
D-FHW-F40082-IL	IL-662, Sangamon County, Ill.....	ER-2	F
D-FHW-F40063-MO	U.S. 54, South of Mexico to East of Mexico, Mo. (FHWA-MO-EIS-76-1-D).	3	H
D-FHW-H40064-KS	Haskell Loop, Sixth and Massachusetts to Eleventh and Haskell, Lawrence, Douglas County, Kans. (FHWA-KS-EIS-76-06-D).	ER-2	H
D-FHW-J40029-ND	U.S. 2, Minot East to Surrey, Ward County, N. Dak.....	LO-2	1
D-UMT-B54001-MA	Red Line Extension, Harvard Square to Arlington Heights, Boston, Suffolk County, Mass.	LO-2	B
	ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION		
D-ERD-A00124-OH	Portsmouth Gaseous Diffusion Plant Expansion, Piketon, Pike County, Ohio.	ER-2	A
	FEDERAL POWER COMMISSION		
D-FPC-C09002-NJ	West Deptford LNG Project, Tenneco LNG Co., Gloucester County, N.J. (Docket CP-7616NJ).	EU-2	C
	GENERAL SERVICES ADMINISTRATION		
D-GSA-B80004-MA	John F. Kennedy Library, Boston, Suffolk County, Mass. (EMA 77001).	ER-2	B
D-GSA-H81003-NB	Meat and Poultry Inspection, Midwestern Multidisciplinary Laboratory, Lincoln, Lancaster County, Nebr.	LO-2	H
	DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT		
D-HUD-D85010-VA	Downtown West Conservation Project, Norfolk, Va. (CDBG)..	ER-2	D
D-HUD-E28017-AL	Castleberry Water System Improvements, Connecuh County, Ala.	LO-1	E
D-HUD-E28019-TN	Town of Wartrace, Bedford County, Tenn.....	LO-2	E
D-HUD-E85016-TN	Belinda City Subdivision Development, Wilson County, Tenn. (HUD-R04-EIS-76-20D).	LO-2	E
D-HUD-G85019-TX	Travis County Subdivision Development, Travis County, Tex..	ER-2	G
D-HUD-G85020-TX	Proposed First Colony Subdivision, Sugar Land, Fort Bend County, Tex.	LO-1	G
D-HUD-G89001-TX	Code Enforcement and Demolition of Unsafe Structures, Dallas County, Tex.	LO-1	G
	NUCLEAR REGULATORY COMMISSION		
DS-NRC-C06004-NY	Atlantic Generating Station, Units 1 and 2, Docket Nos. STN 50-478, Ocean and Atlantic Counties, N.J.	ER-2	C

APPENDIX II

DEFINITIONS OF CODES FOR THE GENERAL NATURE OF EPA COMMENTS

Environmental Impact of the Action

LO—Lack of Objection. EPA has no objections to the proposed action as described in the draft impact statement; or suggests only minor changes in the proposed action.

ER—Environmental Reservations. EPA has reservations concerning the environmental effects of certain aspects of the proposed action. EPA believes that further study of suggested alternatives or modifications is required and has asked the originating Federal agency to reassess these impacts.

EU—Environmentally Unsatisfactory. EPA believes that the proposed action is unsatisfactory because of its potentially harmful effect on the environment. Furthermore, the Agency believes that the potential safeguards which might be utilized may not adequately protect the environment from hazards arising from this action. The Agency recommends that alternatives to the action be analyzed further (including the possibility of no action at all).

Adequacy of the Impact Statement

Category 1—Adequate. The draft impact statement adequately sets forth the environmental impact of the proposed project or

action as well as alternatives reasonably available to the project or action.

Category 2—Insufficient Information. EPA believes that the draft impact statement does not contain sufficient information to assess fully the environmental impact of the proposed project or action. However, from the information submitted, the Agency is able to make a preliminary determination of the impact on the environment. EPA has requested that the originator provide the information that was not included in the draft statement.

Category 3—Inadequate. EPA believes that the draft impact statement does not adequately assess the environmental impact of the proposed project or action, or that the statement inadequately analyzes reasonable available alternatives. The Agency has requested more information and analysis concerning the potential environmental hazards and has asked that substantial revision be made to the impact statement.

APPENDIX III.—*Final environmental impact statements for which comments were issued between Jan. 1, 1977, and Jan. 31, 1977*

Identifying No.	Title	General nature of comments	Source for copies of comments
	CORPS OF ENGINEERS		
F-COE-A32409-00	East Pearl River Project, maintenance dredging, Louisiana and Mississippi.	EPA expressed environmental reservations with this project based on the contaminated nature of the dredged material. EPA expressed the view that the material was not suitable for open water disposal and recommended that it be discharged in a diked upland or beach site above high water.	E
F-COE-A32436-FL	Escambia River, Escambia Bay, maintenance dredging, Escambia and Santa Rosa Counties, Fla.	EPA's concerns were adequately addressed in the final EIS.	E
F-COE-A34112-ID	Lucky Peak Dam and Lake Boise River, Boise County, Idaho.	.....do.....	K
F-COE-A35142-NY	Maintenance of Great South Bay Channel, Patchoque River and Long Island intracoastal waterway, N.Y.	Generally, EPA's concerns were adequately addressed in the final EIS. However, EPA made additional comments with regard to a dredging management plan, shoaling areas and sand-spoil islands.	C
F-COE-D36017-PA	Local Flood Protection Project, Ten Mile Creek, Mariana and Vicinity Flood Prevention, Washington County, Pa.	EPA expressed serious environmental reservations regarding the Army Corps of Engineers' proposal to modify 1.5 miles of stream for the purposes of flood control. Specifically, the principal environmental impacts are the potential for increased flooding downstream of the project limits, the elimination of the stream tree canopy and the disruption of terrestrial, aquatic and benthic habitats.	D
	DEPARTMENT OF DEFENSE		
FS-USA-D81004-VA	Fort Belvoir family housing project, Army Engineer Center and Fort Belvoir, Fort Belvoir, Va.	EPA's concerns were adequately addressed in the final EIS.	D
	DEPARTMENT OF INTERIOR		
F-BIA-G01001-NM	Navajo-Exxon Uranium Development, San Juan County, N. Mex.	The final statement adequately addressed most of EPA's concerns regarding the water and radiation impacts of the project. EPA has requested the BIA provide additional environmental analyses following the initial exploration phase of the development.	G
F-BLM-A02102-AK	Lower Cook Inlet, Proposed 1976 Oil and Gas Lease Sale No. C1, Outer Continental Shelf, OCS, Alaska.	EPA expressed serious environmental reservations regarding the proposal lease sale. EPA's comments noted that the final EIS did not adequately demonstrate that the proposed sale could be implemented without significant risk to the marine ecosystem of lower Cook Inlet. EPA noted that BLM provided inadequate responses to many of the issues which had been raised at the draft EIS stage regarding mitigatory measures and needs for additional information. Specifically, EPA recommended the development of separation sea lanes in Cook Inlet, and the implementation of specific lease stipulations for adequate pipeline corridors, pipeline surveillance, oil detention sensors, and identification and avoidance of environmentally sensitive areas quakes, unstable bottom sediments, tsunamis, volcanism, strong tidal currents, and other severe environmental conditions, the likelihood of catastrophic oil spills must be considered to be high, and that the previously unstressed biotic assemblage of the area would be especially vulnerable to spill damage.	A

Identifying No.	Title	General nature of comments	Source for copies of comments
F-BOR-J61008-CO	Lewis and Clark National Historic Trail, Kansas, Illinois, Missouri, Nebraska, South Dakota, North Dakota, Montana, Idaho, Oregon, and Washington.	EPA's concerns were adequately responded to in the final EIS.	I
F-SFW-A64044-OO	Operation of the National Wildlife Refuge System.	The final EIS adequately responded to EPA's request for additional information on pesticide usage issues raised in the EIS.	A
	DEPARTMENT OF TRANSPORTATION		
F-CGD-A52090-OO	Seadock Deepwater Port License Application, Construction and Operation, 26 miles off Freeport, Tex., Gulf of Mexico.	EPA's review of the final EIS, including the Secretary's decision document, indicated the comments expressed on the draft EIS have been adequately addressed. Additionally, EPA advised the Coast Guard that it is concerned with the hydrocarbon emissions from the secondary development of refineries and Petro chemical industries as a result of the increased availability of crude oil in the Houston-Galveston air quality control region, and that these new or modified sources can only be constructed if they are in compliance with the requirements of the "emission offset" ruling (41 FR 55524, Dec. 21, 1976).	A
F-CGD-A52091-OO	Loop Deepwater Port License Application, Construction and Operation, 18 miles off Grande Isle, La.	EPA's review of the final EIS, including the Secretary's decision document, indicated the comments expressed on the draft EIS have been adequately addressed. Additionally, EPA advised the Coast Guard that it is concerned with the hydrocarbon emissions from secondary development of refineries and petrochemical industries as a result of the increased availability of crude oil, and that these new or modified sources can only be constructed if they are in compliance with the requirement of the "emission offset" ruling (41 FR 55524 Dec. 21, 1976).	A
F-CGD-K81005-CA	Coast Guard Family Housing, Eureka, Humboldt County, Calif.	EPA's concerns were adequately addressed in the final EIS.	J
F-FHW-A42214-WV	I-64, Beckley to Sam Black Church, Raliegh, Summers, and Greenbrier Counties, W. Va.	EPA continues to have environmental reservations on the proposed project, specifically with the number of stream relocations involved. EPA suggested close consultation to develop appropriate mitigating measures during the final design stage of the project.	D
	FEDERAL POWER COMMISSION		
FS-FPC-C03001-NJ	Construction and Operation of an LNG Import Terminal at Raccoon Island, Gloucester County, N.J.	EPA agrees with the conclusion reached in the supplement that the project would present an unacceptable safety risk to the public and that the project should not be approved as proposed.	C
F-FPC-E05004-AL	Holt, Bankhead, and Lewis Smith, Project Nos. 2203 and 2165, Alabama.	Generally, EPA's concerns were adequately addressed in the final EIS. However, EPA believes the turbine aeration devices installed in the draft tubes of Bankhead Project No. 2165 and Holt Project No. 2203 do not adequately protect water quality of assure compliance with the Alabama water quality standards. The installation of a skimming weir would not insure meeting water quality standards at all times but it would improve dissolved oxygen content by as much as 10 to 20 percent and would enable the facility to meet water quality standards during a higher percentage of the time than at present.	E
	GENERAL SERVICES ADMINISTRATION		
F-GSA-J99000-CO	Fuel Conversion, Central Steam Plant, Denver Federal Center, Denver, Colo.	EPA's concerns were adequately responded to in the final EIS.	I
	DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT		
F-HUD-K89016-CA	Mei Lun Yen Development, Chinatown Redevelopment, San Francisco, Calif.	EPA's concerns were adequately addressed in the final EIS.	J

Identifying No.	Title	General nature of comments	Source for copies of comments
	NUCLEAR REGULATORY COMMISSION		
F-NRC-A00115-00	Floating Nuclear Power Plants, site and operation, Docket No. STN 50-437 (NUREG-0056).	EPA indicated that, because certain of EPA's requests made in comments on the draft EIS were not satisfied, the Agency considers the final statement unresponsive. EPA's primary concern was the lack of adequate consideration of inshore siting of floating nuclear power plants (FNP). EPA's opinion is that such sites should not be licensed until a generic study is performed and inshore siting issues are resolved. EPA reiterated its request for an overall generic assessment of the FNP concept, including projections of future plant numbers and cumulative and long-term impacts. In addition, EPA reiterated its request for beginning development of siting criteria: Revisions in the NRC benefit-cost study; and a commitment from NRC to a timely implementation of the recommendations (regarding FNP's) of the nuclear energy center site survey	A
F-NRC-C00005-NY	Indian Point Unit No. 2, Extension of Operating with Once-Through Cooling Consolidated Edison Co. of New York, Inc., Docket No. 50-247.	EPA commented NRC for their responsiveness to EPA's comments on the draft EIS and indicated the proposed extension (beyond May 1, 1979) for operation of the existing once-through cooling system presents no inconsistency between the proposed action (issuance of an amended operating license) and the NPDES permit.	C

APPENDIX IV.—*Final environmental impact statements which were reviewed and not Commented on between Jan. 1, 1977, and Jan. 31, 1977*

Identifying No.	Title	Source of review
	CORPS OF ENGINEERS	
F-COE-A32407-VA	Captains Cove Development, Accomack County, Va	D
F-COE-E36026-KY	Kentucky River Basin Small Flood Control Project, Nicholasville, Ky	E
F-COE-G34016-TX	Operation and Maintenance of Whitney, Waco, Proctor, Stillhouse Hollow, and Somerville Lakes, Tex.	G
F-COE-L39005-AK	Metlakatla Small Boat Harbor Project No. 2, Metlakatla, Alaska	K
F-COE-L39042-OR	Dredging of Oregon Slouth, North Portland Harbor, Oreg	K
	DEPARTMENT OF AGRICULTURE	
F-AFS-B61006-00	Evans Notch Unit Plan, White Mountain National Forest, New Hampshire and Maine.	B
F-AFS-E65013-AL	Timber Management Plan, William B. Bankhead National Forest, Winston, Lawrence, and Franklin Counties, Ala (USDA-FS-R8-FES-ADM-76-23).	E
F-AFS-G65015-NM	Geothermal Leasing, Santa Fe National Forest, Rio Arriba County, N. Mex	G
F-AFS-J61010-00	Fire Management, Selway-Bitterroot Wilderness, Bitterroot, Clearwater, Lolo, and Nezperce National Forests, Montana and Idaho.	I
F-AFS-L61007-OR	Oregon Dunes National Recreation Area Management Plan, Siuslaw National Forest, Oreg. (USDA-FS-R6-FES-ADM-75-01).	K
F-AFS-L64003-AK	Burnett Nonprofit Fish Hatchery, Tongass National Forest, Alaska (USDA-FS-R20-FES-76-06).	K
F-REA-J09000-CO	Combustion Turbine Package Power Plants, Peaking Service, Burlington Generating Station, Denver, Colo.	I
F-SCS-G36050-LA	Central Madison Watershed, Madison Parish, La	G
F-SCS-H30024-IA	Little Sioux River Watershed Flood Prevention, Buena Vista County, Iowa	H
	DEPARTMENT OF COMMERCE	
F-NOA-L00002-00	Troll Salmon Fishery of the Pacific Coast, Preliminary Management Plan	K
F-NOA-L00003-00	Sablefish of the Bering Sea and Northeastern Pacific Ocean, Preliminary Management Plan.	K
F-NOA-L00004-00	Trawl Fishery of the Washington, Oregon, and California Region, Preliminary Management Plan.	K
	DEPARTMENT OF INTERIOR	
F-BOR-B39004-ME	Penobscott Proposed Wild and Scenic River, Somerset, Piscataquis, and Penobscott Counties, Maine (FES-76-63).	B
F-IBR-L36034-WA	Proposed Oroville-Tonasket Unit Extension, Chief Joseph Dam, Okanogan-Similkameen Division, Wash. (FES-76-63).	K
F-IBM-A67012-00	Surface Subsidence Control in Mining Regions	A
F-NPS-L08022-AK	Electric Distribution Line Extension, Mount McKinley National Park, Alaska (FES-76-6).	K

Identifying No.	Title	Source of review
	DEPARTMENT OF TRANSPORTATION	
RF-FAA-A88009-00	Civil Aircraft Fleet Noise Requirements, Far Part 36, Compliance Regulation (Retrofit).	A
F-FAA-A88011-00	Noise Reduction Stages and Acoustical Change Requirements for Subsonic Transport Category Large Airplanes and Turbojet Powered Airplanes.	A
F-FAA-E51016-MS	C.D. Lemons Field Runway Construction, Tupelo, Lee County, Miss.	E
F-FHW-A41457-IA	North-South Freeway 561, Freeway 520 to IA-396N, Dubuque County, Iowa (FHWA-EIS-72-07-F).	H
F-FHW-A42281-KY	U.S. 45, Paducah Rd., Mayfield, Graves County, Ky.	E
F-FHW-E40618-KY	Fourth and Fifth Sts., Washington and Linden Aves., Newport, Campbell County, Ky. (FHWA-KY-EIS-74-07-F).	E
F-FHW-H40083-IA	IA-415, Polk County, Iowa (FHWA-IA-EIS-76-01-F)	H
	DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT	
F-HUD-E28016-AL	Union Community Water System, Greene County, Ala. (CDBG)	E
F-HUD-E89004-FL	Senior Citizens Center, Bayview Park, Pensacola, Fla. (CDBG)	E
	INTERSTATE COMMERCE COMMISSION	
F-ICC-A53042-00	Investigation of Freight Rates for the Transportation of Recyclable/Recycled Materials.	A
F-ICC-A80095-00	Exparte No. MC-37, Sub No. 28, Commercial Zone and Terminal Areas	A

APPENDIX V.—*Regulations, legislation and other Federal agency actions for which comments were issued between Jan. 1, 1977, and Jan. 31, 1977*

Identifying No.	Title	General nature of comments	Source for copies of comments
	DEPARTMENT OF THE INTERIOR		
A-BOR-A61204-TN	Wild and Scenic River Study for the Buffalo River, Tenn.	EPA recommends BOR supervision of the State/local management of the Buffalo River to insure nondegradation of existing water quality.	A
R-DOI-A01045-00	30 CFR Part 211, 43 CFR Part 3041, Surface Management Coal Mining Operating Regulations.	EPA expressed agreement with the proposed amendments to the regulations.	A
R-DOI-A01046-00	30 CFR Part 211, 43 CFR Part 3041, Surface Management Coal Mining Operating Regulations, Steep Slopes (41 FR 56830).	do	A
A-IGS-A02008-00	Oil and Gas Drilling Operations on the Outer Continental Shelf (OCS), Proposed Standard for Training of Personnel Notice.	EPA expressed no comments on the proposal.	A
R-NPS-A01042-00	36 CFR Part 9, Mining and Mining Claims, Interim Regulations and Proposed Comprehensive Regulations.	EPA expressed general agreement with the proposed regulations, which are designed to control mining activities where such activities would conflict with the purposes of the National Park System. The NPS was provided with EPA's suggestion regarding the definition of the term "significantly disturbed for purposes of mineral extraction."	A
A-SFW-A82006-00	Blackbird and Starling Damage Control, Policy and Guidelines.	EPA's comments expressed concerns regarding the availability of criteria to be used in deciding when PA-14 should be used, and alternatives to the use of PA-14. Their detailed criteria should be developed to ensure that PA-14 is not used indiscriminately. In addition, EPA noted that the fish and wildlife service should followup PA-14 applications with evaluations necessary to ensure that human health requirements are satisfied.	A
	DEPARTMENT OF TRANSPORTATION		
R-DOT-A52102-00	49 CFR Part 533, Nonpassenger Automobiles, Model Year 1979, Average Fuel Economy Standard (Docket No. FE 76-3, Notice 1).	EPA's comments on the draft EIS and proposed rulemaking of the same subject indicated general support for the proposed action. In addition EPA offered suggestions for the improvement of the proposed rule and its support material.	A
R-DOT-A52103-00	49 CFR Part 523, Automotive Fuel Economy, Vehicle Classification (Docket No. FE 76-05, 1).	EPA stated that the comments made during interagency review were adequately presented in the preamble of the NRRM.	A
R-FAA-A52104-00	14 CFR Parts 21, 36, and 91, Agricultural Operation and Fire Fighting Propeller Driven Small Airplanes, Noise Abatement Operating.	EPA commented in support of the proposed regulation.	A
R-FRA-A53041-00	49 CFR Part 228, Construction of Railroad Employee Sleeping Quarters, Proposed Amendment to Hours of Service Regulations (HS-2, No. 2).	EPA asked that its March. 27, 1975, comments to the FRA on the advance notice of proposed rulemaking for the same subject be considered once again. Particularly, EPA disagreed with the use of the department of housing and urban development noise criteria for this subject and recommended that the FRA employ a design noise goal of LEQ 8=45dB.	A

Identifying No.	Title	General nature of comments	Source for copies of comments
NUCLEAR REGULATORY COMMISSION			
R-NRC-A00055-00	10 CFR Part 51, Licensing and Regulatory Policy and Procedures for environmental Protection, Uranium Fuel Cycle Impacts from Spent Fuel.	EPA concluded that the report does not meet its stated purpose to clarify and elaborate upon the environmental impact associated with the management of nuclear fuels and nuclear waste. EPA indicated that there is a need for more substantive information and data to support the impact assessments presented. EPA questioned a number of assumptions, approaches, and analyses including the use of a relative hazard index and certain estimates and models from the reactor safety study (WASH-1400).	A

APPENDIX VI

SOURCE FOR COPIES OF EPA COMMENTS

A. Public Information Reference Unit (PM-213), Environmental Protection Agency, Room 2922, Waterside Mall SW., Washington, D.C. 20460.

B. Director of Public Affairs, Region 1, Environmental Protection Agency, John F. Kennedy Federal Building, Boston, Massachusetts 02203.

C. Director of Public Affairs, Region 2, Environmental Protection Agency, 26 Federal Plaza, New York, New York 10007.

D. Director of Public Affairs, Region 3, Environmental Protection Agency, Curtis Building, 6th and Walnut Streets, Philadelphia, Pennsylvania 19106.

E. Director of Public Affairs, Region 4, Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30308.

F. Director of Public Affairs, Region 5, Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois 60604.

G. Director of Public Affairs, Region 6, Environmental Protection Agency, 1201 Elm Street, Dallas, Texas 75270.

H. Director of Public Affairs, Region 7, Environmental Protection Agency, 1735 Baltimore Street, Kansas City, Missouri 64108.

I. Director of Public Affairs, Region 8, Environmental Protection Agency, 1860 Lincoln Street, Denver, Colorado 80203.

J. Director of Public Affairs, Region 9, Environmental Protection Agency, 100 California Street, San Francisco, California 94111.

K. Director of Public Affairs, Region 10, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101.

[FR Doc.77-8404 Filed 3-21-77;8:45 am]

[FRL 700-1]

ADEQUACY OF SO_2 EMISSION LIMITATIONS AND CONTROL STRATEGY IN KENTUCKY IMPLEMENTATION PLAN

Extension of Comment Period

On May 10, 1976 (41 FR 19105), the Administrator published approval/disapproval action on revisions in the Kentucky State implementation plan. Subsequent to this rulemaking notice the Natural Resources Defense Council (NRDC), under section 307 of the Clean Air Act, petitioned the U.S. Court of Appeals for the Sixth Circuit for review of the Administrator's action. NRDC believed that several of the emission limits were not sufficient to protect ambient air quality standards. On December 14, 1976, both parties agreed that the Agency would solicit and respond to additional comments on the adequacy of the revised emission limits now in effect.

A notice to this effect was published in the FEDERAL REGISTER, Vol. 41, No. 252, December 30, 1976, on page 56885. The reopened comment period was to last until March 1, 1977. NRDC has since requested an additional 30 days in which to prepare comments and submit them to EPA. The purpose of this notice is to provide public notice to the effect that EPA will continue to receive and evaluate comments through March 31, 1977, in accordance with NRDC's request.

As the result of this extension, any other dates mentioned in the December 30, 1976, notice may also be extended. A description of the points at issue and additional background information relating to the Kentucky implementation plan and this review thereof can be found in the FEDERAL REGISTER issue described above.

Comments should be addressed to the Air Programs Branch, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street, NE, Atlanta, Georgia 30308. Attention: Mr. John Eagles (404/881-2864). Comments must be received on or before March 31, 1977, to receive consideration. All pertinent documents will be available to the public at the above address throughout the comment period during normal business hours (8:15 am.-4:45 p.m., Monday-Friday).

Dated: March 7, 1977.

JACK E. RAVAN,
Regional Administrator,
Region IV.

[FR Doc.77-8262 Filed 3-21-77;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

NATIONAL ARBORETUM ADVISORY COUNCIL

Public Meeting

Pursuant to the provisions of the Federal Arvisory Committee Act of October 6, 1972, (Pub. L. 92-463, 86 STAT. 770-776), notice is hereby given that a public meeting of the National Arboretum Advisory Council will be held on April 17-19, 1977, at the U.S. National Arboretum, Washington, D.C. The meeting will convene at 2:30 pm on April 17 and 9:00 am on April 18 and 19. The meeting will be open to the public.

In addition to the regular meeting of the Council there will be a ribbon-cutting for the New York Avenue entrance to the Arboretum and a tree planting ceremony on April 17.

The Council reviews progress relating to the Arboretum's mandate which is research and education concerning trees and plant life. The Council submits its findings and recommendations to the Secretary of Agriculture.

Details of the meeting may be obtained from Dr. Hugo O. Graumann, Executive Secretary, National Arboretum Advisory Council, Agricultural Research Service, U.S. Department of Agriculture, Room 324 Administration Building, Washington, D.C. 20250. The telephone number is Area Code 202, 447-3961.

Any person may file a written statement with the Executive Secretary before or after the meeting.

Done at Washington, D.C. this 17th day of March, 1977.

T. W. EDMINSTER,
Administrator.

[FR Doc.77-8491 Filed 3-21-77;8:45 am]

Forest Service

MALHEUR NATIONAL FOREST GRAZING ADVISORY BOARD

Meeting

The Malheur National Forest Grazing Advisory Board will meet at 1:00 p.m. on May 4, 1977, in the upstairs conference room at the Malheur National Forest Supervisor's Office, 139 N.E. Dayton Street, John Day, Oregon, 97845.

The meeting is the annual meeting of the board. Purpose of this meeting is to elect new officers and review proposed plans for the 1977 grazing season.

The meeting will be open to the general public. Persons interested in presenting a subject at the meeting may file a request and brief before the meeting with:

Robert L. Storch, Secretary Designate, Malheur National Forest Grazing Advisory Board, Malheur National Forest, 139 NE. Dayton Street, John Day, Oregon 97845.

Written statements may be filed with the board before or after the meeting.

Dated: March 14, 1977.

DALE L. ROBINSON,
Acting Forest Supervisor.

[FR Doc.77-8467 Filed 3-21-77; 8:45 am]

Office of the Secretary

COMPREHENSIVE REVIEW OF USDA ADVISORY COMMITTEES

MARCH 17, 1977.

Pursuant to OMB Circular No. A-63, Transmittal Memorandum No. 5, notice is hereby given that the Department of Agriculture is conducting its annual comprehensive review of all USDA advisory committees. This review is required by Pub. L. 92-463, the Federal Advisory Committee Act.

The results of this review will be used as the basis for determining which advisory committees should be continued. The committees being reviewed are:

Agricultural Research Policy Advisory Committee
National Agricultural Research Planning Committee
Advisory Council on Child Nutrition
Committee of Nine
Animal and Plant Health Inspection Service Consumer Advisory Committee
Cooperative Forestry Research Advisory Board
Cooperative Forestry Research Advisory Committee
Advisory Committee on Foreign Animal Diseases
General Conference Committee of the National Poultry Improvement Plan
Advisory Committee on Hog Cholera
National Arboretum Advisory Committee
Advisory Committee on Nutrition Evaluation
Advisory Committee on Meat and Poultry Inspection
Perishable Agricultural Commodity Act—Industry Advisory Committee
Plant Variety Protection Board
National Advisory Committee on Safety in Agriculture
Public Advisory Committee on Soil and Water Conservation
Advisory Committee for the U.S. Meat Animal Research Center
Oregon Dunes National Recreation Area Advisory Council
Pacific Crest National Scenic Trail Advisory Committee
Advisory Committee on State and Private Forestry
Citizens Advisory Committee on Civil Rights
Cattle Industry Advisory Committee
Expert Panel on Nitrites and Nitrosamines
Joint Advisory Committee on Agricultural Statistics
National Plant Genetics Resources Board
National Consumer Advisory Committee
Forest Pest R & D Program Board
Quetico-Superior Committee
Advisory Committee on Poultry Health
Agricultural Technical Advisory Committee for Trade Negotiations on Cotton
Agricultural Technical Advisory Committee for Trade Negotiations on Dairy
Agricultural Technical Advisory Committee for Trade Negotiations on Fruits and Vegetables
Agricultural Technical Advisory Committee for Trade Negotiations on Grain and Feeds
Agricultural Technical Advisory Committee for Trade Negotiations on Livestock and Livestock Products
Agricultural Technical Advisory Committee for Trade Negotiations on Oilseeds and Products
Agricultural Technical Advisory Committee for Trade Negotiations on Poultry and Eggs
Agricultural Technical Advisory Committee for Trade Negotiations on Tobacco
Agricultural Policy Advisory Committee for Trade Negotiations
Advisory Committee on Salmonella
Advisory Committee on Regulatory Programs
Apache National Forest Grazing Advisory Board
Bighorn National Forest Grazing Advisory Board
Boise National Forest Grazing Advisory Board
Advisory Committee to the Forest Service, California Region
Caribou National Forest Grazing Advisory Board
Carrizo Grazing Advisory Board
Cascade Head Scenic-Research Area Advisory Council
Challis National Forest Livestock Advisory Board
Cibola National Forest Grazing Advisory Board
Coconino National Forest Grazing Advisory Board
Condor Advisory Committee
Deschutes National Forest Cattlemen's and Woolgrower's Advisory Board
Distributors Advisory Committee
Flue-Cured Tobacco Advisory Committee
Fremont National Forest Grazing Advisory Board
Gila National Forest Grazing Advisory Board
Gunnison Valley Forest Grazing Advisory Board
Hop Marketing Advisory Board
Humboldt National Forest Grazing Advisory Board
Klamath National Forest Grazing Advisory Board
Lyndon B. Johnson National Grasslands Grazing Advisory Board
Malheur National Forest Grazing Advisory Board
Manti-LaSal National Forest—Manti Division Grazing Advisory Board
Medicine Bow National Forest Grazing Advisory Board
Miguel District Grazing Advisory Board
Modoc National Forest Grazing Advisory Board
Montezuma Section, San Juan Grazing Advisory Board
Nebraska National Forest Grazing Advisory Board
North Kaibab Grazing Advisory Board
Northeastern Forest Research Advisory Committee
Ouray District Grazing Advisory Board
Prescott National Forest Grazing Advisory Board
National Advisory Council on Maternal, Infant, and Fetal Nutrition
Rio Grande National Forest Grazing Advisory Board
Routt National Forest Grazing Advisory Board
Samuel R. McKelvie National Forest Grazing Advisory Board
San Isabel National Forest Grazing Advisory Board
San Juan Section, San Juan Grazing Advisory Board
Santa Fe National Forest Grazing Livestock Advisory Board
Shippers Advisory Committee
Shoshone National Forest Livestock Advisory Board
Sitgreaves National Forest Grazing Advisory Board
South Kaibab Grazing Advisory Board
Spearfish District Grazing Advisory Board
Stanislaus Forest-Wide Livestock Advisory Board
Taos-Penasco-Questa Division Grazing Advisory Board
Timpas Unit Grazing Advisory Board
Tonto National Forest Grazing Advisory Board
Uinta National Forest Grazing Advisory Board
Umatilla National Forest Grazing Advisory Board
Union County Grazing Advisory Board
Wallowa-Whitman National Forest Grazing Advisory Board
Winema National Forest Grazing Advisory Board
Tierra Amarilla Division Grazing Advisory Board
Ochoco National Forest Grazing Advisory Board
Caddo National Grasslands Grazing Advisory Board

Comments on the continuation or termination of any of these advisory committees may be directed to C. R. Hanna, Jr., Assistant Director, Management, Office of Managment and Finance, U.S. Department of Agriculture, Washington, D.C. 20250.

The public is invited to coment on any of the advisory committees of USDA at any time. However, to insure that comments submitted pursuant to this notice are received in time for consideration during this review, all such comments should be submitted no later than April 5, 1977.

All written submissions made pursuant to this notice shall be made available for public inspection at the office of the Assistant Director, Management during regular business hours.

J. PAUL BOLDUC,
Assistant Secretary for Administration.

[FR Doc.77-8495 Filed 3-21-77;8:45 am]

CIVIL AERONAUTICS BOARD

[Docket 29123 Agreement C.A.B. 26487 R-1 through R-11]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Passenger Fares and Currency Matters; Agreement

Issued under delegated authority, March 11, 1977.

An agreement has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations between various air carriers, foreign air carriers, and other carriers embodied in the resolutions of Traffic Conference 2 of the International Air Transport Association (IATA). The agreement was adopted at the Reconvened 7th Meeting of Traffic Conference 2 held in Cannes, France on February 7, 1977.

The agreement, which only affects air transportation indirectly, would establish new fare levels between points within Africa effective April 1, 1977 through March 31, 1978. The agreement also establishes currency-related adjustment factors for fares between points within TC2 (Europe/Africa/Middle East), except wholly within Europe, which are intended to relate local currency selling fares more closely to fluctuating foreign exchange values. We will approve those portions of the agreement governing fares which are combinable with fares to/from United States points and thus have indirect application in air transportation as defined by the Act. Jurisdiction will be disclaimed on the balance of the resolutions which govern noncombinable fares and thus have no application in air transportation.

Pursuant to authority duly delegated by the Board in the Board's Regulations, 14 CFR 385.14:

1. It is not found that the following resolutions, incorporated in the agreement as indicated and which have indirect application in air transportation as defined by the Act, are adverse to the public interest or in violation of the Act:

Agreement CAB	IATA No.	Title	Application
26487:			
R-1	001b	TC2—Special Effectiveness Resolution (Tie-in)	2 (within Africa).
R-2	001LL	Special Escape Resolution Within Africa	2.
R-3	002	Standard Readoption Resolution	2 (within Africa).
R-4	022b	TC2 (Except Within Europe) Adjustment Factors for Sales of Passenger Air Transportation (New).	Do.
R-5	052	TC2 First-Class Fares	Do.
R-6	062	TC2 Economy-Class Frres	Do.

2. It is not found that the following resolutions, incorporated in the agreement as indicated, affect air transportation within the meaning of the Act:

Agreement CAB	IATA No.	Title	Application
26487:			
R-7	072b	TC2 Creative Fares Except Europe (Readopting and Amending).	[1] 2
R-8	073a	TC2 Night Fares Salisbury/Bulawayo-Johannesburg (Readopting and Amending).	2
R-9	076c	Affinity Group Fares Within Africa (Readopting and Amending).	2
R-10	081f	TC2 Group Inclusive Tour Fares—Within Africa (Readopting and Amending).	2
R-11	091g	TC2 Family Fares—Within Africa (Readopting and Amending).	2

[1] Within Africa.

Accordingly, it is ordered, that:

1. Those portions of Agreement C.A.B. 26487 described in finding paragraph 1 above and which have indirect application in air transportation as defined by the Act, be and hereby are approved; and

2. Jurisdiction be and hereby is disclaimed with respect to those portions of Agreement C.A.B. 2647 described in finding paragraph 2 above.

Persons entitled to petition the Board for review of this order pursuant to the Board's Regulations, 14 CFR 385.50, may file such petitions within ten days after the date of service of this order.

This order shall be effective and become the action of the Civil Aeronautics Board upon expiration of the above period, unless within such a period a petition for review thereof is filed or the Board gives notice that it will review this order on its own motion.

This order will be published in the FEDERAL REGISTER.

JAMES L. DEEGAN,
Chief, Passenger and Cargo Rates Division, Bureau of Economics.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.77-8398 Filed 3-21-77;8:45 am]

[Docket 29001; Order 77-3-97]

SOUTHERN AIRWAYS, INC., AND TRANS WORLD AIRLINES INC.

Order Denying Request for Waiver of Environmental Regulations

On December 23, 1976, Trans World Airlines filed a request for a waiver from compliance with ordering paragraph 9 of Order 76-12-1 and, thereby, a waiver from Part 312 of the Board's Procedural Regulations requiring the filing of environmental evaluations. TWA claims that it is not an applicant for authority in this proceeding [1] and, at most, will only be transferring unused authority to another carrier. Thus, argues TWA, requiring it to file an environmental evaluation is unnecessary since there would, *ipso facto*, be no major Federal action.

Upon consideration of TWA's request and all relevant considerations, we have decided to deny the application for waiver. In accordance with Part 312 of the Board's Procedural Regulations, especially the applicable portions of section 312.9, the Board, in Order 76-12-1, determined that an environmental evaluation by all applicants was necessary for proper consideration of environmental factors in this case. In its request, TWA has shown no good cause for reversing that determination.

Accordingly it is ordered, That:

Trans World Airline's request for waiver of the Board's regulations be and it hereby is denied.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.77-8487 Filed 3-21-77;8:45 am]

[1] TWA and Southern Airways have applied for approval of an agreement, which if approved, would transfer, for monetary consideration, certain operating authority now held by TWA to Southern.

DELETION OF ITEM FROM MEETING AGENDA

Revised Agenda

TIME AND DATE: 10:00 A.M.—March 17, 1977.

PLACE: Room 1027, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT: 1. Docket 29712, Air California and Docket 29831, Pacific American Airlines, Inc.—applications for disclaimer of jurisdiction or exemption to perform certain interstate contract flights.

STATUS: Open.

PERSON TO CONTACT:
Phyllis T. Kaylor, the Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: In order to meet the deadlines for the preparation of legislative testimony dealing with matters of regulatory reform, the scheduled meeting must be limited to one item. Accordingly, the discussion of Docket 30314, SPDR-53, Part 370 will be deleted from the agenda of the March 17, 1977 meeting and will be rescheduled for discussion at an open meeting to be held on March 24, 1977.

Accordingly, the following Board Members have voted that agency business requires the deletion of Item One, Docket 30314, SPDR-53 Part 370—Employee Responsibilities and Conduct from the meeting scheduled for March 17, 1977 and that no earlier announcement of the change was possible:

Chairman John E. Robson, Vice Chairman Richard J. O'Melia, Member Lee R. West, and Member R. Tenney Johnson.

Member G. Joseph Minetti did not participate.

[FR Doc.77-8484 Filed 3-24-77;8:45 am]

MEETING

The CAB will meet:

TIME AND DATE: 10:00 A.M.—March 23, 1977.

PLACE: Room 1027, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT: Oral Argument, Docket 22162, Sullivan County Case.

STATUS: Open.

PERSON TO CONTACT:
Phyllis T. Kaylor, The Secretary, (202) 673-5068.

[FR Doc.77-8486 Filed 3-21-77;8:45 am]

MEETING

The CAB will meet:

TIME AND DATE: 3:00 P.M.—March 18, 1977.

PLACE: Room 1011, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT: Briefing by Ambassador Boyd on U.S.-U.K., Talks Held in London, February 28-March 11, 1977.

STATUS: Closed.

PERSON TO CONTACT:
Phyllis T. Kaylor, The Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: Ambassador Boyd has only recently returned to this country and is able to brief the Board on March 18, 1977. The follow-

ing Members have voted that agency business requires that the Board be briefed at the earliest possible time and that no earlier notice of the meeting was possible:

Chairman John E. Robson, Vice Chairman Richard J. O'Melia, Member G. Joseph Minetti, Member Lee R. West, and Member R. Tenney Johnson.

Additionally, the following Members have voted that the meeting will be closed to public observation under 5 U.S.C. 552b(c)(9)(B) and 14 CFR 310b.5(9)(B):

Chairman John E. Robson, Vice Chairman Richard J. O'Melia, Member G. Joseph Minetti, Member Lee R. West, and Member R. Tenney Johnson.

EXPLANATION OF THE CLOSING

This meeting will concern the on-going U.S.-U.K. negotiations and the position to be taken by the United States during these negotiations. Public disclosure, particularly to foreign governments, of opinions, evaluations, and strategies in the negotiations could seriously compromise the ability of the United States Delegation to achieve an agreement which would be in the best interests of the United States. Accordingly, the Board finds that public observation of this meeting would involve matters the premature disclosure of which would be likely to significantly frustrate implementation of proposed agency action within the meaning of the exemption provided under 5 U.S.C. 552b(c)(9)(B) and 14 CFR section 310b.5(9)(B) and that the meeting will be closed.[1]

PERSONS EXPECTED TO ATTEND

BOARD MEMBERS

Chairman John E. Robson, Vice Chairman Richard J. O'Melia, Member G. Joseph Minetti, Member Lee R. West, and Member R. Tenney Johnson.

BOARD STAFF

Mr. Howard A. Cohen, Special Counsel to the Chairman; Mr. Elias C. Rodriquez, Executive Assistant to Vice Chairman; Mr. Frederic D. Houghteling, Assistant to Member Minetti; Mr. Charles M. Palmer, Assistant to Member West; Mr. Robert E. Cohn, Assistant to Member Johnson; Mr. John R. Hancock, Staff Assistant to Chairman; Mr. Charles E. Rains, Legal Assistant to Member West; Mr. James L. Casey, Legal Assistant to Member Minetti; and Ms. Deborah A. Lee, Recorder.

OTHER

Ambassador Alan Boyd, Department of State; Dr. Stephen Piper, Assistant to Ambassador Alan Boyd; and Ms. Rose Basiliko, Alderson Reporting Company.

JAMES C. SCHULTZ,
General Counsel.

MARCH 16, 1977.

[FR Doc.77-8485 Filed 3-21-77;8:45 am]

[1] Copy of certification by General Counsel filed as part of the original document.

COMMISSION ON CIVIL RIGHTS

STATE ADVISORY COMMITTEES

Comprehensive Review

In accordance with the Office of Management and Budget (OMB) Circular Number A-63, Transmittal Memorandum Number 5, the U.S. Commission on Civil Rights has begun its annual comprehensive review of its 51 State Advisory Committees to determine: (a) whether such committees are carrying out their purpose; (b) whether consistent with the provisions of applicable statutes, the responsibilities assigned to them should be revised; (c) whether they should be merged with other Advisory Committees; or (d) whether they should be abolished.

THE U.S. COMMISSION ON CIVIL RIGHTS

The United States Commission on Civil Rights, created by the Civil Rights Act of 1957, is an independent, bipartisan agency of the executive branch of the Federal Government. By the terms of the Act, as amended, the Commission is charged with the following duties pertaining to denials of the equal protection of the laws based on race, color, sex, religion, or national origin: investigation of individual discriminatory denials of the right to vote; study of legal developments with respect to denials of the equal protection of the law; appraisal of the laws and policies of the United States with respect to denials of equal protection of the law; maintenance of a national clearinghouse for information respecting denials of equal protection of the law; and investigation of patterns or practices of fraud or discrimination in the conduct of Federal elections. The Commission is also required to submit reports to the President and the Congress at such times as the Commission, the Congress, or the President shall deem desirable.

THE STATE ADVISORY COMMITTEES

An Advisory Committee to the United States Commission on Civil Rights has been established in each of the 50 States and the District of Columbia pursuant to section 105(c) of the Civil Rights Act of 1957 as amended. The Advisory Committees are made up of responsible persons who serve without compensation. Their functions under their mandate from the Commission are to: advise the Commission of all relevant information concerning their respective States on matters within the jurisdiction of the Commission; advise the Commission on matters of mutual concern in the preparation of reports of the Commission to the President and the Congress; receive reports, suggestions, and recommendations from individuals, public and private organizations, and public officials upon matters pertinent to inquiries conducted by the State Advisory Committee; initiate and forward advice and recommendations to the Commission upon matters in which the Commission shall request the assistance of the State Advisory Committee; and attend, as observers, any open hearing or conference which the Commission may hold within the State.

RESPONSES

The review is being conducted under the auspices of the Staff Director of the Commission. Any person wanting to comment may do so in writing; responses received no later than April 8, 1977, by Mr. John A. Buggs, Staff Director, U.S. Commission on Civil Rights, 1121 Vermont Avenue, N.W., Room 800, Washington, D.C. 20425, will be considered.

Dated at Washington, D.C., March 17, 1977.

For the Staff Director.

LOUIS NUNEZ,
Deputy Staff Director.

[FR Doc.77-8489 Filed 3-21-77;8:45 am]

CIVIL SERVICE COMMISSION

DEPARTMENT OF COMMERCE

Title Change in Noncareer Executive Assignment

By notice of September 16, 1975, FR Doc. 75-24596 the Civil Service Commission authorized the Department of Commerce to fill by noncareer executive assignment the position of Deputy Under Secretary for Field Programs, Office of the Secretary, Immediate Office. This is notice that the title of this position is now being changed to Deputy Under Secretary for Regional Affairs, Office of the Secretary, Office of Regional Affairs.

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77-8424 Filed 3-21-77;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

Grant of Authority To Make a Noncareer Executive Assignment

Under authority of section 9.20 of Civil Service Rule IX (5 CFR 9.20), the Civil Service Commission authorizes the Environmental Protection Agency to fill by noncareer executive assignment in the excepted service two positions of Special Assistant to the Administrator, Office of the Administrator.

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77-8425 Filed 3-21-77;8:45 am]

DEPARTMENT OF COMMERCE

Economic Development Administration

KWIK OFFSET PLATE SERVICE, INC.

Determination of Eligibility To Apply for Trade Adjustment Assistance

A petition by Kwik Offset Plate Service, Inc., 1100 West 32nd Street, New York, New York 10001, a producer of offset plates and negatives for printing, was accepted for filing on March 14, 1977, pursuant to section 251 of the Trade Act of 1974 (Pub. L. 93-618) and § 315.23 of the Adjustment Assistance Regulations for Firms and Communities (13 CFR Part 315). Consequently, the United States Department of Commerce has initiated an investigation to determine whether increased imports into the United States of articles like or directly competitive with those produced by the firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of the petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by the Chief, Trade Act Certification Division, Economic Development Administration, U.S. Department of Commerce, Washington, D.C. 20230, no later than the close of business of April 1, 1977.

JACK W. OSBURN, Jr.,
Chief, Trade Act Certification Division, Office of Planning and Program Support.

[FR Doc.77-8412 Filed 3-21-77; 8:45 am]

TARRA HALL CLOTHIERS, INC.

Determination of Eligibility To Apply for Trade Adjustment Assistance

A petition by Tarra Hall Clothiers, Inc., 162 Fifth Avenue, New York, New York 10010, a producer of men's suits, sportcoats and slacks, was accepted for filing on March 15, 1977, pursuant to Section 251 of the Trade Act of 1974 (Pub. L. 93-618) and Section 315.23 of the Adjustment Assistance Regulations for Firms and Communities (13 CFR Part 315). Consequently, the United States Department of Commerce has initiated an investigation to determine whether increased imports into the United States of articles like or directly competitive with those produced by the firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of the petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by the Chief, Trade Act Certification Division, Economic Development Administration, U.S. Department of Commerce, Washington, D.C. 20230, no later than the close of business of April 1, 1977.

JACK W. OSBURN, Jr.,
Chief, Trade Act Certification Division, Office of Planning and Program Support.

[FR Doc.77-8411 Filed 3-21-77;8:45 am]

National Oceanic and Atmospheric Administration

NEW ENGLAND FISHERY MANAGEMENT COUNCIL

Amended Notice of Public Meeting

Notice is hereby given of a change in location for the meeting of the New England Fishery Management Council which appeared in the FEDERAL REGISTER on March 14, 1977, Volume 42, Number 49. The meeting scheduled to be held at the Holiday Inn, Junction of Route 1 and 128, Peabody, Massachusetts, on April 13-14, 1977, will now be held at the Coast Guard Academy, New London, Connecticut. An additional item will be added to the agenda, "Council Groundfish Plan Regulations." The daily convening times remain unchanged.

WINFRED H. MEIBOHM,
Associate Director, National Marine Fisheries Service.

MARCH 16, 1977.

[FR Doc.77-8441 Filed 3-21-77;8:45 am]

WESTERN PACIFIC FISHERY MANAGEMENT COUNCIL

Statement of Organization, Practices, and Procedures

Pursuant to section 302(f)(6) of the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265), each Regional Fishery Management Council is responsible for determining its organization and prescribing its practices and procedures for carrying out its functions under the Act in accordance with such uniform standards as are prescribed by the Secretary of Commerce. Further, each Council must publish and make available to the public a statement of its organization, practices, and procedures. As required by the Act, the Western Pacific Fishery Management Council has prepared and is hereby publishing its Statement of Organization, Practices, and Procedures.

Dated: March 17, 1977.

WINFRED H. MEIBOHM,
Associate Director, National Marine Fisheries Service.

The Western Pacific Fishery Management Council, created by Section 302 (a)(7) of the Fishery Conservation and Management Act of 1976 (the "Act"), hereby publishes a Statement of Organization, Practices, and Procedures, as required by Section 302(f)(6) of the Act. This Statement of Organization, Practices, and Procedures for carrying out the Council's functions under the Act, was adopted by the Council during its public meeting held on February 1-4, 1977 in Honolulu, Hawaii. Copies may be obtained by writing the Executive Director, Western Pacific Fishery Management Council, 1164 Bishop Street, Room 1506, Honolulu, Hawaii.

The Council's permanent offices are located at 1164 Bishop Street, Room 1506, Honolulu, Hawaii 96813, Telephone Number (808) 523-1758.

1. Name of council

The full name of the organization is "Western Pacific Regional Fishery Management Council." For convenience, it is variously referred to as the "Western Pacific Fishery Council" or the "Western Pacific Council" or by its initials "WPRFMC".

2. Location of offices

The Council's headquarters office is at 1164 Bishop Street, Room 1506, Honolulu, Hawaii 96813. The Council has decided in principle to establish "satellite" liaison offices in Guam and American Samoa at some future time.

3 Legal authority

The Council is authorized by the Fishery Conservation and Management Act of 1976, Pub. L. 94-265 (90 Stat. 331).

4. Purpose

The Council is to:

A. Prepare and submit to the Secretary of Commerce a fishery management plan for each fishery within its geographical area of authority and, from time to time, necessary amendments to each plan;

B. Prepare comments on any application for foreign fishing transmitted to it by the Secretary of State, and on any fishery management plan or amendment transmitted to it by the Secretary of Commerce;

C. Conduct public hearings at appropriate times and locations in the geographic area concerned, so as to allow all interested persons an opportunity to be heard in the development of fishery management plans and amendments to such plans, and with respect to the administration and implementation of the provisions of the Fishery Conservation and Management Act;

D. Submit to the Secretary of Commerce:

1. A report, before February 1 of each year, on the Council's activities during the immediately preceding calendar year,

2. Such periodic reports as the Council deems appropriate, and

3. Any other relevant reports which may be requested by the Secretary of Commerce;

E. Review on a continuing basis, and revise as appropriate, the assessments and specifications made with respect to the optimum yield from, and the total allowable level of foreign fishing in, each

fishery within its geographic area of authority; and

F. Conduct any other activities which are necessary and appropriate to the foregoing functions.

5. Council composition

The Western Pacific Regional Fishery Management Council comprises the State of Hawaii and the Territories of Guam and American Samoa, and has authority over the fisheries in the Pacific Ocean seaward of those islands. The Council has 14 members, including 11 voting members, of whom 7 are appointed by the Secretary of Commerce, with the requirement that at least one shall be appointed from each of the three component areas.

The voting members of the Council are:

A. The principal official with marine fishery management responsibility in the Governments of Hawaii, Guam and American Samoa, or the designee of such official;

B. The Director of the Southeast Region of the National Marine Fisheries Service, or his designee; and

C. Seven appointed members from Hawaii, Guam and American Samoa.

The non-voting members of the Council are:

A. The Director of U.S. Fish and Wildlife Service Region 1, or his designee;

B. The Commander of the 14th Coast Guard District, or his designee; and

C. A representative of the U.S. Department of State.

6. Officers and terms of office

The Council elects a Chairman and two Vice-Chairman, with a term of office of one year each. By custom, one officer is elected from each of the three component areas.

7. Staff

A. *Composition:* The staff of the Council comprises an Executive Director, and Administrative Officer and a Secretary and such other staff as are necessary to carry out Council activities.

B. *Functions:* The staff is responsible for administration and execution of Council operations. Functions include budget preparation, financial management, procurement, coordination of planning efforts, liaison with and among Council committees, advisory panels and planning teams, maintenance of Council records, correspondence, preparation of required Council reports and other administrative activities.

C. *Employment Practices:* The Council is an equal opportunity employer in full compliance with all requirements of the non-discrimination clause attached to this Statement. Council staff positions are filed solely on the basis of merit, fitness, competence and qualifications.

1. In setting rates of pay for Council staff, the principle of equal pay for substantially equal work is followed. Variations in basic rates of pay are in proportion to substantial differences in the difficulty and responsibilities of the work performed.

2. Employees of the Council are granted paid leave for Federal holidays, vacations or exigencies such as sickness or civic duties (jury, military reserve obligations) as determined by the Council, up to a maximum of 20 days of paid annual leave and 13 days of sick leave per year.

3. The Council offers its employees the opportunity to participate in group medical insurance, life insurance and retirement plans and will pay a reasonable proportion of the cost of such plans.

4. The Council maintains high standards of ethical conduct for members and staff. These standards are based on the following principles:

No employee of the Council shall use his or her official authority or influence derived from his or her position for the purpose of interfering with or affecting the result of an election to or a nomination for any national, State, county or municipal elective office.

No employee of the Council shall be deprived of employment, position, work, compensation or benefit provided for or made possible by the Fishery Conservation and Management Act on account of any political activity or lack of such activity in support of or in opposition to any candidate or any political party in any national, State, county or municipal election or on account of his or her political affiliation.

No Council member or employee shall pay or offer or promise or solicit or receive from any person, firm or corporation, either as a political contribution or a personal emolument any money or anything of value in consideration of either support or the use of influence, or the promise of support or influence, in obtaining for any person any appointive office, place or employment under the Council.

No employee of the Council shall have a direct or indirect financial interest that conflicts with the fair and impartial conduct of his or her Council duties.

No Council member or employee of the Council shall use or allow the use, for other than official purposes, of information obtained through or in connection with his or her Council employment which has not been made available to the general public.

No Council member or employee shall engage in criminal, infamous, dishonest, notoriously immoral or disgraceful conduct prejudicial to the Council.

No Council member or employee shall use Council property on other than official business. Such property shall be protected and preserved from improper or deleterious operation or use.

8. Standing committees of council members

The Western Pacific Council has no standing committees of Council members. In the event that such a committee is established in the future, the Council will file an amendment to this Statement with the required information.

9. Meetings

A. *Frequency*: The Council meets as often as is necessary to discharge its duties but meets at least once in each quarter of the fiscal year.

B. *Duration*: Council meetings vary in duration but at a minimum last at least one full day.

C. *Location*: Council meetings are held in the main population centers of the three component areas. Criteria for selection of meeting locations include the ease of transportation for both the Council members and the public. The Council endeavors to meet in areas where persons reside who might be immediately affected by actions taken by the Council at the particular meeting.

D. *Agendas*: Notice of Council meetings with agenda are published in the FEDERAL REGISTER at least 20 days prior to the meeting. The Council also issues press releases and uses other media to announce time, location and agenda for each meeting.

E. *Minutes:* Minutes are prepared for all Council meetings and are made available to interested individuals, groups and organizations.

F. *General Rules of Procedure:* The Council meets at the call of the Chairman or upon request of a majority of the voting members. Meetings are conducted in a manner to permit the greatest possible participation by all members of the Council and the public. Decisions by consensus are permitted except when the issue is Council approval or amendment of a fishery management plan (including any proposed regulations) or comments for the Secretary of Commerce on foreign fishing applications or secretarially-prepared management plans, in which cases a vote is required.

1. A majority of the voting members of the Council constitute a quorum for Council meetings, but one or more members may be designated by the Council to hold hearings.

2. When there is a vote, a majority of the voting members present and voting rules. The use of a proxy is not permitted

3. The Council is required to conduct all meetings and hearings within its geographic area of responsibility, execpt when inter-regional resources are concerned.

4. Voting members of the Council who dissent on any issue to be submitted to the Secretary of Commerce are permitted to submit a statement of their reasons for dissent to the Secretary.

G. *Authority of the Chair:* The Chairman, or in his absence the Vice-Chairman designated by him, convenes and presides over Council meetings. The Chairman may designate council members to serve on such committees as may be established and to participate in the meetings of the Council's subsidiary bodies. The Chairman may also designate Council members to officiate at public hearings. The Chairman retains full voting rights.

10. Hearings

The Council holds public hearings in order to provide opportunities for all interested persons to be heard in the development of fishery management plans and amendments thereto and with respect to the administration and implementation of the Fishery Conservation and Management Act. The Council determines when and where such hearings should be held, within the particular geographic area concerned.

A. *Conduct:* When it is determined that a hearing is appropriate, the Chairman of the Council designates at least one voting member of the Council to officiate. Conduct of the hearing, beyond the stipulation that all points of view be given a chance for expression, is within the discretion of the hearing official under whatever instructions the Council may wish to provide.

B. *Notice:* Hearings follow the same requirements for announcement as Council meetings. Advance notice is also given in local media where the hearing is to take place, in a manner sufficient to assure that all interested parties are aware of the opportunity to make their views known.

C. *Record:* A complete and accurate record of the participants and their views, obtained by use of either a court reporter or detailed minutes, is reported back to the Council and maintained as part of the Council's official records.

11. Scientific and Statistical Committee

The Western Pacific Council has a Scientific and Statistical Committee composed of capable scientists and experts from State and Federal agencies, academic institutions and the private sector. The membership represents the disciplines required for preparation and review of fishery management plans. The Committee meets at the call of the Council or with the approval of the Chairman. The general responsibilities of the Committee are to:

A. Identify scientific resources required for the development of management plans and recommend resources for planning teams.

B. Provide a multi-disciplinary blue-ribbon committee to review alternative management plans and advise the Council on their scientific content.

C. Assist the Council in the development, collection and evaluation of such statistical, biological, economic, social and other scientific information as is relevant to the Council's activities.

12. Advisory panels

The Council will establish and select the members of an advisory panel for each fishery management unit for which a plan will be developed. Advisory panels are accountable to and report to the Council, and shall meet with the approval of the Council Chairman. Advisory panels shall have representation from the several groups and interests concerned with the management of the resource or fishery for which they were established. The functions of panels are to advise the Council as to fishery management problems, to provide inputs to the work of the appropriate management planning team, and to advise the Council on the content and effects of management plans.

13. Organization of management plan development teams

A. *Organization:* Management plan development teams (planning teams) are working teams of State, Federal and non-government specialists. A planning team will be established, at the appropriate time, for each management unit which will be the subject of a planning effort. The planning teams will report to the Council through the Executive Director.

B. *Practices and Procedures:* Planning teams are established by the Council. The Scientific and Statistical Committee recommends to the Council persons who should serve or agencies which should be represented on each planning team. One member of each team is designated as team leader or chairman. The team meets or consults as needed with the corresponding advisory panel and with the Scientific and Statistical Committee, with coordination and administrative support being provided by the Executive Director. The Council is informed of progress periodically. The teams develop alternative management plans and thoroughly evaluate the effects of each in terms of objectives or criteria defined by the Council. The planning team must conduct its planning and evaluation work in such a way as to satisfy the requirements of both the Fishery Conservation and Management Act and the National Environmental Policy Act. On completion of the initial planning project, the resulting set of alternatives is transmitted to the Council through the Executive Director. Copies are also transmitted to the Scientific and Statistical Committee and the appropriate advisory panel for review and comment to the Council. The Council evaluates these comments and, if necessary, refers the plan back to the planning team for further work. The revised plan is then submitted to the Council. When the Council is satisfied with the plan, it schedules a public hearing or hearings to solicit additional input from groups or individuals who might be affected by future regulatory action. Before holding public hearings on management alternatives, the Council distributes copies of the plan widely, so that all whose interests might be affected will have an opportunity to review and consider the alternatives from which the Council will be making a selection. After consideration of public comments, the planning team makes such revisions of the alternatives as the Council deems necessary and it may draft proposed regulations. Upon final adoption of a selected alternative, the Council transmits the plan, incorporated into a Draft Environmental Impact Statement, to the Secretary of Commerce for promulgation of implementing regulations.

14. Balance among criteria

A. *Focused responsibility:* The organizational structure of the Council clearly relates the decision-making responsibility of the Council; the advisory responsibilities of planning teams, advisory panels and the Scientific and Statistical Committee; and the coordinating responsibilities of the Executive Director.

B. *Administrative Simplicity:* The organization of the major units of the Council is along major functional lines, with clear lines of authority between and within individual units.

C. *Flexibility:* There is sufficient flexibility in the structure to allow for variations within separate units to accommodate changes in priorities and conditions. Separate fishery-related advisory panels have been preferred over one large comprehensive panel, because the former can be established and terminated in parallel with the work of planning teams and representation can be more selective.

D. *Independence and Relevance of Science:* The Scientific and Statistical Committee is a separate and fundamental unit in the Council's organizational structure, and Committee members have been selected on the basis of their scientific expertise and standing in their several disciplines. This will assure that the Council receives independent and objective scientific advice on alternative management plans and the consequences of these plans. Further, the management planning teams will comprise representatives of diverse disciplines and interests, and these teams will present alternative plans and evaluations for the Council's consideration. Thus, the planning teams will not make judgments as to whether a particular plan is "right" or "wrong", and their evaluations should be complete and objective.

E. *Quality of Scientific and Technical Information:* The selection of highly qualified scientists and technical experts to serve on the Scientific and Statistical Committee will assure that the Council will have made available to it the best and most relevant information that exists.

F. *Minimum Cost:* The organizational structure described is the most cost-effective means to carry out the Council's functions. Planning teams and advisory panels are temporary ad hoc units which will function until an management plan for a specific fishery has been developed and implemented. This approach provides the necessary resources for the planning effort wihout creating a large, permanent organization. Resources can be assigned in accordance with shifts in priorities. Specialized resources can be obtained readily when needed rather than being permanently rtained at high cost.

15. Financial management system

Office of Management and Budget Circular No. A-110 provides uniform administrative requirements applicable to the Western Pacific Fishery Council, in-

cluding standards for financial management, financial reporting, property management and procurement, and the National Marine Fisheries Service has furnished the Council with a recommended financial accounting system. The Council will operate in full compliance with these standards and recommendations.

16. Relationship to uniform standards for council organization

This Statement of Organization, Practices and Procedures is intended to carry out and be in compliance with the requirements of the Interim Regulations published in the FEDERAL REGISTER on September 15, 1976, at Volume 41, No. 180, pages 39436–39445.

[FR Doc.77-8442 Filed 3-21-77;8:45 am]

DEPARTMENT OF DEFENSE

ARMED FORCES EPIDEMIOLOGICAL BOARD, SUBCOMMITTEE ON DISEASE CONTROL

Open Meeting

1. In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463) announcement is made of the following committee meeting:

Name of committee: Subcommittee on Disease Control of the Armed Forces Epidemiological Board.
Date of meeting: 7 April 1977.
Place: Room 5E069, Forrestal Building, 1000 Independence Ave., S.W., Washington, D.C.
Time: 0900–1600.
Proposed agenda: This meeting will be devoted to the consideration of immunization of Armed Forces personnel against polio. This will include matters related to polio vaccine types available, vaccine procurement, vaccine administration, immunity produced and polio epidemiology.

2. This meeting will be open to the public, but limited by space accommodations. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. Interested persons wishing to participate should advise the Executive Secretary, DASG–AFEB, Room 1B472 Pentagon, Washington, D.C. 20310.

Dated: March 14, 1977.

DUANE G. ERICKSON,
LTC, MSC, USA,
Executive Secretary.

[FR Doc.77-8406 Filed 3-21-77;8:45 am]

ARMED FORCES EPIDEMIOLOGICAL BOARD, SUBCOMMITTEE ON DISEASE CONTROL

Open Meeting

1. In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463) announcement is made of the following committee meeting:

Name of committee: Subcommittee on Disease Control of the Armed Forces Epidemiological Board.
Date of meeting: 15 April 1977.
Place: Room 5E069, Forrestal Building, 1000 Independence Ave., S.W., Washington, D.C.
Time: 0900–1600.
Proposed agenda: This meeting will be devoted to the consideration of immunization of Armed Forces personnel against smallpox. This will include discussions of the status of the global smallpox eradication effort, immune status of the U.S. civilian and military populations, future vaccine production and availability, future availability of vaccine immune globulin, the possible future need for vaccination of Armed Forces personnel and development of a DOD policy on smallpox immunization for the Armed Forces.

2. This meeting will be open to the public, but limited by space accommodations. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. Interested persons wishing to participate should advise the Executive Secretary, DASG–AFEB, Room 1B472 Pentagon, Washington, D.C. 20310.

Dated: March 16, 1977.

DUANE G. ERICKSON,
LTC, MSC, USA,
Executive Secertary.

[FR Doc.77-8407 Filed 3-21-77;8:45 am]

DELAWARE RIVER BASIN COMMISSION

PUBLIC HEARING

Notice is hereby given that the Delaware River Basin Commission, P.O. Box 7360, West Trenton, N.J. 08628, will hold a public hearing on Wednesday, March 30, 1977, commencing at 2 p.m. The hearing will be held in the Hall of Flags, Sheraton Hotel, 17th and Kennedy Blvd., Philadelphia, Pa. The subjects of the hearing will be as follows:

I. APPLICATIONS FOR APPROVAL OF THE FOLLOWING PROJECTS AS AMENDMENTS TO THE COMPREHENSIVE PLAN PURSUANT TO ARTICLE 11 OF THE COMPACT AND/OR AS PROJECT APPROVALS PURSUANT TO SECTION 3.8 OF THE COMPACT:

A. *Borough of Trumbauersville (D–77–5 CP).* A well water supply project to augment public water supplies in Trumbauersville, Bucks County, Pa. Designated as Well No. 3, the new facility is expected to yield 220,000 gallons per day.

B. *Burlington County Board of Chosen Freeholders (D–75–122 CP).* A sewage treatment plant in the Borough of Fieldsboro, Burlington County, N.J. The project will be used on an interim basis pending construction of regional sewage facilities. The facility will provide removal of about 90 percent of BOD, from a sewage flow of 100,000 gallons per day. Treated effluent will discharge into the Delaware River.

C. *City of Bridgeton (D–76–39 CP).* A well water supply project to augment public water supplies for the City of Bridgeton, Cumberland County, N.J. Designated as Wells 13, 14 and 15, the facilities will be located in Upper Deerfield and Hopewell Townships and will provide a combined yield of 2.15 million gallons per day.

D. *North Penn Water Authority (D–77–9 CP).* A well water supply project to augment public water supplies in portions of Montgomery and Bucks Counties, Pa. Designated as Wells Nos. 16, 29, 31 and 33, the new facilities will have a combined yield of 1.18 million gallons per day.

E. *Borough of National Park (D–77–18 CP).* A standby well in the Borough of National Park, Gloucester County, N.J. Designated as Well No. 5, the new well is expected to yield 1.1 million gallons per day.

F. *Delmarva Power and Light Co. (D–77–6).* An industrial wastewater treatment project at the company's generation facility at Delaware City, New Castle County, Del. Neutralization and 99 percent removal of suspended solids will be provided for a wastewater flow of approximately 2.2 million gallons per day. Treated effluent will discharge into the sluiceway of the Getty Oil Company and thence into the Delaware River.

G. *Wilbert J. Earnest Jr. (D–76–115).* A well water supply project on the subject farm in Hopewell Township, Cumberland County, N.J. The well is expected to yield approximately 720,000 gallons per day which will be used for various farming purposes.

H. *Amstar Corp. (D–72–214).* A cooling water discharge at the company's refinery in Philadelphia, Pa. About 22.4 million gallons per day of cooling water will discharge to the Delaware River.

Documents relating to the above-listed projects may be examined at the Commission's offices.

II. *Comprehensive Plan Policy—Water Distribution.* It is proposed to amend the Commission's Comprehensive Plan by the addition thereto of the following statement of general policy relating to regionalization of water distribution systems.

REGIONALIZATION OF WATER DISTRIBUTION SYSTEMS

A. It shall be the policy of the Commission to support and promote regional solutions to water distribution problems and the construction of regional systems for the provision for new water supply service. To that end:

1. Established regional water distribution systems will be used by new water users throughout the Delaware River Basin wherever appropriate.

2. Construction of interconnections between established systems, both public and private, is in the public interest and will be encouraged.

3. Proliferation of small water supply systems of insufficient size to maintain an efficient, safe and adequate level of service, will be discouraged.

4. Wherever practicable new water service facilities shall be planned with a view to future expansion on a regional basis or to interconnections with an established regional distribution system.

B. The Commission will cooperate with state and local government agencies, industries and private water com-

panies seeking a regional solution to water distribution problems. It will provide for administration of this policy through the requirements of its comprehensive planning programs and review of proposed projects under Section 3.8 of the Compact. Requirements giving effect to this policy may be imposed by the Commission as conditions to approval of new water supply or distribution projects. Implementation shall be in accordance with the terms and conditions of administrative agreements relating to review of projects in effect between the Commission and the signatory parties.

Persons wishing to testify are requested to notify the Secretary prior to the hearing.

W. BRINTON WHITALL,
Secretary.

MARCH 11, 1977.

[FR Doc.77-8468 Filed 3-21-77;8:45 am]

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

GOVERNMENT IN THE SUNSHINE

Meeting

Pursuant to the provisions of the Government in the Sunshine Act, 5 U.S.C. 552b, the Equal Employment Opportunity Commission will meet on Tuesday, March 22, 1977, in the Chairman's Conference Room, Room No. 5240, on the fifth floor of the Columbia Plaza Office Building, 2401 E Street, NW, Washington, D.C. 20506.

The first portion of the meeting, starting at 9:30 AM (Eastern Time), will be open to the public, and the Commission plans to consider the following matters during this open session:

Five Freedom of Information Act Appeals, Numbers: 76-12-FOIA-300; 77-1-FOIA-2, 3, 6, and 12.

All are in connection with requests for documents contained in the Commission's investigative files. The names of the parties will not be made public, and the Commission will consider the appeals as policy matters.

Immediately after the open session, and departure of the public observers, the Commission plans to consider the following matters in closed session:

(1) *Freedom of Information Act Appeals Numbers 77-1-FOIA-13 and 14.* These appeals involve requests for transmittal memoranda concerning an agency decision on whether or not to bring suit.

(2) *Litigation Authorization; General Counsel Recommendations.* Six cases will be presented to the Commission by the General Counsel recommending authorization to bring suit.

(3) *Proposed Decision in Charge No. 750-74-C5000 and 52 Others.* A proposed decision is to be presented to the Commission for discussion.

If you have any questions concerning the agenda for the March 22, 1977 Commission meeting, please contact the Office of the Executive Secretariat at (202) 634-6748.

Issued March 17, 1977.

By Order of the Commission.

ETHEL BENT WALSH,
Vice Chairman.

[FR Doc.77-8446 Filed 3-21-77;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[Docket Nos. 21143, 21144;
File Nos. 88-A-RL-126, 13-A-L-17]

EXECUTIVE AIR CORP. AND SPOKANE AIRWAYS, INC.

Order Designating Applications for Consolidated Hearing on Stated Issues

Adopted: March 10, 1977.

Released: March 11, 1977.

1. Executive Air Corporation has filed an application for renewal of its license for aeronautical advisory station KGL2 at Spokane International Airport, Spokane, Washington, and Spokane Airways, Inc., has filed an application for new aeronautical advisory facilities at the same airport. Section 87.251(a) of the Commission's rules provides that only one aeronautical advisory station may be authorized to operate at a landing area and, therefore, the above-captioned applications are mutually exclusive. Accordingly, it is necessary to designate the applications for a comparative hearing in order to determine which application should be granted.

2. In view of the foregoing, *it is ordered*, That, pursuant to the provisions of Section 309(e) of the Communications Act of 1934, as amended, and Section 0.331 of the Commission's rules, the above-captioned applications are hereby designated for hearing in a consolidated proceeding at a time and place to be specified in a subsequent Order on the following comparative issues:

(a) To determine which applicant would provide the public with better aeronautical advisory service based on the following considerations:

(1) Location of the fixed-base operation and proposed radio station in relation to the landing area and traffic patterns;

(2) Hours of operation;

(3) Personnel available to provide advisory service.

(4) Experience of applicant and employees in aviation communications, including but not limited to operation of stations in the Aviation Services (Part 87) that may be or have been authorized to the applicant;

(5) Ability to provide information pertaining to primary and secondary communications as specified in Section 87.257 of the Commission's rules;

(6) Proposed radio system including control and dispatch points; and

(7) The availability of the radio facilities to other fixed-base operators.

(b) To determine in light of the evidence adduced on the foregoing issues, which, if either, of the applications should be granted.

3. *It is further ordered*, That to avail themselves of an opportunity to be heard, Executive Air Corporation and Spokane Airways, Inc., pursuant to Section 1.221 (c) of the Commission's rules, in person or by attorney, shall within 20 days of the mailing of this Order file with the Commission, in triplicate, a written appearance stating an intention to appear on the date set for hearing and present evidence on the issues specified in this Order. Failure to file a written appearance within the time specified may result in dismissal of the application with prejudice.

CHARLES A. HIGGINBOTHAM,
Chief, Safety and Special Radio Services Bureau.

[FR Doc.77-8482 Filed 3-21-77;8:45 am]

MEETING

MARCH 17, 1977.

The Commission will hold an open Commission meeting on the subjects listed below on Thursday, March 24, 1977, starting at 10:30 a.m., in Room 856, at 1919 M St., N.W., Washington, D.C.

Agenda	Item No.	Subject
General	1	Proposed notice of inquiry concerning UHF TV channel readout requirements.
Safety and Special Radio Services.	1	Amendment of pt. 81 of the rules to eliminate certain requirements regarding entries in the radiotelegraph log (D-20040).
	2	Proposed amendment of sec. 87.115(g) of the rules concerning aeronautical enroute stations.
	3	Request from citizens band (CB) station licensee, Beacon Marine Corp., Cape Canaveral, Fla. (call sign KFY-7372), for specific authorization pursuant to sec. 95.475(b) of the rules to operate transmitting equipment by means of a wireline remote control link.
	4	Proposed report and order, docket No. 20909, looking toward reallocation of "unassigned" channels in the 470-512 MHz band from "service pools" to a "General Access Pool," and taking other related action to make possible fuller and more efficient use of the available frequencies in this band.
Common carrier	1	Memorandum opinion and notice of proposed rulemaking concerning uniform settlement rates on parallel international communications routes.
	2	Communications Satellite Corp.'s petition for reconsideration of 1976 TAT-6 activation order permitting activation of TAT-6 circuits in 1976 by ITT World Communications, Inc., RCA Global Communications, Inc., and Western Union International, Inc.

Agenda	Item No.	Subject
	3	Notice of proposed rulemaking addressing connection of ancillary telephone equipment to telephone company key telephone and PBX systems, and related item concerning Automation Electronics, Inc., outstanding short-form registration; pt. 68 of the FCC rules.
Cable Television	1	Petition for special relief (CSR-985) filed by Central Plains Cable TV, Inc., and oppositions thereto filed by Buford Television, Inc. (KXON-TV) and Forum Communications, Inc. (KSFY-TV).
	2	Petition for order filed by Forum Communications Co., licensee of station KSFY-TV (NBC, channel 13), Sioux Falls, S. Dak., and letter of response filed by Central Plains Cable TV, Inc.
	3	Application for review filed by Micro-Cable Communications Corp., doing business as Texas Cablevision, operator of a cable television system at San Angelo, Tex., seeking reversal of the Commission's decision, by the chief, Cable Television Bureau, in Micro-Cable Communications Corp. (San Angelo, Tex.), mimeo No. 64388, released May 5, 1976.
	4	Petition for reconsideration for order to show cause filed by WENY, Inc., licensee of station WENY-TV (ABC, channel 36) Elmira, N.Y., requesting reconsideration of the Commission's decision in Reed's TV Cable Service (Wellsboro, Pa.), FCC 75-165, 51 FCC 2d 542 (1975).
	5	Petition for special relief filed by Metro Cable Co., operator of cable television systems at North Park, Loves Park, and certain unincorporated areas in Winnebago County, Ill., and opposition thereto filed by Winnebago Television Corp. (WTVO-TV).
	6	Request for order to show cause (CSC-156) filed by the National Hockey League and the Pittsburgh Penguins, directed against certain of Centre Video Corp.'s cable television systems located within the specified zone of the Pittsburgh, Pa., major television market (No. 10), and opposition thereto filed by Centre Video Corp.
Renewal	1	Petition for reconsideration of the grant, on July 16, 1976, of the renewal application of the Westinghouse Broadcasting Co., Inc., station KYW, Philadelphia, Pa., by the chief of the Broadcast Bureau pursuant to delegated authority.
Aural	1	Application for modification of construction permit and request for waiver filed by Florissant Broadcasting Co., Inc. (KSCF-FM), Florissant, Mo., and motion to dismiss application filed Contemporary Media, Inc. (KIRL).
Television	1	Request of Bethel Broadcasters, Inc. (KYUK-TV, Bethel, Alaska) for waiver of sec. 73.621 of the rules to allow ETV station to carry commercial matter during Alaska satellite demonstration project ending Jan. 15, 1978.

If additional information is required concerning this meeting it may be obtained from Samuel M. Sharkey, Jr., FCC Public Information Officer, telephone number (202) 632-7260.

FEDERAL COMMUNICATIONS COMMISSION,
VINCENT J. MULLINS,
Secretary.

[FR Doc.77-8483 Filed 3-21-77;8:45 am]

FEDERAL DEPOSIT INSURANCE CORPORATION

[26459]

SELECTION OF PRIVATE ATTORNEYS OR LAW FIRMS

Delegation of Authority

Article VI of the Corporation's bylaws provides in part that "the Board of Directors may retain or employ such attorneys * * * as the Board * * * may determine and upon such terms and conditions as the Board * * * shall prescribe." Because of the increasing volume of legal work generated primarily by the Corporation's activities as receiver and liquidator of closed insured banks, the Board of Directors has found it necessary and advisable to delegate to the Corporation's General Counsel, or his designee, certain authority with regard to the selection of private attorneys or law firms. The delegation is designed to expedite the process of selecting private counsel by placing this responsibility directly in the hands of the General Counsel or his designee and by providing a set of factors to be considered in carrying out this responsibility.

Accordingly, the Board of Directors hereby delegates to the Corporation's General Counsel or his designee the authority on behalf of the Board of Directors to select private attorneys or law firms to perform legal services for and provide legal counsel to the Corporation in connection with matters involving or affecting the Corporation or its personnel and in connection with the Corporation's activities as receiver or liquidator of closed insured banks. In carrying out this authority, due consideration shall be given to the following factors:

(1) The reputation of the attorney or law firm in the legal profession and in the locality served by the attorney or law firm;

(2) The experience of the attorney or law firm in the type of legal work required to be performed;

(3) The ability of the attorney or law firm to handle the anticipated volume of work;

(4) The geographic location of the attorney or law firm;

(5) Whether, in the opinion of the General Counsel or his designee, the fee rates to be charged by the attorney or law firm are reasonable;

(6) Whether the attorney or law firm can make available an adequate number of attorneys to handle related matters of a routine or less important nature at a lower fee rate;

(7) Whether the performance of legal services for or provision of legal counsel to the Corporation by the attorney or law firm would constitute a conflict of interest;

(8) Whether a high degree of cooperation could be expected to exist between the representatives of the Corporation and the attorney or law firm; and

(9) Any other factors deemed relevant in each circumstance.

The General Counsel or his designee shall, prior to selecting an attorney or law firm, advise the Chairman of the Board of Directors of the attorney or law firm who is proposed to be selected. The Board of Directors expressly retains the authority from time to time to make recommendations or otherwise assist in the selection of private attorneys or law firms or, in the exercise of its discretion, to make any such decision itself.

This delegation, and the listed criteria, are intended only to govern the initial selection of an attorney or law firm. The continued retention of an attorney or law firm will depend upon the satisfaction of the General Counsel or the Board of Directors with the quality and cost of services rendered.

In any given instance there are likely to be numerous attorneys or law firms that would be considered qualified and acceptable under the listed criteria. Obviously, all such attorneys or law firms cannot be selected to represent the Corporation in connection with a particular matter or a particular receivership or liquidation. Thus, even where the criteria are met, the selection process will, by its very nature, be largely a subjective one, requiring the weighing and balancing of the criteria. Accordingly, inclusion of the nine factors to be considered in carrying out the delegated authority is not intended to afford any attorney, law firm, or other party the right to challenge or contest the selection of counsel by the Corporation. Rather, the criteria are included in order to provide a foundation upon which the General Counsel or his designee may base the selections. As has been the Corporation's customary practice, the Legal Division will continue to consult recognized lawyers' directories such as the Martindale-Hubbell Law Directory to determine the names of the lawyers who practice in the area in which it is desired to retain counsel. Because of the obvious administrative burden which would result, attorneys or law firms should refrain from sending applications or resumes to the Legal Division or otherwise contacting the Corporation concerning their availability to represent the Corporation. In this regard, it is emphasized that the General Counsel or his designee, while giving due consideration to the enumerated factors, will be expected to exercise

independent and sound judgment in selecting private counsel.

This delegation of authority shall become effective immediately.

By order of the Board of Directors, March 15, 1977.

FEDERAL DEPOSIT INSURANCE CORPORATION,
ALAN R. MILLER,
Executive Secretary.

[FR Doc.77-8440 Filed 3-21-77;8:45 am]

FEDERAL ELECTION COMMISSION

MEETING

AGENCY: Federal Election Commission.
LOCATION: 1325 K Street N.W., Washington, D.C.
DATE AND TIME: Thursday, March 24, 1977, 10:00 a.m.
PORTION OF THE MEETING OPEN TO THE PUBLIC:

I. Future meetings.

II. Correction and approval of minutes—March 10, 1977.

III. Certification—Commission memorandum No. 1209.

IV. Advisory opinion 1977-7.

PORTION OF THE MEETING CLOSED TO THE PUBLIC:

V. Executive session: A. Compliance. B. Personnel.

MARJARIE W. EMMONS,
Secretary to the Commission.

[FR Doc.77-8462 Filed 3-21-77;8:45 am]

FEDERAL ENERGY ADMINISTRATION

MANDATORY PETROLEUM ALLOCATION PROGRAM

Modifications to Guidelines for Evaluation of Applications for Assignment of Supplier and Base Period Use to New Gasoline Retail Sales Outlets

On May 6, 1975, FEA issued guidelines regarding the manner in which FEA shall make assignments of suppliers and base period use to new gasoline retail sales outlets (40 FR 20342, May 9, 1975). On August 25, 1976, FEA issued Ruling 1976-5, entitled "Retail Sales Outlet Operator's Entitlement to Motor Gasoline" (41 FR 36647, August 31, 1976). The ruling applied the provisions of § 211.106 to several different factual situations for the purpose of providing guidance as to whether certain renovated or reconstructed motor gasoline retail sales outlets would qualify under the regulations for allocations as new outlets.

In light of the issuance of this ruling, the FEA has determined to modify the guidelines issued on May 6, 1975. Effective immediately the guidelines are modified in this regard by the redesignation of paragraph 3 as paragraph 4 and the addition of a new paragraph 3, which provides additional guidance to FEA Regional Offices with respect to the implications of the ruling. The modified guidelines set forth the substantive criteria to be applied and the procedures to be employed by Regional Offices in consideration of such applications.

The guidelines are also modified, effective immediately, with respect to the assignment of an unwilling supplier to a new retail sales outlet. A clarifying memorandum on this issue was issued on June 24, 1976 by the Assistant Administrator for Regulatory Programs (Federal Energy Guidelines, ¶13,246 at p. 13,243-15). This clarification is included in the guidelines in new paragraph 4(b)(v), so that persons interested in FEA policy with respect to assignments for new gasoline retails sales outlets need only refer to the provisions of the guidelines themselves. The modified guidelines, with the changes indicated above and with certain editorial changes, are set forth in full in the Appendix to this notice.

Written comments regarding these modifications will be accepted and considered if filed by April 15, 1977. Comments should be submitted to Executive Communications, Room 3309, Federal Energy Administration, Box JK, the Federal Building, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20461. Comments should be identified on the outside of the envelope and on documents submitted to FEA with the designation "Clarifications to New Gasoline Retail Sales Outlet Guidelines." Fifteen copies should be submitted.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The FEA reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

Issued in Washington, D.C., March 17, 1977.

ERIC J. FYGI,
Acting General Counsel.

APPENDIX.—GUIDELINES FOR EVALUATION OF APPLICATIONS FOR ASSIGNMENT OF SUPPLIER AND BASE PERIOD USE TO NEW GASOLINE RETAIL SALES OUTLETS

1. SCOPE

Numerous questions have been raised as to the procedures and substantive criteria which FEA should apply to applications for assignment of suppliers and base period use for new gasoline retail sales outlets. These guidelines are intended to provide guidance as to how such applications should be handled both procedurally and substantively under current FEA regulations. In particular, these guidelines will discuss the identification of and service of notice to possible aggrieved parties as required by 10 CFR § 205.33 and the evaluation of applications to determine whether to assign a supplier and, if so, how to determine the assigned base period use pursuant to 10 CFR §§ 205.35 and 211.12(e).

2. NOTICE TO AGGRIEVED PARTIES

(a) *General.* The procedural regulations and criteria applicable to all applications for assignment of suppliers and base period use are set out in Subpart C of Part 205. Section 205.34 requires that the applicant file an application which not only contains various facts regarding the request, but also the "names and addresses of all affected persons (if reasonably ascertainable)," and "[t]he identification of any persons who will be aggrieved by the FEA action sought, including potential suppliers."

Section 205.33(a) provides that: "FEA *shall* serve notice on any person readily identifiable by the FEA as one who will be aggrieved by the FEA action and *may* serve notice on any other person that written comments will be accepted if filed within 10 days of service of the notice * * *" (Emphasis added.)

The word "aggrieved" is defined in § 205.2 as describing or meaning "a person with an interest sought to be protected under the FEAA, EPAA, or Proclamation No. 3279, as amended, who is adversely affected by an order or interpretation issued by the FEA or a State Office."

Thus it is the responsibility of the applicant under § 205.34(b) to supply FEA with a list of potentially aggrieved persons, but the burden is on FEA under § 205.33(a) to serve notice of the application on such aggrieved parties. Moreover, FEA "may serve notice on any other person. * * *"

(b) *Identification of Aggrieved Parties.* The applicant's task of identifying potentially aggrieved persons is not as difficult as it might seem. In most cases this information is known to the applicant because suppliers opening new sites often have made sophisticated studies of the size of the trading area and the competitors located within it before their application is submitted. As a general rule, in the case of a new station located in a typical residential neighborhood, all retail sales outlets, particularly small and independent refiner-operated outlets and all branded and non-branded independent marketer-operated outlets, located within a mile radius of that station should be presumed to be "aggrieved persons" within the meaning of the notice requirements. The geographical trading area affected might be somewhat larger in rural neighborhoods and somewhat smaller in urban neighborhoods. Moreover, because of the peculiarities of traffic flow, an affected trading area might be longer in one direction than another. But, even though it is not possible to prescribe rigid rules for the determination of the perimeters of the trading area, in most cases the FEA's discretion in this area should be freely exercised so long as the general rule of erring on the side of over-inclusion is followed.

It is not necessary that notice be served on other persons also identified by the applicant but not located in the trading area of the proposed new station—even though they might otherwise be affected because their supplies might be reduced—since the administrative burdens of doing so greatly outweigh the minimal effect which comments received from such persons would have on the decision.

(c) *Method of Providing Notice.* Notice should be individually served upon any person identified by the applicant as an aggrieved party and located in the trading area of the proposed new station using the form of notice provided in Attachment A. In addition, FEA should arrange, using imprest funds, for the publication of a notice in local newspapers of general circulation in the market area to be served by the proposed retail sales outlet. The notice should also be substantially in the form of Attachment A to these guidelines and should be published on at least two separate occasions at least one week apart. This procedure should serve to provide notice to those persons not readily identified by the applicant as aggrieved persons and satisfies FEA's independent responsibility to identify and notify aggrieved persons.

(d) *Information in Notice.* It is not necessary to disclose in the notice any of the

information contained in the application except (i) the applicant's name and address, (ii) the location of the station for which application is made, and (iii) an approximation of the base period use sought by the applicant. Only an approximation of the amount being applied for should be given because in some cases applicants have claimed that the actual amount is proprietary information arrived at after a thorough and highly confidential market survey of the area, the disclosure of which would inform the applicant's competitors of the applicant's strategy of market expansion. While such information may not in fact be the type of proprietary information protected from disclosure, there is at least a colorable argument that it is. In any event, the problem can be readily avoided by providing in the notice only an approximation of the actual amount. For example, if the amount applied for is 1,000,000 gallons per year, it could be described as "a high volume station having an aggregate base period use in excess of 800,000 gallons per year." Such a description would give potentially aggrieved parties adequate notice of the relative size of the station and at the same time avoid the unnecessary disclosure of possibly confidential competitive information.

(e) *Comment Period, Hearings and Conferences.* Subpart C of Part 205 requires FEA to give aggrieved parties 10 days from service of the notice in which to file written comments. FEA may also make an independent investigation of facts alleged in the application or comments and may rely on information obtained from any source. *See* § 205.35. A conference and hearing are both discretionary with the agency. *See* § 205.35 and Subpart M of Part 205. A conference with only the applicant in attendance is the recommended means of obtaining additional information if the application and the written comments still leave some unresolved issues. A hearing should be used only rarely and in exceptional circumstances, since most of the information relevant to the application can best be conveyed only in writing.

(f) *Timeliness of FEA Action and Interim Supplies.* FEA is required to act upon an application for assignment of a specified supplier within 90 days after its receipt. Failure to act during such period may be considered by the applicant as a denial from which an appeal may be taken. *See* § 205.37.

It is sometimes difficult, however, to evaluate an application properly within the 90-day period. Moreover, the applicant may need prompt action because the station is idle, perhaps at great expense to the applicant. In such cases it is possible for FEA to issue an order granting a temporary assignment until such time as a full evaluation of the application for a permanent assignment can be completed. (See also discussion below concerning retail sales outlets which operate using surplus products.) The procedures for issuing such temporary orders are found in § 205.39.

As indicated in that section, a temporary assignment can be made "upon application." This does not mean that the applicant must expressly apply for a temporary as well as a permanent assignment. Since an application for a temporary assignment need contain no more information than that required for a permanent assignment, the filing of two applications is unnecessary. Thus, when an application for a permanent assignment has been made and it is apparent from the circumstances that a temporary assignment is warranted pending a final decision and is not objected to by the applicant, the application on file for a permanent assignment may be treated as an application for temporary assignment as well as for a permanent assignment.

An order granting a temporary assignment can be effective for only 60 days and *cannot be renewed.* The temporary order must contain an express finding that circumstances do not permit issuance of an assignment on-phase with the usual processing of permanent assignment orders. *See* § 205.39(b).

3. DETERMINATION OF WHETHER A RETAIL SALES OUTLET IS "NEW"

FEA Ruling 1976-5 clarifies the regulations applicable to assignment of a base period use to the operator of a new retail motor gasoline outlet. While the Ruling states that "whether a particular retail sales outlet has gone out of business depends upon the facts in each case," Regional Offices should assess the varying facts of each case on the basis of uniform procedures and criteria.

(a) *Procedures.*

The following procedures should be followed by all Regional Offices:

(i) Where an application covers a retail sales outlet that qualifies as "new" under the Ruling, the application should be processed in accordance with these guidelines.

(ii) Where necessary after an initial review, additional information relevant to the qualification of the outlet as "new" under the Ruling should be sought.

(iii) Applications may be approved prior to the actual opening of the new retail outlet. In no case, however, should assignments be made effective for any period corresponding to a base period commencing before actual operation of the outlet.

(iv) In those instances where an applicant does not qualify as a new retail outlet and the application is denied, the Regional Office should advise the applicant:

(A) that adjustments to base period use may be sought pursuant to 10 CFR §§ 211.13 (e) and 205.50 *et seq.*; and

(B) that motor gasoline may be obtained through the purchase of surplus product in accordance with 10 CFR § 211.10(g).

(b) *Criteria.*

In determining whether an applicant qualifies for an assignment with respect to a new retail sales outlet under the Ruling, an analysis of the owner's intent, as evidenced by the time elapsed before opening the new outlet and the location of the outlet, should be undertaken. While these factors should be considered in relation to each other, basic guidance as to the evaluation of each individual factor is set forth below.

Each applicant must provide clear evidence of his intent to begin a new business enterprise by establishing a new retail outlet. When the application involves a site where a gasoline retail sales outlet was not previously in operation, such intent may not exist where the applicant simply changes the location of an existing business and transfers the existing allocation entitlement with the change. (See PEA Ruling 1974-3 and § 211.106.)

(i) *Timing.* The time elapsed before the opening of a retail sales outlet is critical in ascertaining whether there exists the requisite intent to establish a "new" retail sales outlet. In determining whether a firm has gone out of business for a sufficient period of time for its successor on the site to be entitled to that firm's allocaiton, § 211.106 (e) refers to a "reasonable period of time". Determinations made under the Ruling should also be made with reference to a "reasonable period of time" under the circumstances.

As set forth in the Ruling, the example covering Firm C and Firm D involved the razing of the former structure and detailed plans as to the new proposed structure. These were documented and clearly revealed the intent of the owner. In that case, an interval of several months occurred between the razing of the station and the construction of the new facilities. However, where the intent of the parties is clear, even a shorter period of time would suffice. It should be noted that it is not the actual razing of the previously existing structure which is determinative in such cases, but rather the intent of the owner. The intent to begin a new business should be documented by such evidence as exploratory offers, contracts, market analyses, and other plans. As a general guideline in such cases, the complete cessation of business for six months would be consistent with a demonstrated intent to begin a new business. Neither a change in the ownership of the real property nor a change in operator would be determinative, nor is the amount of investment in remodeling by itself a valid criterion.

(ii) *Location.* In cases where the application involves an entirely new site, the intent to open a new outlet is usually evident unless the applicant is transferring an ongoing business to the new location. However, when the application involves the site of a former retail outlet, the determination of whether the requisite intent is present requires careful analysis.

In cases where a Regional Office cannot arrive at a clear decision, the National Office should be consulted prior to resolution.

4. SUBSTANTIVE CRITERIA APPLICABLE TO ASSIGNMENT OF SUPPLIER AND BASE PERIOD USE

(a) *General.* The procedural regulations set forth in § 205.35(b) the criteria applicable to the evaluation of applications for assignment of a supplier and new base period use. These criteria restate the criteria set forth in Section 4(b)(1) of the Emergency Petroleum Allocation Act of 1973 applicable to FEA's overall duties in promulgating and applying the Mandatory Petroleum Allocation and Price Regulations.

Like the criteria of Section 4(b)(1) of the EPAA, the various criteria of § 205.35(b) are to be applied only "to the maximum extent possible." As applied to a particular set of circumstances, these criteria may not only be difficult to apply but also conflicting. As the courts have said in applying the various goals of Section 4(b)(1),

* * * "[t]he goals are inherently inconsistent, and no regulation could promote all of them at the same time. Congress recognized this in saying that the regulations shall provide for them 'to the maximum extent practicable.' A balancing of goals is required, and Congress has left the details of this balancing to the Federal Energy Administration. *Union Oil Co.* v. *FEA*, — F. Supp. —, Fed. Energy Guidelines ¶ 26,007, at p. 26,098 (C.D. Cal. 1974); *see also Air Trans. Ass'n. of America* v. *FEA*, 382 F. Supp. 437 (D.C. 1974)." Thus, FEA should be guided by the criteria of § 205.35(b) but have considerable discretion in balancing one against the other.

While it is in appropriate to prescribe precise rules for the application of these criteria to assignments of suppliers and establishment of new base period uses in all circumstances, nevertheless some general principles may be prescribed.

(b) *Whether to Assign a Supplier/Purchaser Relationship.* Three of the criteria which must be taken into account in deciding whether to assign the new outlet a supplier are whether granting the application in question would promote "economic efficiency;" minimize "economic distortion, inflexibility, and unnecessary interference with market mechanisms;" and promote the equitable distribution of petroleum products at equitable prices among all regions of the country and segments of the industry. *See* § 205.35(b)(1) (viii), (ix), and (vi). These three criteria together can be read as stating that even within the context of the

regulatory program, free market forces should be allowed to function to the extent possible. Thus, in the absence of other countervailing considerations, FEA should start with a strong but rebuttable presumption in favor of assigning a supplier/purchaser relationship for a proposed new retail sales outlet. In particular cases there might also be other relevant criteria favoring the application, such as the maintenance of public services and agricultural operations. *See* § 205.35(b)(1) (ii) and (iii).

A possible countervailing consideration may be the preservation of a competitively viable independent sector of the industry.

Thus, in each case the facts must be reviewed to determine whether the general presumption in favor of granting the application should be overridden or sustained by a weighing of these other countervailing considerations.

(i) *Effect on Supplier's Other Purchasers.* Attention should be paid to the effect of any assignment upon the supplier's other customers, particularly the supplier's branded and non-branded independent purchasers. If the assignment will significantly lower the supplier's allocation fraction below one (1.0) then the assignment should be questioned. In general, if the assignment can be expected to reduce the supplier's most recently reported allocation fraction by more than one percentage point (0.010), the reduction may be significant and would warrant especially careful assessment of the supplier's future supply position.

(ii) *Effect on Independent Competitors.* In evaluating applications, the comments solicited from independent and small refiner and branded and non-branded independent marketers operating stations within the same trading area as any new station will not be operated by an independent marketer or small or independent refiner should be carefully reviewed to determine whether or not granting of the application may seriously jeopardize the competitive viability of small and independent refiners and branded and non-branded independent marketers.

The existence of *substantial* evidence that granting the application would result in probable severe and irreversible damage to the existing independent segment in the proposed market may be the basis for denial of an application. Such evidence would not consist of a showing of probable financial impairment to a particular independent marketer, but rather would acquire evidence that the volume of business enjoyed by the independent segment in that marketplace would probably be substantially and permanently reduced.

Although these judgments are extremely difficult to make, FEA cannot ignore clear and compelling evidence that the operation of a a new retail sales outlet which is not operated by an independent marketer will so dominate a trading area as to substantially impair the competitive viability of independent marketers. Generally such evidence is *not* present if: (1) independent marketers in the trading area can remain competitively viable by relying upon customers who will patronize such stations because of the availability of supplementary products and services not provided by the new station; (2) there are other large volume/low profit margin stations in the trading area or in other nearby trading areas, and the presence of such stations has not impaired the competitive viability of independent marketers;[1] and (3) there is a reasonable prospect of considerable growth in demand within the trading area so that the new station, notwithstanding its advantages, will not necessarily acquire most of its business at the expense of the other stations in the area.

This is not meant to be an exhaustive listing of the kinds of evidence that would sustain the granting of such an application notwithstanding a showing of adverse impact upon the various aggrieved parties. Indeed, given the rebuttable presumption in favor of granting such applications in any event, the burden is on those opposing the application to make a clear and convincing showing that the competitive viability of the independent marketing sector within the trading area will be substantially impaired by the opening of a new station which is not to be operated by an independent marketer. This showing is not made merely by a showing of financial harm to, or even of impending bankruptcy by, one or more independent marketers. Finally, such a showing cannot rest upon unsubstantiated assertions or mere speculation. There must be evidence of the specific adverse impacts of the new station's opening before FEA can perform the analysis outlined above and conclude that the application must be denied.

(iii) *Consideration of Applications for Retail Sales Outlets to Be Built in the Future.* FEA has encouraged operators of potentially new retail sales outlets to apply for FEA assignment of a supplier/purchaser relationship and a base period use prior to construction of the new outlet. See § 211.12(e). This policy was established to prevent any hardship which might result from a failure to obtain an assigned supplier or base period use following the operator's expenditure of construction funds and assumption of other obligations connected with the proposed new retail sales outlet. Consequently, consideration of an application should not be delayed because a retail sales outlet is not currently operational or may not become operational before the expiration date of the EPAA. Approvals of such applications may be conditioned upon the retail sales outlets being operational within a certain period of time. Of course, such assignments should be made effective only upon the retail sales outlet's becoming operational.

(iv) *New Retail Sales Outlets Operating Solely on Supplies of Surplus Product.* In some cases new retail sales outlets are being operated with gasoline purchased from suppliers which have certified their gasoline to be surplus product as permitted by § 211.10 (g). Such retail sales outlets, however, are new suppliers as defined by § 211.10(e) which must receive FEA approval before they commence operations. Such approval should ordinarily be freely granted to gasoline retail sales outlets provided it is made clear that such approvals do not create a supplier/purchaser relationship between the retail sales outlet and the supplier of the surplus product and does not establish a base period use for the retail sales outlet. Approvals pursuant to § 211.10(e)(2) need not be conditioned upon application for a supplier and an assigned base period use. Operators of new retail sales outlets under § 211.10(e)(2) should understand, however, that unless they have been assigned a supplier and a base period use pursuant to § 211.12(e), they have no future claim to a supplier or a pro rata share of available supplies in a period when there is no surplus product.

(v) *Unwilling Suppliers.* In the event that a new retail sales outlet is unable, after a reasonable effort (as documented by refusals from local suppliers), to obtain the approval of a willing supplier, FEA should then assist the applicant by contacting those local suppliers to explain the adjustment provisions of § 211.13(c). Should this effort fail, one or more ultimate suppliers should be contacted regarding their possible assignment to the new retail sales outlet and to identify potential local suppliers through which the new retail sales outlet might be supplied. FEA would then further assist the applicant by informing it of these potential suppliers. In no instance, however, should FEA participate in business negotiations between the new outlet and potential suppliers.

For new gasoline retail sales outlets lacking a willing supplier, FEA will not normally assign an unwilling supplier because to do so would be an undesirable interference with market mechanisms and in certain cases may not promote economic efficiency. However, if the facts of a particular case show conclusively that the assignment of an unwilling supplier to a new outlet is required to promote the equitable distribution of petroleum products at equitable prices among all regions of the country and segments of the industry, then assignment of an unwilling supplier may be necessary to serve the objectives of the EPAA.

In effect, the findings set out in this paragraph (b) for denying a mutually agreed upon supplier/purchaser relationship have to be reversed to justify assigning an unwilling supplier. For example, an unwilling supplier should be assigned only if there exists substantial evidence, as distinguished from mere assertion or speculation, that failure to assign such a supplier would result in (1) probable severe and irreversible damage to one or more segments of the industry or (2) failure to assure equitable distribution of available supplies of product at equitable prices among all regions of the country and segments of the industry. This could be the case in a market area that has experienced substantial growth in demand and has a severely limited number of retail outlets such that either (1) adequate supplies of product are likely not to be available to ultimate consumers in the absence of the assignment of an unwilling supplier or (2) the prices charged to ultimate consumers are inordinately high compared to those charged consumers in adjacent market areas because the number of existing outlets is so small relative to the demand that these existing outlets are able to maintain unusually high prices.

The findings must in each case correspond to those set out in these guidelines themselves, such that normally, and in the absence of compelling evidence to the contrary, FEA will not assign an unwilling supplier. However, in the presence of such compelling evidence FEA will assign an unwilling supplier as the best way available to it for achieving the goals of the EPAA.

The case file for each such assignment must contain full justification for the findings that are made to justify assignment of an unwilling supplier and the assignment order itself must set out the finding and briefly summarize th basis therefor. This is required to assure that aggrieved parties have sufficient information on which to base any appeal of the assignment order.

(c) *Assignment of Base Period Use.* Once a decision to assign a supplier/purchaser relationship for a new retail sales outlet is made, FEA must determine the appropriate base period use to be assigned the retail sales outlet. As a general rule, the average base period use for retail sales outlets of a similar size (number of pumps) and nature (full service, gas only, self service, car wash, etc.) in the same market area will be the appropriate assigned base period use. Thus, for example, a station of a particular size and type should receive a base period use approximately equal to other stations of the same kind in the market area. When a new type of station is constructed in a market area, it should receive an allocation commensurate

[1] The FEA must consider, however, whether, given limited demand within the trading area (see item (3) following), the new station, in conjunction with the existing high-volume station, will destroy the competitive viability of the remaining independent marketers.

with the relative treatment of the new type of station compared to existing types in the nearest market area where such comparisons may be made.

The delineation of the market area will vary in each case, and ultimately will be determined by FEA. There can be no hard and fast criteria, but some general guidelines may be observed:

(i) In a city over 25,000 population, the market area to be considered should be the area within a one-mile radius of the proposed new outlet.

(ii) In a suburban area (housing developments, shopping centers, apartments) the market area to be considered should be the area within a two-to-three-mile radius of the proposed new outlet, depending upon the density of recent growth and traffic pattern characteristics in the area.

(iii) On a non-urban arterial highway with full control of access, the market area should include the area within one-fourth mile of the access point at the proposed location of the new outlet and the next two access points in each direction from the proposed location of the new outlet.

(iv) On a non-urban arterial highway with uncontrolled access or partially controlled access, the market area should include five miles in either direction along the highway.

(v) On a through street or through highway in a rural area, the market area should be that area within a five mile radius of the proposed new outlet.

(vi) In a town under 25,000 population, the market area should be a two mile radius from the proposed outlet.

As used in the above guidelines, the following terms have the following meanings:

"Arterial highway" means a highway primarily for through traffic, usually on a continuous route.

"Full control of access" means that the authority to control access is exercised to give preference to through traffic by providing access connections with selected public roads only and by prohibiting crossings at grade or direct private driveway connections.

"Partially controlled access" means that the authority to control access is exercised to give preference to through traffic to a degree that, in addition to access connections with selected public roads, there may be some crossing, at grade and some private driveway connections.

"Through street or through highway" means every highway or portion thereof at the entrance to which vehicular traffic from intersecting highways is required by law to stop or yield before entering or crossing and where appropriate signs are erected as provided by law unless entry or crossing is made on the proper indication of traffic control.

"Uncontrolled access" means that the authority having jurisdiction over a highway, street, or road, does not limit the number of points of ingress or egress except through the exercise of control over the placement and the geometrics of connections as necessary for the safety of the travelling public.

ATTACHMENT A

NOTICE

Pursuant to 10 CFR § 205.33(a), this is to notify you that _____ has applied to the Federal Energy Administration for an order assigning to it a base period volume of [more than] [less than] ____ gallons per month for a retail gasoline station it intends to operate at _____. This retail station will be owned by _____ and operated by _____.

You are invited to submit written comments to FEA in support of or in opposition to the application. If you oppose the application on the ground that approval of it would adversely affect your business, you should set forth in detail the following minimum information:

1. Your name and address.

2. The person or persons who have an ownership interest in the business which you allege would be adversely affected, and the extent of each such person's ownership interest.

3. The location of your business in relation to the retail station for which the application for assignment was made.

4. The person or company from whom you presently purchase gasoline, and whether your business operates under the trademark of your supplier.

5. The volume, in gallons, of gasoline sold by your business in each month from January 1, 1972 until the present.

6. Whether or not there is a demand for gasoline in the trading area in which your business is located which cannot be met by existing retail stations.

7. The adverse effect which you believe approval of the application would have on your business.

8. Detailed factual data and information which support your claim that approval of the application will have an adverse effect on your business. Such data and information should include, at a minimum, audited or unaudited balance sheets and profit and loss statements for a recent, representative time period.

FEA can consider alleged adverse effects on your business only if such allegations are supported by the best available data. Broad and unsubstantiated allegations of adverse impact will be disregarded.

FEA will consider your written comments along with those submitted by the applicant and other interested persons. If you submit written comments, you will be notified of FEA's decision. FEA may, at its discretion, hold a public hearing to consider the application, in which event you will be notified. A copy of that portion of FEA's procedural regulations applicable to these proceedings is enclosed for your information.

Your written comments should be hand delivered or received by mail not later than _____ to the following address:

Unless you claim confidential treatment for your submission, a copy of your comments should be delivered to the applicant. If you want the FEA to treat as confidential the information which you submit to it, it will do so if you so request and if the information is of a type entitled to such confidential treatment under the Freedom of Information Act, 5 U.S.C. § 552, as amended, 18 U.S.C. § 1905, 10 CFR § 205.9, or under other Federal statutes, regulations or rules. Trade secrets and certain commercial and financial information are entitled to confidential treatment if you so request. If you request confidential treatment, you should designate on the original version of your written comments the information which you wish to be kept confidential and submit to FEA and the applicant another version of the document with such confidential information deleted. Information which is not designated as confidential or is not entitled by law or regulation to confidential treatment will be disclosed to the applicant and perhaps to other interested persons.

Sincerely,

_____
(Name and Title)

[FR Doc.77-8461 Filed 3-17-77;1:54 pm]

FEDERAL POWER COMMISSION

CHANGE OF MEETING SUBJECT MATTER

MARCH 16, 1977.

The following items are added to the Commission meeting of March 22, 1977, upon the affirmative vote of Chairman Dunham, and Commissioners Smith, Holloman, and Watt:

P-6—Docket Nos. E-7795 and E-7989, Philadelphia Electric Company.
P-7—Docket No. ER76-221, Potomac Edison Company.
P-8—Project No. 2709, Monongahela Power Company, Potomac Edison Company, West Penn Power Company.

KENNETH F. PLUMB,
Secretary.

[FR Doc.77-8531 Filed 3-18-77;9:57 am]

CHANGE OF MEETING SUBJECT MATTER

MARCH 16, 1977.

The following item is added to the Commission meeting of March 16, 1977, upon the affirmative vote of Chairman Dunham, and Commissioners Smith, Holloman, and Watt:

M-3—Columbia Gas Transmission Corporation.

KENNETH F. PLUMB,
Secretary.

[FR Doc.77-8532 Filed 3-18-77;9:57 am]

[Docket No. E77-57]

EMERGENCY NATURAL GAS ACT OF 1977

Emergency Order Pursuant to Section 6 of Pub. L. 95-2

On March 15, 1977, Morris Cannan (Cannan) filed, pursuant to Section 6 of the Emergency Natural Gas Act of 1977 (Act), Pub. L. 95-2 (91 Stat. 4 (1977)), an application requesting that Texas Eastern Transmission Corporation (Texas Eastern) be authorized to reimburse Cannan approximately $42,812 for the transportation of gas from the wellhead approximately 6850 feet to Texas Eastern's pipeline facilities. Cannan states that Texas Eastern has agreed to purchase approximately 1,000 Mcfd plus any additional gas developed adjacent to this facility at a price of $2.23778 per Mcf (14.65 psia) or $2.25 per Mcf (14.73 psia).

In Pelto Oil Company, Docket No. E77-25 (February 20, 1977), I determined that "any producer which transports gas downstream of the wellhead or installs facilities to effect such transportation, is entitled to recover reasonable actual costs incurred in addition to $2.25 per MMBtu." Thus, Cannan may be reim-

bursed by Texas Eastern for all reasonable actual costs incurred by Cannan in installing and operating facilities to deliver gas to Texas Eastern downstream of the wellhead.

The price to be received by Cannan for the sale of this gas shall not exceed $2.25 per MMBtu.

Texas Eastern shall submit weekly reports as required by Order No. 4.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon Cannan and Texas Eastern.

This order and authorization granted herein are subject to the continuing authority of the Administrator under Pub. L. 95–2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

MARCH 16, 1977.

[FR Doc.77-8528 Filed 3-21-77;8:45 am]

[Docket No. E77-53]

EMERGENCY NATURAL GAS ACT OF 1977

Supplemental Emergency Order Pursuant to Section 6 of Pub. L. 95–2

By order isued March 10, 1977, pursuant to Section 6 of the Emergency Natural Gas Act of 1977 (Act), Pub. L. 95–2 (91 Stat. 4 (1977)), the request of El Paso Natural Gas Company (El Paso) to make certain purchases for which oral agreements were entered into prior to February 22, 1977, notwithstanding Order No. 6 was granted in part and denied in part.

By telegram filed March 15, 1977, El Paso requested reconsideration of the denial of El Paso's request to make a purchase from thirteen wells controlled by Yates Petroleum Corporation, et al. (Yates, et al.) El Paso states that (i) all oral contracts agreed to on February 17, 1977, have been reduced to writing; (ii) prior to Order No. 6, it had acquired or was in the process of acquiring rights-of-way for pipelines to connect ten of the thirteen wells; (iii) it has acquired rights-of-way for connecting four completed wells and one of the connecting pipelines has been completed and the others are being constructed; (iv) it is attempting to acquire all right-of-way to connect four other completed; (v) it has obtained rights-of-way to connect three wells being drilled; and (vi) two additional wells are to be drilled.

The March 10, 1977 order delineated certain purchases which could be made even though a formal written contract had not been executed prior to Order No. 6. The information supplied by El Paso and Mahun Oil and Gas Corporation, et al. (Mahun), in their March 15, 1977 telegrams does not satisfy those criteria. Therefore, El Paso's request for reconsideration of the March 10, 1977 order is hereby denied.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon El Paso, John Yates, Antweil, Yates, Aminoil, Yates, et al., Samedan, Depco, Sabine, Bennett, Inexco, Monsanto, and Mahun, et al. This order shall also be published in the FEDERAL REGISTER and shall remain in effect unless and until Order No. 6 is modified or rescinded.

This order and authorization granted herein are subject to the continuing authority of the Administrator under Pub. L. 85–2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

MARCH 16, 1977.

[FR Doc.77-8529 Filed 3-21-77;8:45 am]

[Docket No. E77-58]

EMERGENCY NATURAL GAS ACT OF 1977

Emergency Order Pursuant to Section 6 of Pub. L. 95–2

On March 16, 1977, Transcontinental Gas Pipe Line Corporation (Transco), as agent for certain of its customers, filed, pursuant to Section 6 of the Emergency Natural Gas Act of 1977 (Act), Pub. L. 95–2 (91 Stat. 4 (1977)), an application for authorization to purchase up to 21 Bcf of natural gas at a rate not to exceed 150,000 Mcfd from Houston Pipe Line Company (Houston). For the reasons set forth below, I find the terms and condtitions of the subject agreement between Houston and Transco to be fair and equitable and (i) authorize and approve the same, (ii) authorize, approve, and order the transportation and delivery of the subject gas to Transco, and (iii) authorize and approve the construction and operation of any facilities necessary to transport and deliver these gas supplies to Transco.

Transco will purchase these supplies at a price of $2.20 per MMBtu inclusive of all state and local taxes and other adjustments. I find this price to be fair and equitable in accordance with Order No. 2.

Houston will deliver this gas to Transco at a mutually agreeable point in Fort Bend County, Texas. Transco will deliver the gas to the customers for which it is purchasing the gas as agent at existing delivery points. Transco will not impose any transportation charges for the delivery of this gas other than the retention of a percentage of the volumes for compressor fuel. In addition, Transco may be required to construct or cause to be constructed certain measuring facilities in order to receive this gas from Houston.

Transco advises and I find that the gas made available by Houston will result in commingling of interstate natural gas with Houston's normal intrastate system gas supply and with volumes of gas owned by other parties. The contractual provisions between Houston and its producers, transporters and other suppliers of gas prohibit the sale of natural gas in interstate commerce and the commingling of their intrastate pipeline system gas supplies with gas moving in interstate commerce. The sale, transportation and delivery of gas for which Transco seeks approval may result in some commingling of interstate natural gas with Houston's normal intrastate gas supplies and with gas owned by other third parties. This order shall be considered as applying to all such commingled gas. Under the provisions of section 9 (b), (c) of Pub. L. 95–2 (91 Stat. at 9), the suppliers of such gas which is so commingled, may not terminate existing contracts with Houston or such other parties or require a redetermination of the prices provided in such contracts by reason of this transaction. Contractual termination, prohibition or dedetermination provisions in any such contracts referred to above are not enforceable by reason of Section 9 of Public Law 95–2 since Houston is selling, delivering and transporting gas for Transco pursuant to Section 6(a) of that Act. Houston and any third person whose gas is commingled with Transco's gas shall refer all relevant information concerning any attempt to terminate existing contracts or require a redetermination of prices to the Administrator for appropriate action.

According to the official files of the Federal Power Commission, Houston is not classified as a natural gas company within the meaning of the Natural Gas Act. Section 6(b)(1)(A) of the Act provides in part that "[t]he provisions of the Natural Gas Act shall not apply * * * to any sale to an interstate pipeline * * * under the authority of subsection (a) or to any transportation by an intrastate pipeline in connection with such sale * * *." 91 Stat. at 8. In addition, section 6(c)(2) provides:

Compliance by any pipeline with any order under this subsection shall not subject such pipeline to regulation under the Natural Gas Act or to regulation as a common carrier under any provision of state law.

Thus, the sale of this gas will not subject Houston or any person supplying gas to Houston to the provisions of the Natural Gas Act or to regulation as a common carrier under state law.

In its application, Transco stated that the customers for which it is purchasing these gas supplies have certified that they are not serving directly or indirectly any natural gas for uses specified in Priorities 4 through 9 (18 CFR 2.78(a)(1)(iv)–(ix), and (ii) will not purchase and receive any of the subject gas if at any time during the term of the agreement they are serving uses specified in Priorities 4 through 9. I find that Transco has complied with Order No. 6.

Transco shall submit weekely reports as required by Order No. 4.

Pursuant to Section 6(a) of the Act, I hereby authorize Houston to sell to Transco up to a total of 21 Bcf (at a rate not to exceed 150,000 Mcfd) of natural gas on the terms and conditions set forth in Transco's filing in this proceeding. Pursuant to Section 6(c)(1) of the Act, I hereby authorize and order Transco to construct, and recover the costs of such construction, and any me-

tering facilities necessary to receive this gas from Houston.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon Houston and Transco. This order shall also be published in the FEDERAL REGISTER.

This order and authorization granted herein are subject to the continuing authority of the Administrator under Pub. L. 95–2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

MARCH 16, 1977.

[FR Doc.77-8530 Filed 3-21-77;8:45 am]

ADVISORY COMMITTEE

Notice of Review

The Federal Power Commission is currently undertaking a review of its advisory committee, as requested by the President. As part of this review process, public comment is invited and will be considered in the formulation of FPC's recommendation to continue or terminate the Gas Policy Advisory Council and its related subgroups and task forces. Should there be any comments or recommendations regarding the committee and/or any of its subelements, please address them, by April 8, 1977 to:

Federal Power Commission, Advisory Committee Management Officer, Office of the Comptroller, Room 4000, 825 N. Capitol Street, Washington, D.C. 20426.

KENNETH F. PLUMB,
Secretary.

[FR Doc.77-8582 Filed 3-18-77;1:18 pm]

[Docket No. E-7756]

EMERGENCY NATURAL GAS ACT OF 1977

Emergency Order

On March 15, 1977, Sumpf-Williams (Sumpf-Williams), Aminoil USA, Inc. (Aminoil), and Nahama & Weagant, Inc. (Nahama & Weagant) filed telegrams with the Administrator indicating that they had uncommitted gas supplies in the State of California which can be sold to an interstate pipeline or a local distribution company pursuant to Section 6 of the Emergency Natural Gas Act of 1977, Pub. L. 95–2 (91 Stat. 4 (1977)). All have agreed to sell at a price of $2.25 per MMBtu.

Sumpf-Williams states that it has up to 3,000 Mcfd in the Sacramento Valley, California, and that additional drilling would increase this volume to 5,000 Mcfd. Aminoil has approximately 8,000 Mcfd available in Soland and Contra Costa Counties, California.[1] Nahama and Weagant states that it has up to 5,000 Mcfd in the Sacramento Valley, California.

At the present time, a number of interstate pipelines and local distribution companies served by interstate pipelines have purchased gas supplies from various utilities in the State of California. The volumes actually delivered pursuant to these arrangements must be repaid in kind. *Southern Natural Gas Company*, Docket No. E77–5 (February 20 and March 8, 1977); *Columbia Gas Transmission Corporation*, Docket No. E77–10 (February 6 and February 20, 1977); *Transcontinental Gas Pipe Line Corporation*, Docket No. E77–17 (February 15, 1977); *Columbia Gas Transmission Corporation, UGI Corporation*, Docket No. E77–21 (February 18, 1977); *Columbia Gas of Kentucky, Inc., et al.*, Docket No. E77–30 (February 26, 1977); *Consolidated Edison Company of New York, Inc.*, Docket No. E77–44 (March 3, 1977). Repayment with gas supplies acquired in areas other than California will result in the incurrence of considerable transportation and fuel charges to deliver such supplies to California. See, *Southern Natural Gas Company, supra*. However, because of their location, the gas supplies available from Sumpf-Williams, Aminoil and Nahama & Weagant could be used to repay the gas owned to the California utilities without the incurrence of such transportation and fuel charges.

Based on the foregoing, I find that the purposes of the Act would be best served by using these gas supplies to repay the California utilities. Therefore, I will make these supplies available to any interstate pipeline or local distribution company served by an interstate pipeline, which has a repayment obligation to any California utility. Any interstate pipeline company or local distribution company served by an interstate pipeline company having a repayment obligation to a California utility which could use the volumes to reduce such obligation shall file with the Administrator on or before Friday, March 25, 1977, an application for authorization to purchase all or part of these supplies.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon Sumpf-Williams, Aminoil, Nahama & Weagant, Southern Natural Gas Company, Columbia Gas Transmission Corporation, Transcontinental Gas Pipe Line Corporation, UGI Corporation, Columbia Gas of Kentucky, Inc., *et al.*, and Consolidated Edison Company of New York, Inc.

This order is subject to the continuing authority of the Administrator under Pub. L. 95–2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

MARCH 17, 1977.

[FR Doc.77-8583 Filed 3-21-77;8:45 am]

[1] Natural Gas Pipeline Company of America's request to buy this gas was denied in Docket No. E77–48 (March 10, 1977).

[Docket No. E77–59]

EMERGENCY NATURAL GAS ACT OF 1977

Emergency Order

On March 16, 1977, Petrolum Evaluation Corporation (PEC) filed, pursuant to Section 6 of the Emergency Natural Gas Act of 1977 (Act), Pub. L. 95–2 (91 Stat. 4 (1977)), an application requesting that Texas Eastern Transmission Corporation (Texas Eastern) be authorized to reimburse PEC approximately $56,070 for the transportation of gas from the wellhead approximately 8900 feet to Texas Eastern's pipeline facilities. PEC states that Texas Eastern has agreed to purchase approximately 1500 Mcfd at a price of $2.23778 per Mcf (14.65 psia) or $2.25 per Mcf (14.73 psia).

In *Pelto Oil Company*, Docket No. E77–25 (February 20, 1977), I determined that "any producer which transports gas downstream of the wellhead or installs facilities to effect such transportation, is entitled to recover reasonable actual costs incurred in addition to $2.25 per MMBtu." Thus, PEC may be reimbursed by Texas Eastern for all reasonable actual costs incurred by PEC in installing and operating facilities to deliver gas to Texas Eastern downstream of the wellhead.

The price to be received by PEC for the sale of this gas shall not exceed $2.25 per MMBtu. In addition, PEC may receive reimbursement for all reasonable actual costs incurred by PEC in installing and operating facilities to deliver gas to Texas Eastern downstream of the wellhead.

Texas Eastern shall submit weekly reports as required by Order No. 4.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon PEC and Texas Eastern. This order shall also be published in the FEDERAL REGISTER.

This order and authorization granted herein are subject to the continuing authority of the Administrator under Pub. L. 95–2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

MARCH 17, 1977.

[FR Doc.77-8584 Filed 3-21-77;8:45 am]

[Docket No. E77–60]

EMERGENCY NATURAL GAS ACT OF 1977

Emergency Order

On March 17, 1977, Panhandle Eastern Pipe Line Company (Panhandle) filed, pursuant to Section 6 of the Emergency Natural Gas Act of 1977 (Act), Pub. L. 95–2 (91 Stat. 4 (1977)), a request for an order authorizing an emergency purchase of approximately 3,000 Mcfd of natural gas from Ran Ricks, Jr. (Ricks). Panhandle is purchasing the subject volumes as agent for its cus-

tomer, Citizens Gas and Coke Utility (Citizens), through July 31, 1977.

Panhandle will purchase the subject volumes at a price of $2.25 per MMBtu. I find this price to be fair and equitable in accordance with Order No. 2.

Panhandle will receive these gas supplies from Ricks and deliver them to Citizens at existing delivery points. Panhandle and Citizens have agreed upon transportation charges of 20 cents per Mcf plus eight (8) percent of the volumes transported for compressor fuel.

Panhandle advises that Citizens has advised that it is not serving any uses set forth in 18 C.F.R. § 2.78 (a)(1)(iv)–(ix) and that the sale complies with Order No. 6. The approval of this sale is conditioned upon the submission of a sworn statement by Citizens that the subject purchase complies with Order No. 6.

Pursuant to Section 6(a) of the Act, I authorize Ricks to sell gas to Panhandle as agent for Citizens. Pursuant to Section 6(c)(1) of the Act, I authorize Panhandle to transport this gas for Citizens. Since the parties have agreed upon the transportation charges, I find no basis on which to fix other charges.

Citizens shall submit weekly reports as required by Order No. 4.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon Panhandle, Ricks, and Citizens. This order shall also be published in the FEDERAL REGISTER.

This order and authorization granted herein are subject to the continuing authority of the Administrator under Pub. L. 95–2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

MARCH 17, 1977.

[FR Doc.77-8585 Filed 3-21-77;8:45 am]

[Docket No. E77-48]

EMERGENCY NATURAL GAS ACT OF 1977

Supplemental Emergency Order

By order issued March 4, 1977, pursuant to Section 6 of the Emergency Natural Gas Act of 1977 (Act), Pub. L. 95–2 (91 Stat. 4 (1977)), I denied, without prejudice, the request of Natural Gas Pipeline Company of America (Natural) to make certain emergency purchases. The order further stated that, where expenditures were made prior to February 22, 1977, for the purpose of delivering such gas supplies to Natural, Natural could make such purchases consistent with the doctrine of Colorado Interstate Gas Company, Docket No. E77–31 (February 28, 1977).

On March 16, 1977, Natural submitted a supplemental petition in which it set forth information indicating that Tortuga Oil and Mineral (Tortuga) had expended $2,000 prior to February 22, 1977 to acquire a low pressure separator and appurtenant facilities and to acquire and coat the pipe to be installed to make deliveries to Natural.[1] By letter filed March 17, 1977, Natural submitted additional information from Tortuga which indicates that (i) the construction of facilities necessary to deliver the subject gas to Natural commenced prior to February 22, 1977, and (ii) the constructed facilities are so designed that they can be used only to deliver this gas to Natural.

The information submitted by Natural satisfies the criteria of Colorado Interstate, supra, and Natural may make the purchase from Tortuga notwithstanding Order No. 6. Such purchase shall be made at a fair and equitable price in accordance with Order No. 2.

Natural shall submit weekly reports as required by Order No. 4.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon Natural and Tortuga. This order shall also be published in the FEDERAL REGISTER.

This order and authorization granted herein are subject to the continuing authority of the Administrator under Pub. L. 95–2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

MARCH 17, 1977.

[FR Doc.77-8586 Filed 3-21-77;8:45 am]

[Project No. 2709]

MONONGAHELA POWER CO., ET AL.

Notice of Petition

MARCH 16, 1977.

Monongahela Power Company, The Potomac Edison Company, West Penn Power Company.

Take notice that on March 15, 1977, the State of West Virginia, represented by the Attorney General of West Virginia, filed a petition to reopen the record for the purpose of admitting into the record the petition of the Honorable John D. Rockefeller IV, Governor of the State of West Virginia in opposition to the issuance of a license in Project No. 2709 proposed to be located in the Canaan Valley, West Virginia.

Governor Rockefeller's petition, which is contained in the petition of West Virginia, makes the following points in brief:

(1) The Canaan Valley in Tucker County is unique and its destruction should not be permitted when reasonably acceptable alternative sites for the construction of an electric generation plant are available.

(2) Although the proposed project would improve the tax base in Tucker County there may be economic alternative developments which would not adversely affect or destroy the uniqueness of Canaan Valley.

(3) The Davis Project or any of the alternative sites will forever destroy and eliminate one of the unique ecosystems in the state.

(4) The Federal Power Commission has a duty under the National Environmental Policy Act and Section 10(a) of the Federal Power Act to develop the alternative of the preservation of Canaan Valley in its natural state, and any project in the Valley would not be "best adapted", within the meaning of Section 10(a).

(5) The Davis and Glade Run Projects would be highly inefficient and wasteful.

(6) To be legally defensible any project must be "best adapted" within the meaning of Section 10(a), and neither the Davis Project nor the Glade Run Project includes a legally sufficient recreational plan.

(7) The Davis Project, including all of West Virginia's mitigation plans, is not legally sufficient pursuant to Section 10(a).

(8) The Glade Run alternative is not legally supported by the evidence.

(9) The Final Environmental Impact Statement on the Davis Project is incomplete and legally insufficient.

(10) It is believed that the United States Fish and Wildlife Service of the Department of the Interior will recommend that a major portion of the Canaan Valley be included in the National Wildlife Refuge System.

The petition of West Virginia asks that the application for the Davis Project and any other alternative projects in the Canaan Valley be denied.

In view of the time that has passed since the inception of this matter, and the issuance of the Initial Decision any answers to the petition of West Virginia shall be filed on or before March 23, 1977.

KENNETH F. PLUMB,
Secretary.

[FR Doc.77-8581 Filed 3-21-77;8:45 am]

FEDERAL RESERVE SYSTEM

FIRST COMMERCE CORP.

Request for Determination and Notice Providing Opportunity for Hearing

Notice is hereby given that a request has been made to the Board of Governors of the Federal Reserve System, pursuant to the provisions of section 2(g)(3) of the Bank Holding Company Act of 1956 as amended (12 U.S.C. 1841(g)(3)) ("the Act"), by First Commerce Corporation ("Commerce"), New Orleans, Louisiana, for a determination that Commerce is not in fact capable of controlling Albert Prevot, an individual residing in McAllen, Texas, following the transfer to Mr. Prevot by First National Bank of Commerce ("First National"), New Orleans, Louisiana, a subsidiary of Commerce, of shares of Planters Trust and Savings Bank, Opelousas, Louisiana, although in connection with the transfer Mr. Prevot will become indebted to First National.

Section 2(g)(3) of the Act provides, in pertinent part, that shares transferred after January 1, 1966, by any bank holding company directly or indirectly to any transferee that is indebted to the trans-

[1] By letter filed March 16, 1977, Tortuga requested approval of the sale.

feror shall be deemed to be indirectly owned or controlled by the transferor, unless the Board, after opportunity for hearing, determines that the transferor is not, in fact, capable of controlling the transferee. Under section 2(g)(1) of the Act, a bank holding company is deemed to own or control indirectly shares owned or controlled by its subsidiaries.

Notice is hereby given that, pursuant to section 2(g)(3) of the Act, an opportunity is provided for filing a request for oral hearing. Any such request or written comments on the application should be submitted in writing (in duplicate) to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received no later than April 14, 1977. If a request for oral hearing is filed, it should contain a statement of the nature of the requesting person's interest in the matter, his reasons for wishing to appear at an oral hearing, and a summary of the matters concerning which such person wishes to give testimony. The Board subsequently will designate a time and place for any hearing it orders, and will give notice of such hearing to the transferor, the transferee, and all persons that have requested an oral hearing. In the absence of an oral hearing, the Board will consider the requested determination on the basis of documentary evidence filed in connection with the application.

Board of Governors of the Federal Reserve System, March 17, 1977.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc.77-8463 Filed 3-21-77;8:45 am]

MARSHALL & ILSLEY CORP.

Order Approving Acquisition of Bank

Marshall & Ilsley Corporation, Milwaukee, Wisconsin, has applied for the Boards' approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)), to acquire 80 percent or more of the voting shares of Fox Heights State Bank, Green Bay, Wisconsin ("Bank").

Notice of the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with section 3(b) of the Act. The time for filing comments and views has expired, and the Federal Reserve Bank of Chicago has considered the application and all comments received in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(a)).

Applicant, the second largest banking organization in Wisconsin, controls 18 bank subsidiaries with aggregate deposits of $1,047.5 million, representing 7.0 percent of the total deposits in commercial banks in the State.[1] Acquisition of Bank (deposits of $15.4 million) would increase Applicant's share of deposits in the State to 7.1 percent and would not result in a significant increase in the concentration of banking resources in Wisconsin.

Bank is the 11th largest of 14 banking organizations in the Green Bay banking market[2] and holds 2.6 percent of the total commercial bank deposits in the market. An insignificant amount of competition presently exists between Applicant's subsidiaries and Bank and it does not appear likely that any significant competition would develop in the future due to the distances involved (Applicant's nearest banking office to Bank is 45 miles away) and the presence of numerous intervening banking offices. Bank's market appears to be adequately serviced at the present time. Applicant's acquisition of Bank represents a foothold entry into the Green Bay market and is an acceptable alternative to *de novo* entry. It is concluded that consummation of the proposed transaction would not have a significant adverse effect on existing or potential competition in the market, and that competitive considerations are consistent with approval of the application.

Considerations relating to the financial and managerial resources and future prospects of Applicant, its existing subsidiary banks, and Bank are generally satisfactory and consistent with approval of the application.

Applicant proposes no major changes in the services offered by Bank. Applicant's expertise and financial strength should allow Bank to continue to be responsive to the needs of its customers in the future. Considerations relating to the convenience and needs of the community to be served are consistent with approval of the application. It is the judgment of this Reserve Bank that the application would be in the public interest and should be approved.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall not be made (a) before the thirtieth calendar day following the effective date of this Order, or (b) later than three months after the effective date of this Order, unless such period is extended for good cause by the Board, or by the Federal Reserve Bank of Chicago pursuant to delegated authority.

By order of the Federal Reserve Bank of Chicago, acting pursuant to delegated authority for the Board of Governors of the Federal Reserve System, effective March 11, 1977.

ROBERT P. MAYO,
President.

[FR Doc.77-8465 Filed 3-21-77;8:45 am]

[1] All deposit data are as of December 31, 1975.

[2] The relevant market is approximated by Brown County excluding the town of Wrightstown.

SEAFIRST CORP.

Proposed Acquisition of Seafirst Life Insurance Co. and SFC Insurance Co.

Seafirst Corporation, Seattle, Washington, has applied, pursuant to § 4(c)(8) of the Bank Holding Company Act (12 U.S.C. § 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR § 225.4(b)(2)), for permission to acquire voting shares of Seafirst Life Insurance Company, Seattle, Washington and SFC Insurance Company, Phoenix, Arizona. Notice of the application was published on February 4, 1977, in The Seattle Times, a newspaper circulated in Seattle, Washington and The Arizona Republic and The Phoenix Gazette, newspapers circulated in Phoenix, Arizona.

Applicant states that the proposed subsidiary would perform de novo the activity of underwriting credit life and credit accident and health insurance which is directly related to extensions of credit by Applicant or its domestic credit extending subsidiaries. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question should be accompanied by a statement summarizing the evidence the person requesting the hearing proposes to submit or to elicit at the hearing and a statement of the reasons why this matter should not be resolved without hearing.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of San Francisco.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than April 13, 1977.

Board of Governors of the Federal Reserve System, March 16, 1977.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc.77-8464 Filed 3-21-77;8:45 am]

GENERAL SERVICES ADMINISTRATION

GENERAL SERVICES ADMINISTRATION, PRIVACY ACT OF 1974

System of Records

Pursuant to the provisions of the Privacy Act of 1974, Pub. L. 93-579, 5 U.S.C.

552a, the General Services Administration (GSA) hereby publishes for comment a new system of records that will be maintained by GSA.

A new system report was filed with the Speaker of the House, the President of the Senate, the Privacy Protection Study Commission, and the Office of Management and Budget on February 9, 1977.

Any person interested in commenting on the routine use portions of the system of records contained in this notice may do so by submitting comments in writing to General Services Administration (BR), Washington, DC 20405. Comments must be submitted on or before April 21, 1977.

23–00–0103 (GSA/OAD 36)

System name:

Defunct Agency Records, GSA/OAD.

System location:

The system records are located in the GS Building, 18th and F Streets NW., Washington, DC 20405, and in the GSA Regional Office Building, 7th and D Streets SW., Washington, DC 20407.

Categories of individuals covered by the system:

Employees of defunct agencies, including but not limited to Presidential commissions, committees, small agencies, and boards, the records of which were serviced by GSA under a reimbursable administrative support agreement.

Categories of records in the system:

Varied payroll and financial records including but not limited to time and attendance cards, payment vouchers, comprehensive listing of employees, health benefits records, requests for deductions, tax forms, W–2 forms, overtime requests, leave data, retirement records, and vendor register and payment tapes.

Authority for maintenance of the system:

The Economy Act, 31 U.S.C. 686 and the Federal Property and Administrative Services Act of 1949, as amended, 63 Stat. 377.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

The records are used by GSA personnel in concluding the administrative operations of the defunct agency. Routine uses of records maintained in the system shall include providing a copy of an employee's Department of the Treasury Form W–2, Wage and Tax Statement, to the State, city, or other local jurisdiction which is authorized to tax the employee's compensation. The record will be provided in accordance with a withholding agreement between the State, city, or other local jurisdiction and the Department of the Treasury pursuant to 5 U.S.C. 5516, 5517, and 5520, or in the absence thereof, in response to a written request from an appropriate official of the taxing jurisdiction to the Director of Administration, General Services Administration (B), Washington, DC 20405. The request must include a copy of the applicable statute or ordinance authorizing the taxation of the compensation and should indicate whether the authority of the jurisdiction to tax the employee is based on place of residence, place of employment, or both.

Pursuant to a withholding agreement between a city and the Department of the Treasury (5 U.S.C. 5520), copies of executed city tax withholding certificates shall be furnished the city in response to a written request from an appropriate city official to the Director of Administration, General Services Administration (B), Washington, DC 20405.

Records are also released to the General Accounting Office for audits, to the Internal Revenue Service for investigations, and to the Civil Service Commission (CSC) concerning pay, benefits, retirement deductions, and other information necessary for the CSC to carry out its Government-wide personnel management functions.

Also those routine uses contained in the appendix following the GSA Notices.

Policies and practices of storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

Paper records in file folders and card files, microfilm records in reels and cabinets, magnetic tapes and cards in cabinets and storage libraries, and computer records within a computer and attached equipment.

Retrievability:

Payroll records are retrieved by the social security number and all other records by name.

Safeguards:

When not in use by an authorized person, the records are stored in lockable metal containers or in secured rooms.

Retention and disposal:

Disposition of records will be in accordance with the HB, GSA Records Maintenance and Disposition System (OAD P 1820.2).

System managers and addresses:

The system manager for those records which were being serviced under agreement by the Agency Liaison Division at the time the agency expired is the Director, Agency Liaison Division, GS Building, 18th and F Streets NW., Washington, DC. Mailing address: General Services Administration (BRZ), Washington, DC 20405. The system manager for those records which were being serviced under agreement by the Office of Finance is the Director of Finance, General Services Administration, 18th and F Streets NW., Washington, DC. Mailing address: General Services Administration (BC), Washington, DC 20405.

Notification procedures:

Requests for assistance should be made to the Director of Information, General Services Administration (AVI), Washington, DC 20405.

Access and contest procedures:

GSA procedures for record access and contesting records are contained in 41 CFR 105–64. Address request in writing to the system manager. The legend "Privacy Act Request" shall appear on the letter and envelope.

Record source categories:

Upon termination, the agency being serviced by GSA publishes a notice in the FEDERAL REGISTER transferring administrative responsibilities for the records to GSA.

Dated at Washington, D.C., on March 11, 1977.

C. L. MORRISON, Jr.,
Acting Director of Administration.

[FR Doc.77–8420 Filed 3–21–77;8:45 am]

Federal Preparedness Agency

NATIONAL HEALTH RESOURCES ADVISORY COMMITTEE

Continuation of Advisory Committee

In accordance with the review of Federal advisory committees directed by the President's letter of February 25, 1977 and Transmittal Memorandum No. 5, OMB Circular No. A–63 of March 7, 1977, notice is hereby given to provide the public an opportunity to comment on the continuation of the National Health Resources Advisory Committee of the Federal Preparedness Agency, GSA. This Committee advises the Administrator, GSA on the development of policies, plans, and programs related to health preparedness for national emergencies.

Interested persons may comment on this proposal, including recommendations for continuance or termination, by writing to Federal Preparedness Agency (EE), General Services Administration, Washington, DC 20405 by April 1, 1977.

Dated: March 17, 1977.

LESLIE W. BRAY, Jr.,
Director Federal Preparedness Agency.

[FR Doc.77–8694 Filed 3–21–77;10:34 am]

PROGRAM ADVISORY COMMITTEE

Continuation of Advisory Committee

In accordance with the review of Federal advisory committees directed by the President's letter of February 25, 1977 and Transmittal Memorandum No. 5, OMB Circular No. A–63 of March 7, 1977, notice is hereby given to provide the public an opportunity to comment on the continuation of the Program Advisory Committee of the Federal Preparedness Agency, GSA. This Committee advises the Director, FPA on preparedness matters dealing with the adequacy and allocation of resources for emergencies and other civil emergency matters.

Interested persons may comment on this proposal, including recommendations for continuance or termination, by

writing to Federal Preparedness Agency (EE), General Services Administration, Washington, DC 20405 by April 1, 1977.

Dated: March 17, 1977.

LESLIE W. BRAY, JR.,
Director,
Federal Preparedness Agency.

[FR Doc.77-8695 Filed 3-21-77;10:35 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Alcohol, Drug Abuse, and Mental Health Administration

UNIVERSITY OF TENNESSEE, CENTER FOR HEALTH SCIENCES

Research on Mental Health; Authorization of Confidentiality

Under the authority vested in the Secretary of Health, Education, and Welfare by section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)), all persons who—

1. are employed by the University of Tennessee Center for Health Sciences, Memphis, Tennessee; and

2. have, in the course of that employment, access to information which would identify individuals who are the subjects of the research on mental health which is assisted by the Department of Health, Education, and Welfare grant numbered R01 MH 28051, entitled "The Evaluation and Treatment of Sexual Aggressives";

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

As provided in section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)):

> Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

This authorization does not authorize employees of the University of Tennessee Center for Health Sciences to refuse to to reveal to qualified personnel of the Department of Health, Education, and Welfare, for the purpose of management or financial audits or program evaluation, the names or other identifying characteristics of individuals who are the subjects of the research conducted pursuant to Department of Health, Education, and Welfare grant numbered R01 MH 28051. Such personnel will hold any identifying information so obtained strictly confidential in accordance with 45 CFR 5.71.

This authorization is applicable to all information obtained pursuant to Department of Health, Education, and Welfare grant numbered R01 MH 28051 which would identify the individuals who are the subjects of the research conducted under that grant.

Dated: February 22, 1977.

THOMAS F. A. PLAUT,
Deputy Director, National Institute of Mental Health.

Dated: February 23, 1977.

ROBERT L. DUPONT,
Director, National Institute on Drug Abuse.

Dated: March 4, 1977.

FRANCIS N. WALDROP,
Deputy Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc.77-8469 Filed 3-21-77;8:45 am]

Office of the Assistant Secretary for Health

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

Meeting; Confirmation of Public Hearings

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research will meet on April 8 and 9, 1977, in Conference Room 6, C Wing, Building 31, National Institutes of Health, 90000 Rockville Pike, Bethesda, Maryland. The meeting will convene at 9:00 a.m. each day and will be open to the public, subject to the limitations of available space. Topics identified in the mandate to the Commission under the National Research Act (Pub. L. 93-348), as amended, including research involving children, the Special Study (section 203 of Pub. L. 93-348), and the identification of ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects, will be the agenda for this meeting.

As previously announced in the FEDERAL REGISTER on February 3, 1977 (42 FR 6641), the National Commission for the Protection of Human Subjects will also conduct public hearings on the performance of the Institutional Review Boards (IRBs) which review research involving human subjects. The hearings on IRBs will commence at 9:00 a.m. on the dates and at the locations noted below:

April 5, 1977: Room 204A, Dirksen Federal Building, 219 Dearborn Street, Chicago, Illinois.

April 15, 1977: Room 15018, U.S. Court Federal Building, 450 Golden Gate Avenue, San Francisco, California.

May 3, 1977: Conference Room 6, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland.

Written materials of any length may be submitted to the Commission at any time. Requests for information should be directed to Ms. Betsy Singer, Public Information Officer (301-496-7776), Room 125, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland 20016.

Dated: March 15, 1977.

MICHAEL S. YESLEY,
Staff Director, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

[FR Doc.77-8490 Filed 3-21-77;8:45 am]

Food and Drug Administration

[Docket No. 76N-0325; DESI 3265 and 4681]

CERTAIN ANTICHOLINERGIC DRUGS

Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing

The Food and Drug Administration is reclassifying the less-than-effective indications for certain anticholinergic drugs, offering an opportunity for a hearing on certain indications considered to lack substantial evidence of effectiveness, and announcing the conditions under which the drugs may be marketed for the indications for which they are regarded as effective. Persons who wish to request a hearing may do so on or before April 21, 1977.

In a notice (DESI 3265; Docket No. FDC-D-303 (now Docket No. 76N-0325)) published in the FEDERAL REGISTER of June 18, 1971 (36 FR 11754), the Food and Drug Administration announced its conclusions that the drugs described below are:

1. (a) Effective for use as adjunctive therapy in the treatment of peptic ulcer; (b) In addition, methantheline bromide preparations (oral and parenteral) are effective for use for uninhibited, hypertonic neurogenic bladder. The parenteral form is also effective for use as preanesthetic medication.

2. (a) Probably effective for use as adjunctive therapy in the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis, acute enterocolitis, and functional gastrointestinal disorders); and for use as adjunctive therapy in neurogenic bowel disturbances (including the splenic flexure syndrome and neurogenic colon).

(b) The pediatric preparations are probably effective for use in the treatment of infant colic.

3. (a) Possibly effective for the treatment of hyperhidrosis and excessive salivation; adjunctive therapy in the treatment of hiatus hernia; treatment of urinary bladder spasm and urethral spasm (i.e., smooth muscle spasm); use as an adjunct in the treatment of esophagitis, diverticulitis, aerospasm, pancreatitis, ulcerative colitis, and regional enteritis; use as an adjunct in the treatment of constipation, i.e., chronic constipation, irregular bowel habits, functional constipation, and spastic constipation; use as an adjunct in the treatment of diarrheas, i.e., loose stools, functional diar-

rheas, post-gastrectomy diarrheas (post-gastrectomy syndrome, dumping syndrome), drug-induced diarrheas, acute enteritis, intestinal viral infection, colitis, ileocolitis, and diarrheas with ileostomies and ileoanal anastamoses; use as an adjunct in the treatment of premenstrual cramps and dysmenorrhea; and in the treatment of migraine headaches. (b) The drugs in injectable dosage form are also possibly effective for use in the treatment of hyperemesis gravidarum.

4. Lacking substantial evidence of effectiveness for the treatment of chronic hypertrophic gastritis; treatment of pylorospasm, duodenitis, cardiospasm, and pyloroduodenal irritability; treatment of biliary dyskinesias, cholelithiasis, cholecystitis, and biliary spasm; pyrosis; use in preoperative preparation for gastrectomy; treatment of psychogenic enuresis; and for the treatment of the following vague conditions: gastrointestinal spasm, intestinal colic, nonspecific gastroenteritis, indigestion, and "other upper gastrointestinal tract disorders".

That notice also offered an opportunity for a hearing concerning the indications concluded at that time to lack substantial evidence of effectiveness. No person has submitted any data in support of the probably effective and possibly effective indications, and they are now reclassified to lacking substantial evidence of effectiveness.

In another notice (DESI 4681) published in the FEDERAL REGISTER of October 21, 1970 (35 FR 16422), the Food and Drug Administration had announced its conclusions that Prantal Tablets (diphemanil methylsulfate) is possibly effective and lacking substantial evidence of effectiveness for its labeled indications. Prantal Injection was classified as effective in the June 18, 1971 notice. The classification of the tablet form as possibly effective as an anticholinergic was based upon the question raised by the National Academy of Sciences-National Research Council, Drug Efficacy Study Group concerning the absorption of diphemanil methylsulfate when administered orally. The effectiveness of the drug entity itself was not questioned. Pursuant to the October 21, 1970 notice, Schering Corporation submitted data from two clinical studies which show that Prantal Tablets produce the conventional anticholinergic effect on gastric acid secretion. Therefore, Prantal Tablets is hereby reclassified to effective for use as adjunctive therapy for the treatment of peptic ulcer and lacking substantial evidence of effectiveness for all other indications.

The notice that follows does not pertain to the indications stated in the June 18, 1971 notice to lack substantial evidence of effectiveness. No person requested a hearing concerning them and they are no longer allowable in labeling. Any such product labeled for those indications is subject to regulatory action.

1. NDA 3–265; Metropine Tablets, Hypodermic Tablets, Drops, Elixir and Injection, each containing methylatropine nitrate; Pennwalt Prescription Product Division, P.O. Box 1766, Rochester, NY 14603.

2. That part of NDA 7390 pertaining to Banthine Tablets; and

3. NDA 8–091; Banthine Powder for Injection, each containing methantheline bromide; G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680.

4. NDA 8–398; Prantal Injection containing diphemanil methylsulfate; previously marketed by Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033.

5. NDA 8–114; Prantal Tablets containing diphemanil methylsulfate; Schering Corp.

6. That part of NDA 8–492 pertaining to Antrenyl Bromide Tablets, Pediatric Drops, and Syrup, each containing oxyphenonium bromide; Ciba Pharmaceutical Co., Division of Ciba-Geigy Corp., 556 Morris Ave., Summit, NJ 07901.

7. NDA 8–885; Centrine Tablets and Elixir, each containing aminopentamide sulfate; previously marketed by Bristol Laboratories, Division Bristol-Myers Co., Box 657, Syracuse, NY 13201.

8. NDA 12–827; Robinul Tablets and Robinul Forte Tablets, each containing glycopyrrolate; A. H. Robins Co., Inc., 1407 Cummings Dr., Richmond, VA 23220.

9. That part of NDA 9–427 pertaining to Piptal Tablets, Capsules and Elixir, each containing pipenzolate bromide; Merrell National Laboratories, Division Richardson-Merrell, Inc., 110 E. Amity Rd., Cincinnati, OH 45215.

10. NDA 8–868; Elorine Chloride Pulvules containing tricyclamol chloride; and Elorine Sulfate Pulvules containing tricyclamol sulfate; both previously marketed by Eli Lilly & Co., P.O. Box 618, Indianapolis, IN 46206.

11. That part of NDA 8–910 pertaining to Tricoloid Tablets containing tricyclamol chloride; previously marketed by Burroughs Wellcome & Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709.

12. That part of NDA 9–032 pertaining to Monodral Bromide Caplets and Elixir, each containing penthienate bromide; previously marketed by Winthrop Laboratories, Division of Sterling Drug, Inc., 90 Park Ave., New York, NY 10016.

13. NDA 12–459; Nacton Tablets containing poldine methylsulfate; McNeil Laboratories Inc., Camp Hill Rd., Fort Washington, PA 19034.

14. NDA 8–848; Pamine Tablets; NDA 9–262; Pamine Syrup; and NDA 9–958; Pamine Sterile Solution, each containing methscopolamine bromide; The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002.

15. That part of NDA 10–679 pertaining to Cantil Tablets and Liquid, each containing mepenzolate bromide; Merrell National Laboratories.

16. NDA 6–856; Dibulin Sulfate Injection containing dibutoline sulfate; previously marketed by Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, PA 19486.

17. That part of NDA 8–732 pertaining to Pro-Banthine Tablets and Half-Strength Tablets; and NDA 8–843; Pro-Banthine Powder for Injection, each containing propantheline bromide; G. D. Searle & Co.

18. That part of NDA 9–489 pertaining to Pathilon Tablets; and NDA 9–729; Pathilon Parenteral, each containing tridihexethyl chloride; Lederle Laboratories, Division American Cyanamid Co., P.O. Box 500, Pearl River, NY 10965.

19. NDA 10–744; Darbid Tablets containing isopropamide iodide; Smith, Kline, & French Laboratories, Division SmithKline Corp., Inc., 1500 Spring Garden St., Philadelphia, PA 19101.

20. NDA 11–612; Daricon Tablets containing oxyphencyclimine hydrochloride; Pfizer Laboratories, Division of Pfizer, Inc., 235 E. 42nd St., New York, NY 10017.

21. That part of NDA 10–599 pertaining to Tral Tablets containing hexocyclium methylsulfate; Abbott Laboratories, 14th & Sheridan Rd., North Chicago, IL 60064.

22. That part of NDA 11–687 pertaining to Tral Drops containing hexocyclium methylsulfate; Abbott Laboratories.

23. NDA 13–428; Valpin Tablets; and NDA 13–429; Valpin Elixir, each containing anisotropine methylbromide; Endo Laboratories, Inc., 1000 Stewart Ave., Garden City, NY 11533.

Other drugs included in the October 21, 1970, and June 18, 1971 notices are not affected by this notice. Some of the dosage forms listed above were not included in either initial notice, but are affected by this notice. The following new drug applications were not included in the initial notices, but are also affected by this notice.

1. NDA 9–801; Antrenyl Bromide Injection containing oxyphenonium bromide; previously marketed by Ciba Pharmaceutical Co.

2. NDA 10–281; Monodral Tablets containing penthienate bromide; previously marketed by Winthrop Laboratories, Inc.

3. That part of NDA 11–999 pertaining to Gastrix Tablets containing oxyphencyclimine hydrochloride; previously marketed by Rowell Laboratories, Inc., Baudette, MN 56623.

4. NDA 14–764 and NDA 17–558; Robinul Injection containing glycopyrrolate; A. H. Robins Co., Inc. This notice only pertains to the drug's anticholinergic indications.

5. NDA 8–494; Malcotran Tablets containing homatropine methylbromide; Pennwalt Corp.

In a notice published in the FEDERAL REGISTER of March 18, 1972 (37 FR 5711), the approval of NDA 6–856 for Dibuline Sulfate Injection was withdrawn on the grounds of failure to submit required reports under section 505 (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). At the time that notice was published, no final conclusion concerning its probably effective and possibly effective indications had been reached. That conclusion has now been reached, and the purpose of including Dibuline Sulfate Injection (NDA 6–856) in this notice is to inform all interested persons of such

conclusion and offer them the opportunity to request a hearing concerning all issues relating to its legal status.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice applies to all persons who manufacture or distribute a drug product, not the subject of an approved new drug application, that is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20857.

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that the drugs are effective for the indications listed in the labeling conditions below. The drugs now lack substantial evidence of effectiveness for the indications evaluated as probably effective and possibly effective in the June 18, 1971 notice, and for the possible effective indications in the October 21, 1970 notice not upgraded to effective.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* The drugs are in tablet, capsule, or liquid form suitable for oral administration if listed above in such form; or in sterile aqueous solution form suitable for parenteral administration, if listed above.

2. *Labeling conditions.* a. The labels bear the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drugs are labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indications may be stated as shown either in (i) or (ii) below. As a result of previous Bureau of Drugs' recommendations, some NDA holders have begun to use the language in item (ii). The Bureau anticipates that that language will be in the indications section of the full labeling text that is to be published as a labeling guideline for anticholinergic drug products in the future. However, at the present time labeling will be considered acceptable if either item (i) or (ii) is used for the indication.

(i) For use as adjunctive therapy for the treatment of peptic ulcer.

(ii) For use as adjunctive therapy for the treatment of peptic ulcer. (Name of drug) has not been shown to be effective in contributing to the healing of peptic ulcer, decreasing the rate of recurrence or preventing complications.

(iii) *For methantheline bromide, add:* For use for uninhibited, hypertonic neurogenic bladder.

(iv) *For methantheline bromide parenteral, add:* The parenteral form of the drug is also indicated for use as preanesthetic medication.

3. *Marketing status.* a. Marketing of such drug products that are now the subject of an approved or effective new drug application may be continued provided that, on or before May 23, 1977, the holder of the application submits, if he has not previously done so, (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)) to the extent required in abbreviated applications (21 CFR 314.1(f)).

b. (i) Approval of an abbreviated new drug application (21 CFR 314.1(f)) must be obtained prior to marketing such product. Marketing prior to approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

(ii) With respect to diphemanil methylsulfate tablets, bioavailability studies are required as a part of the abbreviated new drug application (ANDA). Such studies shall consist of either blood level comparisons to Prantal Tablets (Schering) in adult volunteers after single or multiple dose administration or clinical trials performed in patients. Multiple dose studies and clinical trials require the submission of a Notice of Claimed Investigational Exemption for a New Drug (IND) and a protocol to assure the safety and proper procedures in patients. In addition, it is advisable that firms submit a protocol with the ANDA and obtain approval of the protocol prior to undertaking a single dose study in human subjects. Abbreviated new drug applications for diphemanil methylsulfate shall also include in vitro dissolution rate data.

C. *Notice of opportunity for hearing.* On the basis of all the data and information available to him, the Director of the Bureau of Drugs is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111 (a)(5), demonstrating the effectiveness of the drug(s) for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A. of this notice.

Notice is given to the holder(s) of the new drug application(s), and to all other interested persons, that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application(s) (or, if indicated above, those parts of the application(s) providing for the drug product(s) listed above) and all amendments and supplements thereto providing for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A. of this notice on the ground that new information before him with respect to the drug product(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug product(s) will have all the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. An order withdrawing approval will not issue with respect to any application(s) supplemented, in accord with this notice, to delete the claim(s) lacking substantial evidence of effectiveness.

In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962; or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicant(s) and all other persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above (21 CFR 310.6), are hereby given an opportunity for a hearing to show why approval of the new drug application(s) providing for the claim(s) involved should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and all identical, related, or similar drug products.

If an applicant or any person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before April 21, 1977, a written notice of appearance and request for hearing, and (2) on or before May 23, 1977, the data, information, and analyses on which he

relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of such drug product. Any such drug product labeled for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A. of this notice may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice of opportunity for hearing shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk (address given below) during working hours, Monday through Friday.

Communications forwarded in response to this notice should be identified with the reference number DESI 3265 or 4681, as appropriate, directed to the attention of the appropriate office below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements (identify with NDA number): Division of Cardio-Renal Drug Products (HFD-110), Rm. 16B-30, Bureau of Drugs.

Original abbreviated new drug applications (identify as such): Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Request for Hearing (identify with Docket number appearing in the heading of this notice): Hearing Clerk, Food and Drug Administration (HFC-20), Rm. 4-65.

Requests for the report of the National Academy of Sciences-National Research Council: Public Records and Document Center (HFC-18), Rm. 4-62.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.31) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)).

Dated: March 11, 1977.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.77-8287 Filed 3-21-77;8:45 am]

[Docket No. 76N-0302; DESI 8867]

CERTAIN RESERPINE PREPARATIONS

Drugs For Human Use; Drug Efficacy Study Implementation; Amendment

In the FEDERAL REGISTER of August 5, 1976 (41 FR 32767), the Food and Drug Administration published conclusions concerning the effectiveness of oral reserpine in potencies of 1 milligram or less in standard dosage form. That notice did not name the following reserpine product:

NDA 10-124; Serpalan Tablets containing reserpine 0.1, 0.25, and 1 mg per tablet; The Lannett Co., 9000 State Rd., Philadelphia, Pa. 19136.

The notice of August 5, 1976, is hereby amended to include the above new drug application.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053 as amended; (21 U.S.C. 352, 355)) and under authority delegated to the Director of Bureau of Drugs (21 CFR 5.31) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)).

Dated: March 11, 1977.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.77-8288 Filed 3-21-77;8:45 am]

Food and Drug Administration

ADVISORY COMMITTEES

Meetings

Correction

In FR Doc. 77-7522 appearing at page 14175 in the issue for Tuesday, March 15, 1977, the name of the second committee listed on page 14175 not reading "Miscellaneous External Drug Products Panel" should have read "Miscellaneous Internal Drug Products Panel".

DENTIFRICE AND DENTAL CARE PANEL

Notice of Rescheduling

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announced in a notice published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14175), public advisory committee meetings and other required information in accordance with provisions set forth in section 10(a) (1) and (2) of the act.

Notice is hereby given that the Dentifrice and Dental Care Panel meeting scheduled for April 21 and 22, 1977, has been rescheduled for April 20 and 21, 1977, in Conference Rm. B, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD, with the open session beginning at 9 a.m.

Dated: March 16, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-8556 Filed 3-21-77;8:45 am]

Health Services Administration

ASSISTANCE UNDER THE PUBLIC HEALTH SERVICE ACT PROJECT GRANTS FOR HEMOPHILIA TREATMENT CENTERS

Announcement of Availability of Grants

The Bureau of Community Health Services, Health Services Administration, announces that competitive applications for grants for hemophilia treatment centers are being accepted under authority of section 1131(a) of the Public Health Service Act (42 U.S.C. 300c-21).

Section 1131(a) (42 U.S.C. 300c-21) authorizes grants to public and nonprofit private entities for support of hemophilia treatment projects. Grants to eligible applicants may be made by the Secretary for projects which provide diagnosis and treatment of individuals suffering from hemophilia on an outpatient basis which assures access to services for all such individuals residing within the geographic area served by the project. Priority will be given to projects which will operate in areas having the greatest number of people in need of services.

Application kits, including all necessary forms, instructions and information may be obtained (by written request) from, and completed applications returned to, the address below:

Grants Management Branch, Bureau of Community Health Services, Health Service Administration, Room 7A-39, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Programmatic information relative to development of an application is available from the Office for Maternal and Child Health, Bureau of Community Health Services, Room 7-15, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone 301-443-6600.

Completed application must be received by June 1, 1977.

The amount available for grants under this announcement is $3 million.

Dated: March 9, 1977.

JOHN H. KELSO,
Acting Administrator,
Health Services Administration.

[FR Doc.77-8470 Filed 3-21-77;8:45 am]

Public Health Service

HEALTH MAINTENANCE ORGANIZATIONS

Requirements for Applicants Submitting Marketing Plans

Notice is hereby given that pursuant to 42 CFR 110.604 an applicant submitting an application for a determination by the Secretary under section 1310(d) of the Public Health Service Act that it is a qualified health maintenance organization must comply with the requirements set forth below.

On February 3, 1977, "New qualification review procedures" were published in the FEDERAL REGISTER (42 FR 6640) which described review procedures designed to expedite the processing of the present backlog and future submissions of qualification applications. The following notice is to further clarify and elaborate the procedures outlined in 42 FR 6640.

NEW QUALIFICATION REVIEW PROCEDURES

The revised procedures are based on a series of screens, intended to identify as early as possible in the review process applications with either incomplete information or major compliance problems. The first screen, completeness of the application, is intended to eliminate an applicant's incentive to submit an incomplete application in order to acquire an early place in the review process. In this regard, notice is hereby given that once an application has been received by the Office of Health Maintenance Organizations Qualification and Compliance (OHMOQ&C), no new material will be accepted as part of the official application unless this material is specially requested by OHMOQ&C in a notification of incompleteness or its submission is otherwise requested by OHMOQ&C. The remaining screen, which is applied to all applications found to be complete, is based on the most frequent reason for denial of qualification: an unacceptable marketing plan.

Any applicant whose application is found to be incomplete will be so notified in writing and will have 60 days from the date of notification to provide the missing materials. Should the missing information be received within 30 days from the date of notification, the application will be processed according to the original date of receipt. For these applications, the marketing screen will be completed within 30 days of the receipt of the new information. If the application's marketing plan satisfies the criteria for this marketing screen (see below), the application will be fully reviewed in its turn as determined by the date of receipt of the original application.

Should the missing information be received by the 60th day but after the 30th day, the marketing screen will be completed within 30 days of the receipt of the new information. If the application's marketing plan satisfies the criteria for the marketing screen (see below), the application will be fully reviewed in its turn as determined by the date of receipt of the additional information.

Any application not complete within the 60 day period will be denied qualification under the authority of 42 CFR 110.605(a), and the applicant will be notified promptly.

ADDITIONAL DATA REQUIREMENTS

Pursuant to 42 CFR 110.604(b)(2)(xx), all applications must contain a detailed marketing plan. In addition to the information specified in the application instructions, with respect to such plan, the following information is required:

1. Projected enrollment data for each month by category of enrollee (employer groups, individuals, Medicaid, Medicare, Federal Employees' Health Benefits Plan, etc.). For each category, indicate the number from new contracts and the number representing accounts growth.

2. Employer specific data on proposed new accounts to include:

a. Name of employer.

b. Number of eligible employees (as defined in 42 CFR 110.801: "Eligible employee means an employee who meets the terms and conditions established by an employer or its designee to participate in a health benefits plan") in service area. Cite the number of union and the number of non-union eligible employees.

c. Percentage of anticipated penetration among eligible employees over time.

d. Premium or dues structure and employer and employee monetary contributions to existing health benefits plan(s).

e. Description of existing health benefit plan(s) coverage.

f. Existing health benefits plan(s) contract anniversary date(s).

g. Anniversary date(s) of union contract(s), if applicable.

3. Evidence of employer interest to offer the qualified health maintenance organization (HMO) (e.g., letter of intent, records of informal commitment).

4. Information on proposed HMO rates by type of contract (e.g., composite, individual, family, 3-tier) and rates by type of contract for competing indemnity and other prepaid health plans in the service area.

These data must be provided by all applicants for the period covering the first 12 months after anticipated qualification. Pre-operational plans, plans which are currently operating at a deficit as evidenced by the most recently audited financial statements, and those plans which do not meet the requirement that more than 50% of the enrollment be non-Medicaid and non-Medicare enrollees, will be required to submit the data for an additional 2 years: on a quarter-by-quarter employer specific basis for year 2, and quarter-by-quarter aggregate basis for year 3. Applicants for a Federal loan must submit, in addition to the monthly data required for the first year, the employer specific data on a month-by-month basis for year 2; aggregated data on a month-by-month basis for year 3; and aggregated data on a quarter-by-quarter basis for years 4 and 5.

ENROLLMENT WAIVER

Section 1301(c)(3) of the Public Health Servict Act and 42 CFR 110.108(c) (the implementing regulations) require a qualified HMO to offer enrollment to persons who are broadly representative of the various age, social, and income groups within the area it serves. 42 CFR 110.109(c) requires a qualified HMO to have at least 50% of its members not entitled to Medicare insurance benefits or to medical assistance under Medicaid, but authorizes the Secretary to grant a waiver of the membership limitation requirement for purposes of qualification under Title XIII, for "good cause shown."

Section 1903(m)(1)(B) of the Social Security Act prohibits Federal financial participation in the costs of a Medicaid-HMO risk-based contract with an HMO which has more than one-half (50%) of its membership who are insured under Title XVIII (Medicare) or who receive benefits under Title XIX (Medicaid) except that, if the entity demonstrates to the satisfaction of the Secretary, by the submission of plans for each year of a 3-year period, that it is making "continuous efforts and progress toward achieving compliance" with the 50% limitation, this requirement can be delayed. The 3-year period to achieve compliance by enrolling non-Medicaid and non-Medicare members is either 3 years from October 8, 1976, when the requirement was enacted, or 3 years from the signing of the initial contract with the State, whichever occurs later. There will be no extension or waiver of this specific time frame to achieve compliance.

The Secretary will grant a "good cause" waiver of the 50% limitation of 42 CFR 110.109(c) if:

1. The entity submits an acceptable three-year plan, identical to both the time frame and criteria of the plans, referred to above, which would demonstrate the entity's ability to make "continuous efforts and progress towards achieving compliance," with the enrollment limitation of Section 1903(m)(1)(B), or

2. The applicant demonstrates that the socio-economic characteristics of the service area indicate that an enrollment of more than 50% Title XVIII and/or Title XIX beneficiaries is a broadly representative enrollment.

Further, the total marketing plan must provide:

1. Documentation to support the projected penetration rates.

2. Projected monthly and quarterly enrollments consistent with the penetration rates.

3. An explanation of any heavy influx of enrollment projected for a single 12 month period.

If it is determined that the marketing plan submitted as a part of the application does not meet the conditions for a "good cause" waiver or does not satisfactorily establish that the HMO will have a fiscally sound operation, qualification will be denied, and the applicant will be promptly notified in writing.

APPLICATION DEFICIENCIES

Application deficiences uncovered by the complete application review will be communicated to the applicant by letter. The applicant will then have 30 days from the date of notification to satisfy the indicated deficiencies. Should these deficiencies not be corrected within the 30 days, the applicant will be denied qualification under the authority of 42 CFR 110.605(a).

COMPUTATION OF TIME

When a period specified herein ends on a Saturday, Sunday, or legal holiday, the time shall be extended to the next working day.

Dated: March 11, 1977.

WILLIAM 3. MUNIER,
Director,
Office of Quality Standards.

[FR Doc.77-8471 Filed 3-21-77;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

PUEBLO OF ISLETA, NEW MEXICO

Transfer of Federally Owned Lands

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Commissioner of Indian Affairs by 230 DM 2.

On November 17, 1976, pursuant to authority contained in the Federal Property and Administrative Services Act of 1949, as amended by Public Law 93-599 dated January 2, 1975 (88 Stat. 1954), the below-described properties and improvements were transferred by the Director, Real Property Division, Fort Worth Regional Office, of the General Services Administration, to the Secretary of the Interior, without reimbursement, to be held in trust for the benefit and use of the Pueblo of Isleta in New Mexico:

LOWER DAY SCHOOL SITE

The following described parcels of land in Bernalillo County, New Mexico;

In the SE¼NE¼ section 23, T. 8 N., R. 2 E., New Mexico Principal Meridian, described as follows:

From a post 15 inches long, set firmly in the ground, from which a cottonwood 18 inches diameter bears North 37° West about 100 feet distant; and a cottonwood 18 inches diameter bears North 75°40' West, about 120 feet distant, thence South 79°30' West 195 feet, thence North 3°30' East 152.5 feet; thence South 86°30' East 225 feet; thence South 22° West 112.5 feet to point of beginning, containing 0.64 acre, more or less.

In the SE¼NE¼ and in the NE¼SE¼ section 23, T. 8 N., R. 2 E., New Mexico Principal Meridian, described as follows:

Beginning at the southeast corner of the present day school tract, which corner is the beginning corner of said tract, and from which the east quarter corner of section 23, T. 8 N., R. 2 E., N.M.P.M., bears South 88°57' East 888.36 feet, thence South 79°30' West 201.4 feet to Corner No. 2, thence South 77°02' West 212.7 feet to Corner No. 3, thence South 38°47' East 281.7 feet to Corner No. 4, thence North 36°58' East 380.5 feet to the point of beginning, containing 1.22 acres, more or less.

PORTION OF HIGH SCHOOL TRACT

A parcel of land located in the NW¼SE¼ section 23, T. 8 N., R. 2 E., New Mexico Principal Meridian in Bernalillo County, described as follows:

Beginning at a point South 38°47'30" West 1490.58 feet from A. P. 2 of Isleta Pueblo Indian School land as shown on G.L.O. Plat No. 7 of a survey made by F. E. Joy, showing private claims within the Isleta Pueblo Grant, approved by the General Land Office on April 22, 1919; thence South 38°38' West 184.5 feet to a point; thence North 56°48' West 162.0 feet to a point; thence South 40°07' West 99.0 feet to a point; thence North 58°36' West 138.0 feet to a point; thence North 55°15' West 129.0 feet to a point; thence North 32°42' East 106.5 feet to a point; thence South 77°48' East 492.0 feet to a point and place of beginning, containing 1.59 acres, more or less.

These lands, totalling 3.45 acres, are to be treated as and receive the same benefits and protection as other trust lands held for the benefit and use of the Pueblo of Isleta. Appropriate notation will be made in the land records of the Bureau of Indian Affairs.

THEODORE C. KRENZKE,
Acting Deputy
Commissioner of Indian Affairs.

[FR Doc.77-8472 Filed 3-21-77;8:45 am]

Bureau of Reclamation

[Int Des 77-11]

ANG COAL GASIFICATION COMPANY; NORTH DAKOTA PROJECT

Availability of Draft Environmental Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a draft environmental statement on a coal gasification project proposed by ANG Coal Gasification Company for Mercer County, North Dakota. The statement covers impacts of construction and operation of the gasification plant and its associated facilities (i.e., coal mine, railroad spur, water intake and pipeline, and product delivery pipeline). It also addresses major cumulative impacts of construction and operation of an 880-MW coal-fired electric generating plant to be constructed adjacent to the gasification plant.

Written comments may be submitted to the Regional Director (address below) within 45 days of this notice.

Copies are available for inspection at the following locations:

Office of Assistant to the Commissioner—Ecology, Room 7622, Bureau of Reclamation, Department of the Interior, Washington, D.C. 20240, Telephone 202-343-4091.

Division of Engineering Support, Technical Service Branch, E&R Center, Denver Federal Center, Denver, Colorado 80225, Telephone 303-343-3007.

Office of the Regional Director, Attention: 415, Bureau of Reclamation, P.O. Box 2553, Federal Building, Billings, Montana 59103, Telephone 406-657-6605.

Missouri-Souris Projects Office, Bureau of Reclamation, P.O. Box 1017, Bismarck, North Dakota 58501, Telephone 701-255-4011.

Single copies of the draft environmental statement may be obtained on request to the Commissioner of Reclamation or the Regional Director. Please refer to the statement number above.

Dated: March 17, 1977.

STANLEY D. DOREMUS,
Deputy Assistant
Secretary of the Interior.

[FR Doc.77-8527 Filed 3-21-77;8:45 am]

National Park Service

NATIONAL REGISTER OF HISTORIC PLACES

Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before March 14, 1977. Pursuant to section 60.13(a) of 36 CFR Part 60, published in final form on January 9, 1976, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the Keeper of the National Register, National Park Service, U.S. Department of the Interior, Washington, D.C. 20240. Written comments or a request for additional time to prepare comments should be submitted by April 1, 1977.

JERRY L. ROGERS,
Chief, Office of Archeology
and Historic Preservation.

DELAWARE

New Castle County

Stanton vicinity, *Clyde Farm Site*, S of Stanton.

INDIANA

Floyd County

New Albany, *Scribner House*, 106 E. Main St.

MINNESOTA

Hennepin County

Minneapolis, *Como-Harriet Streetcar Line and Trolley*, 42nd St. W. and Queen Ave. S.

Ramsey County

St. Paul, *Beebe, Dr. Ward, House*, 2022 Summit Ave.

St. Paul, *Old Main, Macalester College*, 1600 Grand Ave.

St. Paul, *University Hall, Hamline University*, 1536 Hewitt Ave.

NEW HAMPSHIRE

Merrimack County

Hopkinton, *Long, William H., Memorial*, Main St.

NEW MEXICO

Socorro County

Socorro, *Val Verde Hotel*, 203 Manzanares St.

NEW YORK

New York County

New York, *Old New York Evening Post Building*, 20 Vesey St.

Onondaga County

Syracuse, *Gridley, John, House*, 205 E. Seneca Turnpike.

Putnam County

Garrison vicinity, *Boscobel*, N of Garrison on NY 9D.

PENNSYLVANIA

Centre County

Boalsburg, *Boalsburg Historic District*, U.S. 322.

McKean County

Mount Jewett vicinity, *Kinzua Viaduct*, 4.2 mi. NE of Mount Jewett.

Washington County

Canonsburg, *Administration Building, Washington and Jefferson College*, Washington and Jefferson College campus.

York County

Wrightsville vicinity, Dritt Mansion, 3.5 mi. S of Wrightsville on PA 624.

TEXAS

Garza County

Post vicinity, *Cowhead Mesa Archeological District*, SW of Post.

[FR Doc.77-8408 Filed 3-21-77;8:45 am]

INTERNATIONAL TRADE COMMISSION

[TA-201-22]

FRESH CUT FLOWERS

Times and Places of Public Hearings and of Change of Date and Site for Florida Hearing

Notice is hereby given that the public hearing in this matter previously scheduled to begin on Tuesday, May 3, 1977, in Miami, Florida, will now be held beginning Thursday, April 14, 1977, in Coral Gables, Florida. The hearing will commence at 10 a.m., e.s.t., in Room 226C and D, Student Union Building, University of Miami, Coral Gables, Florida.

As previously announced, a second public hearing in this matter will be held in San Francisco, California, beginning Tuesday, April 19, 1977. Notice is hereby given that this hearing will commence at 10 a.m., p.s.t., in Conference Room 2007, Federal Building, 450 Golden Gate Ave., San Francisco, California.

Notice of the investigation and hearings was published in the FEDERAL REGISTER of February 22, 1977 (42 FR 10347).

By order of the Commission:

Issued: March 17, 1977.

KENNETH R. MASON,
Secretary.

[FR Doc.77-8525 Filed 3-21-77;8:45 am]

[USITC SE-77-22A]

GOVERNMENT IN THE SUNSHINE

Meeting; Additional Agenda Item

In deliberations held March 17, 1977, the United States International Trade Commission, acting on the authority of 19 U.S.C. 1335 in conformity with 19 C.F.R. 201.37, voted to add the following item to its agenda for the meeting of March 21, 1977:

9. Vote on the revised language of finding and recommendation in Investigation TA-201-19 (Television Receivers).

Commissioners Minchew, Parker, Leonard, Moore, and Bedell determined by recorded vote that Commission business requires the change in subject matter by addition of the agenda item, and affirmed that no earlier announcement of the addition to the agenda was possible, and directed the issuance of this notice at the earliest practicable time. Commissioner Ablondi was not present for the vote.

If you have any questions concerning the agenda for the March 21, 1977, Commission meeting, please contact the Secretary to the Commission at (202) 523-0161. Access to documents to be considered by the Commission at the meeting is provided for by access to the public files of the Commission, or when such documents are not in such files, as provided for in Subpart C of the Commissions' rules (19 C.F.R. 201.17-201.21).

On the authority of 19 U.S.C. 1335 and in conformity with 19 CFR 201.38(a), when a persons' privacy interests may be directly affected by holding a portion of a Commission meeting in public, that person may request the Commission to close such portion to public observation. Such requests should be communicated to the Office of the Chairman of the Commission.

By order of the Commission:

Issued: March 17, 1977.

KENNETH R. MASON,
Secretary.

[FR Doc.77-8524 Filed 3-21-77;8:45 am]

DEPARTMENT OF JUSTICE

Law Enforcement Assistance Administration

NATIONAL INSTITUTE OF LAW ENFORCEMENT AND CRIMINAL JUSTICE

Meeting

Notice is hereby given that the Advisory Committee of the National Institute of Law Enforcement and Criminal Justice, Law Enforcement Assistance Administration, will meet on April 6, 1977 from 9:15 a.m. to 5:00 p.m. and April 7, 1977 from 9:15 a.m. to 12:00 p.m. at the Hospitality House, U.S. Rt. 1, Arlington, Virginia.

The major topic of discussion will concern long-range planning for Institute-sponsored research and evaluation.

The meeting will be open to the public.

For further information, please contact Gerald M. Caplan, National Institute of Law Enforcement and Criminal Justice, Law Enforcement Assistance Administration, U.S. Department of Justice, 633 Indiana Avenue, N.W., Washington, D.C. 20531. (202) 376-3606.

JAY BROZOST,
Attorney-Advisor,
Office of General Counsel.

[FR Doc.77-8422 Filed 3-21-77;8:45 am]

DEPARTMENT OF LABOR

Office of the Secretary

[TA-W-1547]

BALI COMPANY, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1547: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on January 4, 1977 in response to a worker petition received on December 14, 1976 which was filed by the International Ladies Garment Workers Union on behalf of workers and former workers of the Jersey City, New Jersey facility of the Bali Company, Incorporated.

The Notice of Investigation was published in the FEDERAL REGISTER on January 28, 1977 (42 FR 5448). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bali Company, Incorporated, and the International Ladies Garment Workers Union.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales, or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or tfhreat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

The Bali Company, Incorporated is a wholly owned subsidiary of the Hanes Corporation, Winston-Salem, North Carolina. Bali produces brassieres and related products. The Jersey City, New Jersey facility was the distribution center for Bali. The New Jersey facility was closed in August 1976.

Evidence developed in the Department's investigation reveals that any separations that occurred at the Jersey City, New Jersey facility of Bali were a direct result of the company's decision to transfer their disribution activities to another domestic location. In August 1976, Bali transferred all distribution operations to a new facility in North Carolina.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that imports did not contribute importantly to the total or partial separations of the workers at the Jeresy City, New Jersey facility of the Bali Company, Incorporated as required in section 222 of the Trade Act of 1974. The petition is therefor denied.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8509 Filed 3-21-77;8:45 am]

[TA-W-1135]

DIEBOLD INC.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1135: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on October 5, 1976 in response to a worker petition received on October 5, 1976 which was filed by the International Brotherhood of Boilermakers, Iron Ship Builders, Blacksmiths, Forgers and Helpers on behalf of workers and former workers producing safety deposit boxes, vault doors and bank equipment at the Canton, Ohio facility of Diebold, Inc.

The notice of investigation was published in the FEDERAL REGISTER on October 29, 1976 (41 FR 47621). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Diebold, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat, thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The Department's investigation revealed that all four of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

Total employment of production workers at the Canton, Ohio facility of Diebold, Inc., declined 31 percent in 1975 compared to 1974 and declined 38 percent in the fourth quarter of 1975 compared to the like 1974 quarter. Total employment further declined 34 percent in the first nine months of 1976 compared to the same period in 1975.

Employment in the Safety Deposit Box Department declined 6 percent in 1975 compared to 1974 and 12 percent in the fourth quarter of 1975 compared to the like 1974 quarter and declined 45 percent in the first nine months of 1976 compared to the like 1975 period.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Production is integrated at all four locations in the Canton, Ohio area except for the production of safety deposit boxes.

Total production at the Canton Ohio facility decreased 21 percent in 1975 compared to 1974 and 34 percent in the fourth quarter of 1975 compared to the like quarter in 1974.

Production in the Safety Deposit Box Department declined 17 percent in 1975 compared to 1974 and declined 16 percent in the fourth quarter of 1975 compared to the like 1974 quarter.

INCREASED IMPORTS

Imports of safety deposit boxes and vault doors increased each year from $1.5 million in 1971 to $3.0 million in 1975. Imports increased from $2.9 million in 1974 to $3.0 million in 1975. Imports increased in the first quarter of 1976 to $925,000 from $640,000 in the quarter immediately preceding. Imports in the second, third and fourth quarters successively declined to $549,000; $483,000 and $462,000, respectively.

Imports of safes, strong-boxes and other bank equipment of base metal increased in value each year from $2.7 million in 1971 to $5.5 million in 1975. Imports of safes, strong-boxes and other banking equipment increased from $5.4 million in 1974 to $5.5 million in 1975.

CONTRIBUTED IMPORTANTLY

The investigation revealed that Diebold lost several bids in 1975 and 1976 to produce and install safety deposit boxes, vault doors and other banking equipment to other companies which install imported bank equipment.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with safety deposit boxes, vault doors and other banking equipment at the Canton, Ohio facility of Diebold, Incorporated contributed importantly to the total or partial separation of the workers of that firm. In accordance with the provisions of the Trade Act of 1974, I make the following certification:

All workers at the Canton, Ohio facility of Diebold, Incorporated located at 818 Mulberry Street, S.E.; 618 Mulberry Street, S.E.; 1410 Fourth Street, S.E. and 1101 Third Street, S.E. who became totally or partially separated from employment on or after September 22, 1975 and before April 1, 1976 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974. All workers who became separated on or after April 1, 1976 are denied adjustment assistance.

Signed at Washington, D.C., this 4th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8510 Filed 3-21-77;8:45 am]

[TA-W-1529]

EASTERN PLASTICS OF MAINE, INC., ET AL.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-1529: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated in December 30, 1976 in response to a worker petition received on that date which was filed on behalf of workers and former workers producing shoe heels and soles at Eastern Plastics of Maine, Incorporated. The investigation was expanded to include York Heel of Maine, Incorporated and National Heel of Massachusetts, Incorporated. All three firms are subsidiaries of Eastern York, Incorporated, Sanford, Maine.

The notice of investigation was published in the FEDERAL REGISTER on January 18, 1977 (42 FR 3371). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Eastern York, Incorporated, the U.S. International Trade Commission, the U.S. Department of Commerce and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard as to whether the other criteria have been met, criterion (3) has not been met.

Eastern Plastics produces heels and soles of plastic and rubber for men's, women's and children's shoes. York Heel produces heels and soles from wood and urethane. National Heel performs finishing operations on heels and soles produced by Eastern Plastics and York Heel. Eastern York maintains no corporate affiliation with any of the shoe manufacturing firms for which its subsidiaries supply heels and soles.

Imports of shoe heels and soles are negligible, having amounted to less than one percent of the domestic market in recent years.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that imports of articles like or directly competitive with shoe heels and soles produced by Eastern Plastics of Maine, Incorporated; York Heel of Maine, Incorporated; and National Heel of Massachusetts, Incorporated, all subsidiaries of Eastern Yok, Incorporated, Sanford, Maine did not increase as required for certification under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8511 Filed 3-21-77;8:45 am]

[TA-W-1389]

GUTMAN-KESSLEN SHOES, INC.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1389: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on December 8, 1976 in response to a worker petition received on December 8, 1976 which was filed on behalf of workers and former workers producing women's shoes at the Manchester, New Hampshire plant of Gutman-Kesslen Shoes, Inc.

The Notice of Investigation was published in the FEDERAL REGISTER on January 4, 1977 (42 FR 881). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Gutman-Kesslen Shoes, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all four of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of workers employed at the Manchester, New Hampshire plant of Gutman-Kesslen Shoes, Inc. increased 4.2 percent in 1975 compared to 1974 and then declined 2.9 percent in 1976 compared to 1975. Employment declined 1.4 percent in the first quarter of 1976 compared to the first quarter of 1975 and then increased 19.9 percent in the second quarter of 1976 compared to the second quarter of 1975. Employment declined 2.9 percent and 21.3 percent, respectively, in the third and fourth quarters of 1976 compared to the corresponding quarters in 1975.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Production of women's shoes at the Manchester, New Hampshire plant of Gutman-Kesslen Shoes, Inc. declined 7.3 percent in 1975 compared to 1974 and then increased 4.7 percent in 1976 compared to 1975. Production increased 20.0 percent, 24.9 percent, and 0.7 percent, respectively, in the first, second and third quarters of 1976 compared to the corresponding quarters in 1975, and then declined 20.3 percent in the fourth quarter of 1976 compared to the corresponding quarter in 1975. Production declined 10.5 percent in tht second half of 1976 compared to the same period of 1975.

INCREASED IMPORTS

Imports of women's nonrubber footwear, except athletic, increased absolutely and relatively in 1972 compared to 1971 and in 1973 compared to 1972. Imports declined absolutely and relatively in 1974 compared to 1973. Imports increased 2.1 percent in 1975 compared to 1974. The ratios of imports to domestic production and consumption increased from 107.6 percent and 51.8 percent, respectively, in 1974 to 119.1 percent and 54.4 percent, respectively, in 1975. Imports increased 16.9 percent in the first nine months of 1976 compared to the first nine months of 1975. The ratios of imports to domestic production and consumption declined from 114.2 percent and 53.3 percent, respectively, in the first nine months of 1975 to 110.3 percent and 52.5 percent, respectively, in the first nine months of 1976.

Imports of women's nonrubber footwear, except athletic, with leather uppers increased absolutely and relatively in 1972 compared to 1971, and then declined absolutely, but increased relatively in 1973 compared to 1972. Imports declined absolutely and relatively in 1974 compared to 1973. Imports increased 6.0 percent in 1975 compared to 1974. The ratios of imports to domestic production and consumption increased from 76.1 percent and 43.2 percent, respectively, in 1974 to 87.5 percent and 46.7 percent, respectively, in 1975. Imports increased 2.9 percent in the first nine months of 1976 compared to the first nine months of 1975. The ratios of imports to domestic production and consumption declined from 95.0 percent and 48.7 percent, respectively, in the first nine months of 1975 to 80.8 percent and 44.7 percent, respectively, in the first nine months of 1976.

CONTRIBUTED IMPORTANTLY

Customers of Gutman-Kesslen Shoes, Inc. indicated that they have switched purchases of women's shoes from Gutman-Kesslen Shoes, Inc. to imported women's shoes.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with the women's shoes produced by the Manchester, New Hampshire plant of Gutman-Kesslen Shoes, Inc. contributed importantly to the total or partial separations of the workers of that plant. In accordance with the provisions of the Act, I make the following certification:

All workers at the Manchester, New Hampshire plant of Gutman-Kesslen Shoes, Inc. who became totally or partially separated from employment on or after June 26, 1976 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8512 Filed 3-21-77;8:45 am]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

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, Bureau of International Labor Affairs, has instituted investigations pursuant to section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. 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.

Pursuant to 29 CFR 90.13, 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 April 1, 1977.

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 April 1, 1977.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210.

Signed at Washington, D.C., this 8th day of March 1977.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Bunker Ramo Corp. (IS MAW).	Janesville, Wis.	Mar. 7, 1977	Feb. 22, 1977	TA-W-1,774	Trimmer, standard pot and customer pot, counting dial, conductive plastic pot and transducer.
Hamilton Standard (IA MAW).	Windsor Locks, Conn.	do	Feb. 28, 1977	TA-W-1,775	Aircraft accessory parts.
Leverenz Shoe Co. (company).	Sheboygan, Wis.	do	Mar. 3, 1977	TA-W-1,776	Men's dress and casual shoes.
New Britain Machine Hand - Tools Division (ILMAW).	Newington, Conn.	do	Mar. 2, 1977	TA-W-1,777	Hand tools.
South Haven Coil, Inc. (workers).	Bedford, Ind.	do	Mar. 3, 1977	TA-W-1,778	Inductor coils, assemble forms, lugs, collars, and epoxy, wind and lace, solder, core, test, and pack.
Stangl Pottery (IBPAW)	Trenton, N.J.	do	Mar. 2, 1977	TA-W-1,779	Dinnerware, flower pots, crock pots, artware.
U.S. Steel, American Bridge (workers).	Ambridge, Pa.	do	Mar. 3, 1977	TA-W-1,780	Structural shapes (all sizes).

[FR Doc.77-8506 Filed 3-21-77;8:45 am]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

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, Bureau of International Labor Affairs, has instituted investigations pursuant to section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. 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.

Pursuant to 29 CFR 90.13, 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 April 1, 1977.

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 April 1, 1977.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210.

Signed at Washington, D.C., this 3rd day of March 1977.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: (union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Kathie Din (ILGWU)	El Monte, Calif.	Mar. 1, 1977	Feb. 14, 1977	TA-W-1,734	Ladies' sportswear.
Ka'u Sugar Co. (ILWU)	Pahala, Hawaii	Feb. 28, 1977	Feb. 23, 1977	TA-W-1,735	Raw sugar.
Laura Ann (workers)	Port Isabel, Tex.	Feb. 17, 1977	Feb. 11, 1977	TA-W-1,736	Catching and selling of shrimp.
Linda Jo Shoe Co., Inc. (USWA).	Gainesville, Tex.	Feb. 22, 1977	Feb. 16, 1977	TA-W-1,737	Women's sport shoes.
Lamured Corp. (workers)	Woodbridge, N.J.	Feb. 23, 1977	Feb. 18, 1977	TA-W-1,738	Ladies' handbags.
M & G Sportswear Co., Inc. (workers).	Fall River, Mass.	Feb. 28, 1977	Feb. 25, 1977	TA-W-1,739	Boys' sportswear and outerwear.
Magaw Electric (IBEW)	Kenosha, Wis.	Feb. 23, 1977	Feb. 14, 1977	TA-W-1,740	Electric work on new construction and machinery.
Maline Sewing Corp. (ILGWU).	Philadelphia, Pa.	Mar. 1, 1977	Feb. 28, 1977	TA-W-1,741	Sportswear.
Manchester Modes (company).	Manchester, Conn.	Feb. 14, 1977	Feb. 11, 1977	TA-W-1,742	Women's apparel.
Manchester Modes (company).	Somersville, Conn.	do	do	TA-W-1,743	Do.

Petitioner: union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Mauna Kea Sugar Co. (ILWU).	Papaikou, Hawaii.	Feb. 28, 1977	Feb. 23, 1977	TA-W-1,744	Raw sugar.
Michele Dress Co. (ILGWU).	Philadelphia, Pa.	do	Feb. 24, 1977	TA-W-1,745.	Dresses.
Miss Alta (workers)	Port Isabel, Tex.	Feb. 17, 1977	Feb. 11, 1977	TA-W-1,746.	Catching and selling of shrimp.
Miss Monica (company)	Brownsville, Tex.	do	do	TA-W-1,747.	Do.
Monique Sportswear (ILGWU).	Whittier, Calif.	Mar. 1, 1977	Feb. 14, 1977	TA-W-1,748.	Ladies' sportswear.
O'Keefe Drilling Co. (International Union of Operating Engineers).	Butte, Mont.	Feb. 28, 1977	Feb. 25, 1977	TA-W-1,749.	Exploratory and leach drilling in copper mine.
Paul Louis, Inc. (workers).	Peabody, Mass.	Feb. 23, 1977	Feb. 14, 1977	TA-W-1,750.	Leather jackets, coats, hats, vests, pocketbooks.
RCA Electronics Division, RCA Corp. (IBEW).	Bloomington, Ind.	Feb. 25, 1977	Feb. 21, 1977	TA-W-1,751.	Printed circuit boards, front and back control brackets, wafer lines VHF and UHF tuners, color, black and white chassis lines.
Republic Sportswear, Inc. (ACTWA).	Republic, Pa.	Feb. 28, 1977	Feb. 22, 1977	TA-W-1,752	Men's sportcoats.
Savini Dress	Belmar, N.J.	Feb. 17, 1977	Feb. 14, 1977	TA-W-1,753	Women's dresses and pants suits.
L. K. Shapiro Associates (ILGWU).	Los Angeles, Calif.	Mar. 1, 1977	do	TA-W-1,754	Ladies' coats and suits.
Susan Garment (ILGWU).	Philadelphia, Pa.	Feb. 28, 1977	Feb. 24, 1977	TA-W-1,755	Sportswear.
Terri Lee (ILGWU)	Upland, Calif.	Mar. 1, 1977	Feb. 14, 1977	TA-W-1,756	Ladies' coats and suits.
Tiffany & Co. (International Jewelry Workers Union).	Newark, N.J.	Feb. 25, 1977	Feb. 18, 1977	TA-W-1,757	Flatware, hollow-ware and trophies.
Trimfoot Co. (Boot & Shoe Workers Union).	Farmington, Me.	Feb. 23, 1977	do	TA-W-1,758	Infants' shoes.
True Form Foundations (ILGWU).	Darby, Pa.	Mar. 1, 1977	Feb. 28, 1977	TA-W-1,759	Women's underwear.
True Temper Corp. (ACTWU).	Anderson, S.C.	Feb. 27, 1977	Feb. 23, 1977	TA-W-1,760	Citizen band radios.
Wailuku Sugar Co. (ILWU).	Wailuku, Hawaii.	Feb. 28, 1977	Feb. 23, 1977	TA-W-1,761	Raw sugar.
Weider of Calif. (ILGWU).	North Hollywood, Calif.	Mar. 1, 1977	Feb. 14, 1977	TA-W-1,762	Ladies' coats and suits.
Whitin Machine Works, Inc. (U.S.A.).	Whitinsville, Mass.	Mar. 2, 1977	Feb. 21, 1977	TA-W-1,763	Textile preparatory machinery.

[FR Doc.77-8505 Filed 3-21-77;8:45 am]

[TA-W-1400]

KEYSTONE STEEL AND WIRE DIVISION OF KEYSTONE CONSOLIDATED INDUSTRIES, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1400: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on December 13, 1976 in response to a worker petition received on December 13, 1976 which was filed by the United Steelworkers of America on behalf of workers producing steel channels, fence posts, rail sections, merchant and reinforcing bars, and miscellaneous shapes at the Peoria, Illinois plant of Keystone Steel and Wire Division of Keystone Consolidated Industries, Inc.

The Notice of Investigation was published in the FEDERAL REGISTER on January 4, 1977 (42 FR 886). No public hearing was requested and none was held.

The information upon which the determination was made was obtained from the United Steelworkers of America and Keystone Consolidated Industries, Inc.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales, production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (1) has not been met.

The Peoria, Illinois plant of Keystone Steel and Wire Division produces studded tee steel fence posts, steel channels, small rail shape sections, merchant and reinforcing bars, and miscellaneous steel shapes.

Evidence developed in the Department's investigation reveals that no involuntary separations occurred from November 1, 1975, one year prior to the signature date of the petition, to the present.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that a significant number or proportion of the workers at the Peoria, Illinois plant of Keystone Steel and Wire Division of Keystone Consolidated Industries, Incorporated have not become totally or partially separated as required in section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8513 Filed 3-21-77;8:45 am]

[TA-W-1549]

K. P. HYDRAULICS CO.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1549: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on January 2, 1977 in response to a worker petition received on January 2, 1977 which was filed by the United Electrical, Radio and Machine Workers of America on behalf of workers and former workers producing hydraulic bottle jacks at the Hudson, Wisconsin plant of K. P. Hydraulics Company.

The notice of investigation was published in the FEDERAL REGISTER on January 28, 1977 (42 FR 5452). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of K. P. Manufacturing Company, K. P. Hydraulics Company and its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated,

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all four of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

Employees were first hired in the second quarter of 1974 when the Hudson plant opened. Employment increased throughout 1975. Employment terminated in 1976 when most of the workers were laid off as a result of the plant closure. Some workers remained after the closure to handle shutdown operations.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Production of hydraulic bottle jacks began in late 1974. Production continued throughout 1975. All production ceased at the end of 1976 when the plant closed.

INCREASED IMPORTS

Imports of hydraulic jacks in terms of value increased 31.7 percent in 1973 compared with 1972, increased 29.0 percent in 1974 compared with 1973; increased 4.3 percent in 1975 compared with 1974 and increased 7.6 percent in 1976 compared with 1975. The ratios of imports to domestic production and consumption increased from 247.7 percent and 71.7 percent, respectively, in 1975 to 263.5 percent and 73.3 percent, respectively, in 1976.

CONTRIBUTED IMPORTANTLY

K. P. Hydraulics Company was unable to reduce the prices of its jacks to be cost competitive with the imported jacks and therefore, lost its major customer in December 1976 to foreign producers. Faced with the lost of this customer and the inability to cut prices any further to generate new business, K. P. Hydraulics was closed. K. P. Manufacturing Company will import a limited number of jacks to service its remaining accounts.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with hydraulic bottle jacks formerly produced by K. P. Hydraulics Company in Hudson, Wisconsin contributed importantly to the total or partial separation of the workers of that plant. In accordance with the provisions of the Act, I make the following certification:

All workers engaged in employment related to the production of hydraulic bottle jacks at K. P. Hydraulics Company in Hudson, Wisconsin who became totally or partially separated from employment on or after December 1, 1976 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Dtrector, Office of Management, Administration and Planning.

[FR Doc.77-8514 Filed 3-21-77;8:45 am]

[TA-W-1580]

LINETT TAILLEURS, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1580: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on January 18, 1977 in response to a worker petition received on January 18, 1977 which was filed on behalf of workers and former workers producing men's suits and sport coats at Linett Tailleurs, Incorporated, New York, New York, a subsidiary of Linett, Ltd., New York, New York.

The notice of investigation was published in the FEDERAL REGISTER on January 28, 1977 (42 FR 5453). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Linett Tailleurs, Incorporated, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat therof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether the other criteria have been met, the investigation reveals that the first and second criteria have not been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of production workers employed at Linett Tailleurs declined 6.5 percent in 1975 compared to 1974 and then increased 20.9 percent in 1976 compared to 1975. Employment increased in every quarter of 1976 compared to like quarters in 1975.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales and production of suits and sport coats at Linett Tailleurs, adjusted for price changes, increased 7.5 percent in value in 1975 compared to 1974 and rose 11.4 percent in value in 1976 compared to 1975.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that a significant number or proportion of workers at Linett Tailleurs, Incorporated, New York, New York have not become totally or partially separated and that sales or production at the firm have not decreased absolutely as required for certification under Section 22 of the Trade Act of 1974.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 77-8515 Filed 3-21-77;8:45 am]

[TA-W-1620]

McGEE-KENYON, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1620: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 31, 1977 in response to a worker petition received on January 17, 1977 which was field by three workers on behalf of workers producing shoe patterns at McGee-Kenyon, Incorporated, New York, New York.

The notice of investigation was published in the FEDERAL REGISTER on February 18, 1977 (42 FR 10078). No public hearing was requested and none was held.

The information upon which the determination was made was obtained from the officials of McGee-Kenyon, Inc., publications of the U.S. Department of Commerce, American Footwear Association and information from the U.S. Customs Bureau.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) That a significant or proportion of the workers in such workers' firm or an appropriate subdivision of the firm have become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations or threat thereof; and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whehter any other criteria have been met, criterion (3) has not been met.

According to various industry sources there are no known quantities of imports of shoe patterns into the United States.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that imports of shoe patterns like or directly competitive with those produced at McGee-Kenyon, Incorporated have not increased as required in Section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8516 Filed 3-21-77;8:45 am]

[TA-W-1,233]

PIHER CORP., WOBURN, MASS.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance; Correction

In FR Doc. 77-3109 appearing at page 6022 in the FEDERAL REGISTER of February 1, 1977, the 10th line from the top of the first column, appearing on page 6023, is corrected by deleting the words "and before February 1, 1977" immediately after the word "1975."

Signed at Washington, D.C., this 15th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8517 Filed 3-21-77;8:45 am]

[TA-W-1583]

SHENANGO, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1583: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on January 18, 1976 in response to a worker petition received on January 18, 1976 which was filed by the United Steelworkers of America on behalf of workers producing cast iron molds at the Buffalo, New York plant of Shenango, Incorporated.

The Notice of Investigation was published in the FEDERAL REGISTER on January 28, 1977 (42 FR 5455). No public hearing was requested and none was held.

The information upon which the determination was made was obtained from the United Steelworkers of America and Shenango, Incorporated.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm or an appropriate subdivision of the firm have become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations or threat thereof; and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (1) has not been met.

The Buffalo, New York plant of Shenango, Incorporated produces cast iron molds.

Evidence developed in the Department's investigation reveals that no involuntary separations occurred from December 27, 1975, one year prior to the signature date of the petition, to the present.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that a significant number or proportion of the workers at the Buffalo, New York plant of Shenango, Incorporated have not become totally or partially separated as required in section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8518 Filed 3-21-77;8:45 am]

[TA-W-1569]

SOUTH END TRANSPORTATION, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1569: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on January 11, 1977 in response to a worker petition received on that date which was filed on behalf of workers and former workers at South End Transportation, Incorporated, Trout Creek, Michigan.

The Notice of Investigation was published in the FEDERAL REGISTER on January 28, 1977 (42 FR 5455). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of South End Transportation, Incorporated and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or produtcion, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

If any of the above criteria is not satisfied a negative determination must be made.

South End Transportation, Incorporated, Trout Creek, Michigan, does not produce an article within the meaning of Section 222(3) of the Act, and this Department has already determined that the performance of services is not covered by the adjustment assistance program. See Notice of Determination in *Pan American World Airways, Incorporated* (TA-W-153, 40 FR 54639). The only question in this case is whether the White Pine Copper Company, i.e., a firm which produces an article, namely refined copper, and for whom the services are provided, can be considered the "workers' firm". The Department has also previously determined that an independent firm for whom such services are provided cannot be considered the "worker's firm". See Notice of Determination in *Nu-Car Driveway, Incorporated* (TA-W-393, 41 FR 12749).

South End Transportation was founded in 1969 and is licensed as a common carrier by the State of Michigan. Workers at South End Transportation maintain and drive three large passenger buses and a passenger van. South End Transportation owns the facilities at Trout Creek and owns the passenger vehicles. South End Transportation does not produce any finished goods.

South End Transportation is primarily engaged in providing transportation services for workers of the White Pine Copper Company who commute to and from their jobs at White Pine, Michigan. South End Transportation has no business contracts, common ownership, investment, or any other affiliations with either the White Pine Copper Company or its parent firm Copper Range. All employees involved in providing transportation services for White Pine workers are employed and paid by South End Transportation.

CONCLUSION

After careful review of the issues and facts involved, I have determined that services of the kind provided by South End Transportation, Incorporated, Trout Creek, Michigan are not "articles" within the meaning of Section 222(3) of the Trade Act of 1974, and that the White Pine Copper Company cannot be considered the "workers' firm". The petition for trade adjustment assistance is, therefore, denied.

Signed at Washington, D.C., this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8519 Filed 3-21-77;8:45 am]

[TA-W-1250]

TERRACE FOOTWEAR, INC.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1250: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on November 9, 1976 in response to a worker petition received on November 9, 1976 which was filed on behalf of workers and former workers producing women's casual footwear at the Norwalk, Connecticut plant of Terrace Footwear, Incorporated.

The notice of investigation was published in the FEDERAL REGISTER on November 23, 1976 (41 FR 51634). No public hearing was requested, and none was held.

The information upon which the determination was made was obtained principally from officials of Terrace Footwear, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation revealed that all of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of production workers declined 16.1 percent in the third quarter of 1976 compared to the third quarter of 1975. All production workers were laid off on October 29, 1976 when the plant was shut down.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales declined 56.2 percent in the third quarter of 1976 compared to the second quarter of 1976. Sales ceased on October 29, 1976 when the plant was shut down.

INCREASED IMPORTS

U.S. imports of women's and misses' nonrubber footwear were 185.0 million pairs in 1971 and increased to 204.2 million pairs and 218.4 million pairs, respectively, in 1972 and 1973.

U.S. imports declined to 187.6 million pairs in 1974 and increased to 190.7 million pairs in 1975. U.S. imports increased from 89.5 million pairs in the first half of 1975 to 109.5 million pairs in the first half of 1976.

CONTRIBUTED IMPORTANTLY

A survey of Terrace Footwear's single largest customer, representing approximately 80 percent of Terrace Footwear's sales in 1975 and 1976 indicated that this customer now purchases the type of shoes which were manufactured by Terrace Footwear from foreign sources, exclusively.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women's casual footwear contributed importantly to the total or partial separations of the workers at that plant. In accordance with the provisions of the Act, I make the following certification:

All workers engaged at the Norwalk, Connecticut plant of Terrace Footwear, Incorporated who became totally or partially separated from employment on or after July 1, 1976 and on or before October 30, 1976 are eligible to apply for adjustment assistsance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 11th day of March 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc.77-8520 Filed 3-21-77;8:45 am]

LEGAL SERVICES CORPORATION

LEGAL AID SOCIETY OF OMAHA/COUNCIL BLUFFS

Grants and Contracts; Application

MARCH 16, 1977.

The Legal Services Corporation was established pursuant to the Legal Services Corporation Act of 1974, Pub. L. 93-355, 88 Stat. 378, 42 U.S.C. 2996-2996*l*. Section 1007(f) provides: "At least thirty days prior to the approval of any grant application or prior to entering into a contract or prior to the initiation of any other project, the Corporation shall announce publicly, and shall notify the Governor and the State Bar Association of any State where legal assistance will thereby be initiated, of such grant, contract, or project * * *."

The Legal Services Corporation hereby announces publicly that it is considering the grant application submitted by: Legal Aid Society of Omaha/Council Bluffs, Omaha, Nebraska to serve the counties of Dodge and Washington.

Interested persons are hereby invited to submit written comments or recommendations concerning the above application to the Regional Office of the Legal Services Corporation at:

Chicago Regional Office, 310 South Michigan Avenue, 24th Floor, Chicago, Illinois 60604.

THOMAS EHRLICH,
President.

[FR Doc.77-8444 Filed 3-21-77;8:45 am]

NEIGHBORHOOD LEGAL SERVICES

Grants and Contracts; Application

MARCH 16, 1977.

The Legal Services Corporation was established pursuant to the Legal Services Corporation Act of 1974, Pub. L. 93-355, 88 Stat. 378, 42 U.S.C. 2996-2996*l*. Section 1007(f) provides: "At least thirty days prior to the approval of any grant application or prior to entering into a contract or prior to the initiation of any other project, the Corporation shall announce publicly, and shall notify the Governor and the State Bar Association of any State where legal assistance will thereby be initiated, of such grant, contract, or project * * *".

The Legal Services Corporation hereby announces publicly that it is considering the grant application submitted by: Neighborhood Legal Services, Charleston, South Carolina to serve the counties of Beaufort, Jasper and Colleton.

Interested persons are hereby invited to submit written comments or recommendations concerning the above applications to the Regional Office of the Legal Services Corporation at:

Atlanta Regional Office, 615 Peachtree Street, N.E., Room 503, Atlanta, GA 30308.

THOMAS EHRLICH,
President.

[FR Doc.77-8445 Filed 3-21-77;8:45 am]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 77-20]

SPACE PROGRAM ADVISORY COUNCIL (SPAC) APPLICATIONS COMMITTEE

Meeting

The NASA SPAC Applications Committee will meet on April 27, 1977, at NASA Headquarters, Federal Office Building 10B, Room 226A, 600 Independ-

ence Avenue, SW, Washington, DC. Members of the public will be admitted to the meeting at 9:00 a.m. on a first-come, first-served basis. The seating capacity of the room is 35 people. Visitors will be requested to sign a visitor's register.

The NASA SPAC Applications Committee serves in an advisory capacity only. It is concerned with the total range of applications of space-derived, space-related technology including communications, meteorology, earth resources survey (includes agriculture/forestry, cartography, geography, geology/hydrology, oceanography), earth and ocean physics, solar energy conversion, space processing, and other technology applications. Currently the Committee compromises 12 members including the Chairman, Mr. Thomas Rogers.

For further information regarding the meeting, please contact Mr. Louis B. C. Fong, Washington, D.C., (202 755-8617. The approved agenda for the meeting on April 27, 1977, is as follows:

Time	*Topic*
9:00 a.m.	Opening Remarks by Chairman.
9:30 a.m.	Search and Rescue Satellite Program. As a followup action to the meeting on Feb. 28, 1977, this program, which is an interagency effort under the Interagency Committee on Search and Rescue (ICSAR), will be reviewed for members' recommendations and comments. ICSAR consists of representations from the Departments of Commerce, Defense, Transportation, the Federal Communications Commission, and NASA.
10:30 a.m.	Satellite Telecommunications Program. A preliminary report on its findings and recommendations will be given by the ad hoc informal Subcommittee on Satellite Telecommunications.
4:00 p.m.	Adjourn.

JOHN M. COULTER,
Acting Assistant Administrator for Department of Defense and Interagency Affairs.

MARCH 16, 1977.

[FR Doc.77-8414 Filed 3-21-77;8:45 am]

OFFICE OF THE FEDERAL REGISTER

"SUNSHINE ACT" MEETING NOTICES

90-Day Trial Program

AGENCY: Office of the Federal Register, GSA.

ACTION: Notice.

SUMMARY: This notice announces a 90-day trial program of special handling and formatting for "Government in the Sunshine Act" meeting notices. The program is intended to provide the public with information about these meetings as quickly as possible and in a simple and very usable form.

DATES: Trial program begins: March 22, 1977. Trial program ends: June 20, 1977.

ADDRESS: Send letters to: Samuel Jacobs, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT:

Samuel Jacobs (address as shown above) 202-523-5240.

SUPPLEMENTARY INFORMATION: On March 12, the "Government in the Sunshine Act" became effective. Under that Act, many Federal agencies are required to publish in the FEDERAL REGISTER a notice of each meeting that the agency holds (5 U.S.C. 552b(e)(3). This notice must state the time, date, place, and subject matter of the meeting; whether it is open or closed to the public; and the name and phone number of a person to contact for more information. To make it easier to find out about "Sunshine Act" meetings, the Office of the Federal Register (OFR) will publish these notices in a new section of the FEDERAL REGISTER. The first page of this section will be captioned with the title "Sunshine Act Meetings" and will contain a standard brief introductory paragraph. Following this paragraph will be a listing of the individual meeting notices.

The OFR will place each "Sunshine Act" notice on public inspection immediately upon receipt.

Affected agencies are invited to participate in a 90-day trial program designed to simplify preparation and transmittal of these notices and to provide the public with information about meetings in a usable format as quickly as possible. The program has three parts: (1) Agencies preparing the notices in a standard format, (2) agencies using facsimile equipment to transmit the notices to the OFR, and (3) the OFR publishing the notices on a two-day schedule.

STANDARDIZED FORMAT

The OFR has developed three format variations covering the types of announcements that an agency may be publishing: Format Number 1 for announcing a meeting that is either completely open to the public or completely closed to the public. Format Number 2 for announcing a meeting that is partially open to the public and partially closed to the public. Format Number 3 for announcing a change in a previously announced meeting. See Attachments 1, 2, and 3 for the specifics of each format. All agencies are urged to submit meeting notices in the appropriate standard format. Agencies transmitting notices by facsimile equipment must use the appropriate standard format.

FACSIMILE EQUIPMENT

The OFR will accept meeting notices submitted in the appropriate format via facsimile equipment. Using facsimile equipment a typed page can be transmitted over normal telephone lines in four or six minutes. We have facsimile equipment that is compatible with most models now in use (contact our office for a list of the equipment compatible with our machine). Agencies transmitting "Sunshine Act" notices to the OFR using facsimile equipment will be required to transmit only one copy of the notice instead of the original and two duplicates that we normally require.

In addition, we will not require a signature on notices submitted via facsimile equipment. We strongly urge agencies sending meeting notices via facsimile equipment to limit their notices to one page each.

Agencies using facsimile equipment will be given a special telephone number devoted solely to facsimile transmissions. To insure that only authentic notices are transmitted, agencies will be asked to designate the person or persons authorized to transmit notices.

The OFR feels that using facsimile equipment will benefit participating agencies and the public because it will expedite the publication process. In addition, using this method will result in a significant savings of energy, since agencies will not need to use messengers to transmit these notices. However, agencies not using facsimile equipment may transmit "Sunshine Act" meeting notices by normal means (i.e., by messenger or through the mails). The OFR will publish notices that conform to the appropriate standards format on a two-day publication schedule.

2-DAY PUBLICATION SCHEDULE

Normally the FEDERAL REGISTER operates on a three-day publication schedule. That is, a document appears in the FEDERAL REGISTER on the third work day after it is received at our office. However, we will publish the notices of "Sunshine Act" meetings of agencies using the appropriate standardized format on a two-day schedule. Notices must be at the OFR by 11:30 a.m. two working days before publication. In other words, if we receive—either via facsimile or normal means—a notice on Monday by 11:30 a.m., it will appear in Wednesday's FEDERAL REGISTER. We are able to offer this abbreviated schedule because the standardized format will enable our editors to process the notices more quickly.

WHAT THE AGENCY MUST DO

Any Federal agency that wants to participate in this program, should send us a letter indicating the agency's intention to participate and asking us to publish its unsigned notices submitted via facsimile (where that is the case) for the 90-day trial period.

Agencies that will use facsimile equipment, should include the names of the person or persons authorized to transmit meeting notices. The letter should state further that the agency agrees to read each of its "Sunshine Act" meeting notices published in the FEDERAL REGISTER and to notify us at once if there are any errors in the notice. This letter should be signed by the officer who would nor-

mally sign the agency's meeting notice. The letter should be addressed to:

Office of the Federal Register, National Archives and Records Service (GSA), Washington, DC 20408, ATTN: Samuel Jacobs.

Upon receipt of an agency's letter, we will provide that agency with the telephone number designated for facsimile transmission and that agency may begin using this service.

This program is completely voluntary. We will accept notices of "Sunshine Act" meetings in any reasonable format submitted using the normal means and include these in the "Sunshine Act Meetings" section of the FEDERAL REGISTER. These will be published on a three-day schedule. We will not accept any notice via facsimile equipment that does not strictly conform to the appropriate standard format.

The program will operate for a 90-day trial period. After three months we will evaluate the program and if it is working well and to everyone's advantage, we will continue the program on a more permanent basis.

FRED J. EMERY,
Director of the Federal Register.

ATTACHMENT 1

AGENCY HOLDING THE MEETING:

TIME AND DATE:

PLACE:

STATUS:

MATTERS TO BE CONSIDERED:

CONTACT PERSON FOR MORE INFORMATION:

ATTACHMENT 2

AGENCY HOLDING THE MEETING:
TIME AND DATE:
PLACE:
STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.
MATTERS TO BE CONSIDERED: Portions open to the public:
...
...
...
Portions closed to the public:
...
...
...
CONTACT PERSON FOR MORE INFORMATION:

ATTACHMENT 3

AGENCY HOLDING THE MEETING:
FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT:
PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:
CHANGES IN THE MEETING:

[FR Doc.77-8438 Filed 3-21-77;8:45 am]

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

SUNSHINE ACT

Meeting

In accordance with 29 CFR 2203.3(d)(1) (regulations under The Government in The Sunshine Act), announcement is made of the following Commission meeting:

Date: March 25, 1977.
Place: Room 1101, 1825 K Street NW., Washington, D.C.
Time: 9:30 a.m.
Proposed agenda: Discussion of possible revisions in the Commission's Rules of Procedure.

This meeting will be open.

Mrs. Nori Heuberger, (202) 634-7970 and Ms. Lottie Richardson (same phone number), have been designated to respond to inquiries about this meeting.

Dated: March 16, 1977.

For the Commission.

PAUL R. WALLACE,
Counsel to the Commission.

[FR Doc.77-8439 Filed 3-21-77;8:45 am]

OFFICE OF THE SPECIAL REPRESENTATIVE FOR TRADE NEGOTIATIONS

ADVISORY COMMITTEE FOR TRADE NEGOTIATIONS

Request for Public Comment in Review

In accordance with Section 7(b) of the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. V, 1975), the Office of the Special Representative for Trade Negotiations (STR) will conduct an annual review of the Advisory Committee for Trade Negotiations (the Committee). By order of the President, a zero-based review of every executive advisory committee is to be undertaken, with the presumption that all committees should be abolished except those (1) for which there is a compelling need; (2) which have a truly balanced membership; and (3) which conduct their business as openly as possible, consistent with the law and their mandate. Based on this review, a determination is to be made whether to continue, merge, terminate, or revise responsibilities of each advisory committee. The STR is required to submit a report on the results of this review to the Office of Management and Budget by April 15, 1977.

The Trade Act of 1974 required establishment of an Advisory Committee for Trade Negotiations to provide overall advice on certain trade agreements referred to in Section 135 of the Trade Act (19 U.S.C. 2255). The Committee is composed of 45 individuals drawn from government, labor, industry, agriculture, small business, service industries, retailers, consumer interests, and the general public. Members of the Committee are appointed by the President for a period of two years and may be reappointed for additional periods.

The Committee is chaired by the Special Representative for Trade Negotiations and meets at his request. The STR is authorized to make available to the Committee such staff, information, personnel, and administrative services and assistance as it may reasonably require to carry out its activities.

The Committee provides advice to the President, the Congress, and to United States negotiators on the multilateral trade negotiations presently underway in Geneva. Public access to meetings of the Committee has been restricted pursuant to 5 U.S.C. 552(b)(1), since disclosure of information discussed in such meetings could seriously harm U.S. foreign policy interests.

The Committee shall terminate as soon as practical after January 3, 1980, upon submission of reports required under Section 135(e)(2) of the Trade Act of 1974.

Comments, or requests for further information, should be directed to Phyllis O. Bonanno, Executive Secretary for the Advisory Committee for Trade Negotiations, 1800 G Street, N.W., Washington, D.C., 20506, no later than April 5, 1977.

PAUL T. O'DAY,
Assistant Special Representative for Trade Negotiations.

MARCH 16, 1977.

[FR Doc.77-8416 Filed 3-21-77;8:45 am]

SUGAR

Solicitation of Public Views

Pursuant to section 201 of the Trade Act of 1974, the United States International Trade Commission (USITC) has reported to the President on the case of sugar (Investigation No. TA-201-16). On March 18, 1977 the STR received the USITC report containing an affirmative determination that sugar, sirups, and molasses, derived from sugar cane or sugar beets, provided for in TSUS item 155.20 and 155.30 are being imported in such increased quantities as to be a substantial cause of the threat of serious injury to the domestic industry producing articles like or directly competitive with the imported articles.

The Commission[1] finds and recommends that the imposition of a quantitative restriction in the aggregate amount of 4,275,000 short tons, raw value, should be established on sugars, sirups and molasses provided for in items 155.20 and 155.30 of the TSUS, for calendar year 1977, and for each calendar year thereafter, up to and including 1981. The Commission further recommended that such annual quota be allocated among supplying countries on a basis determined by the President to be equitable.

[1] Commissioners Parker, Moore, and Bedell.

Within 60 days of receiving a report from the USITC containing an affirmative determination, the President must determine what method and amount of import relief he will provide or determine that the provision of relief is not in the national economic interest, and whether he will direct expeditious consideration of adjustment assistance petitions.

In determining whether to provide import relief and what method and amount of import relief he will provide, the President must take into account, in addition to other considerations, the following factors:

(1) the probable effectiveness of the import relief as a means to promote adjustment, the efforts being made or to be implemented by the industry concerned to adjust to import competition, and other considerations relevant to the position of the industry in the nation's economy;

(2) the effect of import relief on consumers and on competition in the domestic markets for such articles;

(3) the effect of import relief on the international economic interest of the United States;

(4) the impact on United States industries and firms as a consequence of any possible modification of duties or other import restrictions which may result from international obligations with respect to compensation;

(5) the geographic concentration of imported products marketed in the United States;

(6) the extent to which the United States market is a focal point for exports of such article by reason of restraints on exports of such article to, or on imports of such article into, third country markets;

(7) the economic and social costs which would be incurred by taxpayers, communities and workers if import relief were or were not provided.

The Office of the Special Representative for Trade Negotiations chairs the interagency Trade Policy Committee structure that makes recommendations to the President as to what action, if any, he should take on reports submitted by the USITC under section 201 (d). In order to assist the Trade Policy Staff Committee in developing information on possible action which may be taken under section 202 and 203 of the Trade Act of 1974, the Committee welcomes briefs from interested parties on the above listed subjects. (Further information on this case is available in the Report of the USITC on Sugar—Investigation No. TA-201-16).

Briefs should be submitted in twenty (20) copies to Chairman, Trade Policy Staff Committee, Room 728, Office of the Special Representative for Trade Negotiations, 1800 G Street, N.W., Washington, D.C. 20506.

To be considered by the Trade Policy Staff Committee, submissions should be received in the Office of the Special Representative for Trade Negotiations no later than April 6, 1977.

WILLIAM B. KELLY,
Chairman, Trade Policy Staff Committee.

[FR Doc.77-8655 Filed 3-21-77;8:45 am]

RENEGOTIATION BOARD

MEETING; CHANGE IN PUBLIC ANNOUNCEMENT

Pursuant to RBR 1482.3(b) of its regulations, the Renegotiation Board hereby announces that the date of its meeting originally scheduled for March 15, 1977, as announced in the FEDERAL REGISTER of March 9, 1977 (42 FR 13167-8), and subsequently changed to March 22, 1977, as announced in the FEDERAL REGISTER of March 15, 1977 (42 FR 14187), is further changed to March 29, 1977.

Dated: March 16, 1977.

GOODWIN CHASE,
Administrator.

[FR Doc.77-8415 Filed 3-21-77;8:45 am]

SMALL BUSINESS ADMINISTRATION

LITTLE ROCK DISTRICT ADVISORY COUNCIL

Public Meeting

The Small Business Administration Little Rock District Advisory Council will hold a public meeting at 1:30 p.m., Thursday, April 7, 1977, in the 10th Floor Conference Room, Blue Cross-Blue Shield Building, 7th and Gaines Streets, Little Rock, Arkansas, to discuss such matters as may be presented by members, staff of the Small Business Administration, or others present. For further information, write or call Maurice Britt, District Director, U.S. Small Business Administration, P.O. Box 1401, Little Rock, Arkansas 72203 (501) 740-5871.

Dated: March 10, 1977.

ANTHONY S. STASIO,
Acting Assistant Administrator for Advocacy and Public Communications.

[FR Doc.77-8447 Filed 3-21-77;8:45 am]

LOWER RIO GRANDE VALLEY DISTRICT ADVISORY COUNCIL

Public Meeting

The Small Business Administration Lower Rio Grande Valley District Advisory Council will hold a public meeting at 9:30 a.m. Tuesday, April 19, 1977, at the Kleberg First National Bank, 200 E. Kleberg, Kingsville, Texas, to discuss such matters as may be presented by members, staff of the Small Business Administration, or others present. For further information, write or call James R. Woodall, District Director, U.S. Small Business Administration, P.O. Box 2567, Harlingen, Texas 78550, (512) 734-4533.

Dated: March 10, 1977.

ANTHONY S. STASIO,
Acting Assistant Administrator for Advocacy and Public Communications.

[FR Doc.77-8451 Filed 3-21-77;8:45 am]

OKLAHOMA CITY DISTRICT ADVISORY COUNCIL

Public Meeting

The Small Business Administration Oklahoma City District Advisory Council will hold a public meeting from 8:00 a.m. until 4:30 p.m., Friday, April 15, 1977 at the Southgate Inn, 5245 S. 135, Oklahoma City, Oklahoma, to discuss such matters as may be presented by members, staff of the Small Business Administration, or others present. For further information, write or call Truman Branscum, District Director, U.S. Small Business Administration, Suite 840, 50 Penn Place, Oklahoma City, Oklahoma 73116, (405) 736-5237.

Dated: March 16, 1977.

ANTHONY S. STASIO,
Acting Assistant Administrator for Advocacy and Public Communications.

[FR Doc.77-8450 Filed 3-21-77;8:45 am]

SALT LAKE CITY DISTRICT ADVISORY COUNCIL

Public Meeting

The Salt Lake City District Advisory Council will hold a public meeting at 9:30 a.m., Friday, April 15, 1977 in the Conference Room of the Chamber of Commerce, 52 West 2nd North, Logan, Utah, to discuss such matters as may be presented by members, staff of the Small Business Administration, or others present. For further information, write or call Clair R. Hopkins, District Director, U.S. Small Business Administration, 2237 Federal Building, Salt Lake City, Utah 84138 (801) 524-5804.

Dated: March 14, 1977.

ANTHONY S. STASIO,
Acting Assistant Administrator for Advocacy and Public Communications.

[FR Doc. 77-8452 Filed 3-21-77;8:45 am]

SAN ANTONIO DISTRICT ADVISORY COUNCIL

Public Meeting

The Small Business Administration San Antonio District Advisory Council will hold a public meeting at 9:00 a.m., Friday, April 15, 1977, at the Hilton Hotel, Riverside Mall, Laredo, Texas 78040, to discuss such matters as may be presented by members, staff of the Small Business Administration, or others pres-

ent. For further information, write or call James S. Reed, 727 East Durango, San Antonio, Texas 78206 (512) 229–6268.

Dated: March 15, 1977.

ANTHONY S. STASIO,
Acting Assistant Administrator for Advocacy and Public Communications.

[FR Doc.77-8448 Filed 3-21-77;8:45 am]

SEATTLE DISTRICT ADVISORY COUNCIL

Public Meeting

The Small Business Administration Seattle District Advisory Council will hold a public meeting at 9:00 a.m., Thursday, April 21, 1977, in the Federal Building, 915 Second Avenue, Seattle, Washington 98174, to discuss such matters as may be presented by members, staff of the Small Business Administration, or others present. For further information, write or call Robert F. Caldwell, District Director, U.S. Small Business Administration, at the above address, (206) 399–7791.

Dated: March 14, 1977.

ANTHONY S. STASIO,
Acting Assistant Administrator for Advocacy and Public Communications.

[FR Doc.77-8449 Filed 3-21-77;8:45 am]

[Declaration of Disaster Loan Area No. 1282; Amdt No. 1]

MINNESOTA

Declaration of Disaster Loan Area

The above numbered Declaration (See 42 FR 4567), is amended by extending the filing date for physical damage until the close of business on April 18, 1977, and for economic injury until the close of business on November 18, 1977.

Dated: March 15, 1977.

ROGER H. JONES,
Acting Administrator.

[FR Doc.77-8522 Filed 3-21-77;8:45 am]

[Declaration of Disaster Loan Area No. 1304]

NEW YORK

Declaration of Disaster Loan Area

Rockland County and adjacent Counties within the State of New York, constitute a disaster area because of damage resulting from flash flooding which occurred on February 24–25, 1977. Eligible persons, firms and organizations may file applications for loans for physical damage until the close of business on May 16, 1977, and for economic injury until the close of business on December 15, 1977, at:

Small Business Administration, District Office, 26 Federal Plaza, Room 3100, New York, New York 10007.

or other locally announced locations.

Dated: March 15, 1977.

ROGER H. JONES,
Acting Administrator.

[FR Doc.77-8523 Filed 3-21-77;8:45 am]

DEPARTMENT OF STATE

[Public Notice 531]

CULTURALLY SIGNIFICANT PAINTINGS FROM THE UNION OF SOVIET SOCIALIST REPUBLICS

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), Executive Order 11312 of October 14, 1966 (31 FR 13415, October 18, 1966) and delegation of authority number 113 of December 23, 1966 (32 FR 58, January 5, 1967), I hereby determine that (1) the paintings described in the list filed as a part of this determination[1] imported from the Union of Soviet Socialist Republics pursuant to a loan agreement between the Ministry of Culture of the USSR and Mr. Thomas Hoving on behalf of the Metropolitan Museum of Art and the Fine Arts Museum of San Francisco for temporary exhibition without profit within the United States are of cultural significance and that (2) the temporary exhibition or display of such paintings entitled "Russian and Soviet Paintings—Icons to the Present" at the Metropolitan Museum of Art in New York City on or about April 13, 1977, to on or about June 26, 1977, and at the Fine Arts Museum of San Francisco, California on or about August 6, 1977, to on or about October 9, 1977, is in the national interest.

Public notice of this determination is ordered to be published in the FEDERAL REGISTER.

WILLIAM K. HITCHCOCK,
Acting Assistant Secretary for Educational and Cultural Affairs.

MARCH 15, 1977.

[FR Doc.77-8475 Filed 3-18-77;10:30 am]

[1] List of and description of 155 paintings from the Union of Soviet Socialist Republics filed as a part of the original document.

DEPARTMENT OF THE TREASURY

Office of the Commissioner of Customs

ANTIDUMPING DUTIES—TANTALUM ELECTROLYTIC FIXED CAPACITORS

AGENCY: United States Customs Service.

ACTION: Notice of petition filed by American manufacturer, producer or wholesaler.

SUMMARY: This notice is to advise the public that a petition has been filed by an American manufacturer requesting that antidumping duties be assessed with regard to tantalum electrolytic fixed capacitors from Japan. Interested persons are invited to comment on this action.

EFFECTIVE DATE: This notice is effective on March 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Michael Lublinska, Classification and Value Division, U.S. Customs Service, 1301 Constitution Avenue, N.W., Washington, D.C. 20229 (202–566–2938).

On February 3, 1977, a petition was received in proper form, pursuant to section 516(a) of the Tariff Act of 1930, as amended by the Trade Act of 1974 (19 U.S.C. 1516(a)), from counsel acting on behalf of Sprague Electric Company, asserting that a finding of dumping be issued and antidumping duties be assessed on those entries of tantalum electrolytic fixed capacitors from Japan where it has been determined that sales were being made at prices less than the foreign market (or constructed) value, within the meaning of the Antidumping Act of 1921, as amended (19 U.S.C. 160 et seq.). As a result of a negative determination of injury rendered by the International Trade Commission on October 29, 1976 (41 FR 47604), a finding of dumping was not made in this matter, and therefore merchandise of the class or kind in question was not subject to appraisement under the Antidumping Act.

The petition requested the following relief:

1. The Secretary of the Treasury or his delegate should conclude that the International Trade Commission erred, as a matter of law, when it determined that an industry in the United States was not being injured and was not likely to be injured, and was not prevented from being established, by reason of imports of tantalum electrolytic fixed capacitors from Japan sold at less than fair value ("LTFV");

2. The Secretary of the Treasury or his delegate should publish a finding of dumping with respect to tantalum electrolytic fixed capacitors from Japan forthwith;

3. Appropriate Customs officers should make Antidumping Act appraisements [foreign market (or constructed) value and purchase (or exporter's sales) price] for every entry of tantalum electrolytic fixed capacitors from Japan; and

4. Appropriate Customs officers should assess antidumping duties on those entries of tantalum electrolytic fixed capacitors from Japan where it has been determined that the foreign market (or constructed) value exceeds the purchase (or exporter's sales) price.

In accordance with the provsions of § 175.21(a) of the Customs Regulations (19 CFR 175.21(a)), notice is hereby given that a domestic producer has filed a petition requesting that antidumping duties be assessed with regard to tantalum electrolytic fixed capacitors from Japan. Before a decision is made with regard to this petition, consideration will be given to any relevant data, views or arguments submitted in writing. Submissions should be addressed to the Commissioner of Customs, 1301 Constitution Avenue, N.W., Washington, D.C. 20229, in time to be received by his office not later than March 28, 1977.

Written submissions will be available for public inspection in accordance with section 103.8(b) of the Customs Regula-

tions (19 CFR 103.8(b)), at the Classification and Value Division, Headquarters, United States Customs Service, Washington, D.C., during regular business hours.

VERNON D. ACREE,
Commissioner of Customs.

MARCH 16, 1977.

[FR Doc.77-8466 Filed 3-21-77;8:45 am]

Office of the Secretary

ADVISORY COMMITTEE ON PRIVATE PHILANTROPY AND PUBLIC NEEDS

Notice of Meeting

Notice is hereby given that a meeting of the advisory Committee on Private Philanthropy and Public Needs will be held on Thursday, April 7, 1977, beginning 10:45 a.m. and ending 3:15 p.m. approximately. The meeting will be held in Room 4119, Main Treasury Building, 15th and Pennsylvania Avenue, N.W., Washington, D.C.

The Agenda of the meeting, subject to change, is as follows:

1. Relationship of the Committee to the Treasury.
2. Tax Reform: Simplification and Public Accountability in the Philanthropic Area.
3. Design of a "Truth in Charitable Solicitation" Proposal.

The meeting will be open to the public. Public attendance must be arranged in advance because space in the room is limited and admission to the Main Treasury Building is restricted. Request for public attendance should be made no later than April 5 by phone to Nancy Kawtoski (202-566-5911). Admission will be granted in order of receipt of request.

J. ELTON GREENLEE,
Acting Assistant Secretary (Administration).

[FR Doc.77-8557 Filed 3-21-77;8:45 am]

NUCLEAR REGULATORY COMMISSION

MEETINGS DURING THE WEEK OF MARCH 14, 1977

Change Notice

In accordance with the requirements of the Government in the Sunshine Act and the Commission's Rules implementing the Act, this Notice identifies changes in the meeting announcements covering meetings for the week of March 14, 1977.

CHANGES

FRIDAY, MARCH 18

On Friday, March 18, the Commission voted unanimously to close the following additional meeting: 11:30 a.m. Discussion of Midland Opinion. (Authority to close: 5 U.S.C. 552b(d)(1) and 5 U.S.C. 552b(c)(10) and 9.105(a) and 9.104(a)(10) of the Commission's Rules).

The Commission will consider a formal agency adjudication presently before the Commission.

Those persons expected to be present are: The Commissioners and their staff, P. Strauss, the General Counsel, and members of his office, B. Huberman, the Director of Policy Evaluation and members of his staff, and S. Chilk, the Secretary and members of his staff. One or more persons may also attend to operate the recording or transcribing equipment used to make a record of the meeting.

By unanimous vote on March 18, 1977, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and § 9.107(a) of the Commission's Rules that Commission business requires that this agenda item be held on less than one week's notice to the public.

The meeting will be held in the Commissioners' Conference Room, 1717 H Street, N.W., Washington, D.C. For further information, contact Walter Magee, Office of the Secretary, telephone: 634-1410.

Dated at Washington, D.C., this 18th day of March, 1977.

For the Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc.77-8668 Filed 3-21-77;10:12 am]

MEETINGS DURING THE WEEK OF MARCH 21, 1977

Change Notice

In accordance with the requirements of the Government in the Sunshine Act and the Commission's Rules implementing the Act, this Notice identifies changes in the meeting announcements of March 14 and 15, covering meetings for the week of March 21, 1977. The changes are necessitated by the scheduling of Congressional testimony by Commissioners during that week.

CHANGES

MONDAY, MARCH 21

The items scheduled at 10:00 a.m. (Briefing on Arrangement with the Executive Branch on Nuclear Export Functions), at 1:30 p.m. (Commission Legislative Program) and at 2:30 p.m. (NRC and International Physical Protection Standards) are cancelled.

The following open and closed meetings, originally scheduled for Tuesday, March 22, have been moved forward and added to Monday's schedule: 1:30 p.m., Discussion of Seabrook Opinion (closed meeting), 2:30 p.m., Discussion of Hartsville (closed meeting).

TUESDAY, MARCH 22

The items csheduled for 10:00 a.m. (Briefing on Resident Inspector Program) and for 11:00 a.m. (Briefing on Status of GESMO) are cancelled. The item scheduled for 12:00 Noon (Affirmation of Action on FOIA Appeal) was affirmed in a Public Meeting, March 18, 1977.

ADDITIONAL CLOSED MEETING

On Friday, March 18, 1977, the Nuclear Regulatory Commission (all members participating) voted unanimously to hold the following closed meeting:

TUESDAY, MARCH 22

10:00 a.m., Discussion of Proposed Congressional Testimony on S. 897—The Nuclear Nonproliferation Act of 1977. (Authority to close: 5 U.S.C. 552(d)(1) and 5 U.S.C. 552b(c)(9)(B) and § 9.105(a) and 9.104(a)(9).)

The meeting will onclude discussion of proposed Congressional testimony.

Attendees will include the Commissioners and their staff, P. Strauss, the General Counsel, and members of his office, B. Huberman, the Director of the Office of Policy Evaluation, and members of his staff, H. Shapar, the Executive Legal Director, and members of his staff, James Shea and Michael Guhin of the Commission's Office of International Programs, and S. Chilk, the Secretary, and members of his staff. One or more persons may also attend to operate the recording or transcribing equipment used to make a record of the meeting.

By unanimous vote on March 18, 1977, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and § 9.107(a) of the Commission's Rules that Commission business requires that this agenda item be held on less than one week's notice to the public.

The meeting will be held in the Commissioners' Conference Room, 1717 H Street, N.W., Washington, D.C. For further information, contact Walter Magee, Office of the Secretary, telephone: 634-1410.

A revised Schedule of Meetings for the week is attached.

Dated at Washington, D.C., this 18th day of March 1977.

For the Commission.

JOHN C. HOYLE,
Assistant Secretary of the Commission.

MEETINGS, WEEK OF MARCH 21

Revised

MONDAY, MARCH 21

11:00 a.m., Tarapur: Consolidation of Other Aspects (Closed Meeting). 1:30 p.m., Discussion of Seabrook Opinion (Closed Meeting). 2:30 p.m., Discussion of Hartsville (Closed Meeting).

TUESDAY, MARCH 22

10:00 a.m., Discussion of Proposed Congressional Testimony (Closed Meeting.

(Wednesday, Thursday, Friday—No Meetings Scheduled)

[FR Doc.77-8669 Filed 3-21-77;10:12 am]

INTERSTATE COMMERCE COMMISSION

[Notice No. 351]

ASSIGNMENT OF HEARINGS

MARCH 17, 1977.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include

cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 140511 (Sub-2), Autolog Corporation now being assigned May 9, 1977 (1 week) at New York, New York in a hearing room to be later designated.

MC 2900 (Sub-293), Ryder Truck Lines, Inc., now being assigned June 6, 1977 (1 week) for continued hearing at Charlotte, North Carolina and will be held at the Sheraton Center, 555 South McDowell Street.

MC 130393, John R. Benn Travel Service, Inc., now assigned April 19, 1977, at Columbus, Ohio is canceled and reassigned for April 19, 1977 (3 days) in Conference Room, 25th Floor, Kroger Building, 1014 Vine Street, Cincinnati, Ohio.

MC 124878 (Sub-9), Lapadula Air Freight Transfer, Inc., now being assigned May 16, 1977 (1 week) at New York, New York in a room to be later designated.

MC 117604 (Sub-11), Meadors Freight Lines, Inc., now being assigned June 6, 1977 (2 weeks), at Atlanta, Georgia, in a hearing room to be later designated.

MC 119428 (Sub-2), Napoleon J. Eno and Paul Eno, dba Nap & Paul's Marine now being assigned May 23, 1977 (1 week) at New York, New York in a hearing room to be later designated.

MC-C 9382, Tucker Freight Lines, Inc.—Investigation and Revocation of Certificates now being assigned June 1, 1977 (3 days) at Chicago, Illinois in a hearing room to be later designated.

MC-FC 75721, General Movers, Inc., East St. Louis, Illinois, Transferee and Fasgo Motor Express, Inc., East St. Louis, Illinois, Transferor, and Modern Truck Lines, Inc., East St. Louis, Illinois, Transferor, MC 120879 Sub 3, General Movers, Inc. Extension and MC 120879 (Sub-2), Generals Movers, Inc. now being assigned June 6, 1977 (1 week) at Chicago, Illinois in a hearing room to be later designated.

MC 125808 (Sub-1), AAACon Auto Transport, Inc.—Petition Seeking Modification of Permit (Certificates), now being assigned Prehearing Conference April 22, 1977 at the Offices of the Interstate Commerce Commission, Washington, D.C.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8502 Filed 3-21-77;8:45 am]

[Notice No. 36]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

MARCH 14, 1977

The following are notices of filing of applications for temporary authority under Section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

No. MC 45764 (Sub-No. 29TA), filed March 3, 1977. Applicant: ROBBINS MOTOR TRANSPORTATION, INC., Industrial Highway and Saville Ave., P.O. Box 38, Eddystone, Pa. 19013. Applicant's representative: Edward Kells (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Machinery*, the transportation of which because of size or weight requires the use of special equipment or handling and *related machinery parts*, moving on through trailers in foreign commerce, from Callery and Erie, Pa., Dalton, Ohio and Roanoke, Va., to the International Boundary line between the United States and Mexico, at Brownsville and Laredo, Tex., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: CCS/Braeburn Alloy & Steel, 12 Commerce Drive, Cranford, N.J. 07016. Send protests to: Monica A. Blodgett, Transportation Assistant, Interstate Commerce Commission, 600 Arch St., Room 3238, Philadelphia, Pa. 19106.

No. MC 59282 (Sub-No. 8TA), filed March 3, 1977. Applicant: THOMAS K. BEITELMAN, 1602 N. 27th St., Allentown, Pa. 18104. Applicant's representative: Paul B. Kemmerer, 1620 N. 16th St., Allentown, Pa. 18104. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Linoleum, felt and felt rugs, and other floor coverings, floor covering laying accessories and materials and floor covering preservatives*, from the plantsite of Armstrong Cork Company, in E. Hempfield Township, Lancaster County, Pa., to Albany, N.Y., for 180 days. Supporting shipper: Armstrong Cork Company, Liberty & Charlotte Sts., Lancaster, Pa. 17604. Send protests to: Monica A. Blodgett, Transportation Assistant, Interstate Commerce Commission, 600 Arch St., 3238, Philadelphia, Pa. 19106.

No. MC 60122 (Sub-No. 9TA), filed February 28, 1977. Applicant: JOHN VIANO AND EDWARD VIANO, doing business as, VIANO BROTHERS, Harding Highway, Landisville, N.J. 03326. Applicant's representative: J. Raymond Clark, Suite 1150, 600 New Hampshire Ave., N.W., Washington, D.C. 20037. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages*, in containers, from Syracuse, N.Y., to Landisville, N.J., for 180 days. Supporting shipper: Thomas Fornataro, Inc., Buena Vista Ave., Landisville, N.J. 08326. Send protests to: Dieter H. Harper, District Supervisor, Interstate Commerce Commission, 428 E. State St., Room 204, Trenton, N.J. 08608.

No. MC 102295 (Sub-No. 29TA), filed March 3, 1977. Applicant: GUY HEAVENER, INC., 480 School Lane, Harleysville, Pa. 19438. Applicant's representative: Maxwell A. Howell, 1100 Investment Bldg., 1511 K St., N.W., Washington, D.C. 20005. Authority sought to operatae as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Gravel*, from points in Cecil County, Md., to Bethlehem, Pa., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: George F. Pettinos, Inc., 123 Coulter Ave., Ardmore, Pa. 19003. Send protests to: Monica A. Blodgett, Transportation Assistant, Interstate Commerce Commission, 600 Arch St., Room 3238, Philadelphia, Pa. 19106.

No. MC 103993 (Sub-No. 881TA), filed February 28, 1977. Applicant: MORGAN DRIVE AWAY, INC., 28651 U.S. 20 West, Elkhart, Ind. 46514. Applicant's representative: James B. Buda (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Motor vehicles and chassis*, from the plantsite of Ford Motor Co., at or near Lorain, Ohio, to points in Michigan, Indiana, Illinois, Kentucky, Pennsylvania, West Virginia, New York, Wisconsin, Maryland, Missouri, Iowa and New Jersey, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Ford Motor Company, P.O. Box 1529B, Rotunda Drive at Southfield, Dearborn, Mich. 48121. Send protests to: J. H. Gray, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 343 W. Wayne St., Suite 113, Fort Wayne, Ind. 46802.

No. MC 107515 (Sub-No. 1058TA), filed March 4, 1977. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, 3901 Jonesboro Road, S.E., Forest Park, Ga. 30326. Applicant's representative: Alan E. Serby, 3379 Peachtree Road, N.W., Suite 375, Atlanta, Ga. 30326. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products and meat by-products* (except hides and commodities in bulk), in vehicles equipped with mechanical refrigeration, from the plantsite and storage facilities of Elm Hill Meats, Inc., at or near Lex-

ington, Ky., to points in Illinois, Indiana, Ohio, Michigan, Wisconsin, Pennsylvania, Massachusetts, and Norfolk, Va., and points in its commercial zone, and Gulfport, Miss., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Elm Hill Meats, Inc., Box 496, Lexington, Ky. 40501. Send protests to: Sara K. Davis, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, 1252 W. Peachtree St., N.W., Room 546, Atlanta, Ga. 30309.

No. MC 107515 (Sub-No. 1059TA), filed March 4, 1977. Applicant: REFRIGERATED TRANSPORT CO., INC., 3901 Jonesboro Road, P.O. Box 308, Forest Park, Ga. 30050. Applicant's representative: Alan E. Serby, Suite 375, 3379 Peachtree Road, N.E., Atlanta, Ga. 30326. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Food and foodstuffs*, in vehicles equipped with mechanical refrigeration (except commodities in bulk, in tank vehicles), from the plant and warehouse facilities of Kraft, Inc., at Champaign, Ill., to points in Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and the District of Columbia, restricted to traffic orginating at the above-named origin and destined to the above-named destination points, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Kraft, Inc., 500 Peshtigo Court, Chicago, Ill. 60609. Send protests to: Sara K. Davis, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, 1252 W. Peachtree St., N.W., Room 546, Atlanta, Ga. 30309.

No. MC 108297 (Sub-No. 26TA), filed March 3, 1977. Applicant: FOX TRANSPORT SYSTEM, 21 S. Fifth St., Philadelphia, Pa. 19106. Applicant's representative: James Fox (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Cable scrap, lead covered copper and reels, cable*, electric on vehicles with specialized equipment for loading or unloading, between points in Berks, Cumberland, Dauphin, Perry, Lancaster, Lebanon and York Counties, Pa., on the one hand, and, on the other, Kearny, N.J., and Tottenville, N.Y., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: American Telephone and Telegraph Company, 5554 Port Royal Road, Springfield, Va. 22151. Send protests to: Monica A. Blodgett, Transportation Assistant, Interstate Commerce Commission, 600 Arch St., Room 3238, Philadelphia, Pa. 19106.

No. MC 114015 (Sub-No. 21TA), filed February 28, 1977. Applicant: HUSS, INCORPORATED, Highway 47 West, P.O. Box 666, Chase City, Va. 23924. Applicant's representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, N.Y. 10048. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Adhesives, paint and paint products, building materials, gypsum and gypsum products and lime* (except in bulk), from United States Gypsum Company, Norfolk, Va., to points in Pennsylvania and Ohio, under a continuing contract with United States Gypsum Company, 53 Perimeter Center East, Atlanta, Ga. Send protests to: Paul D. Collins, District Supervisor, Bureau of Operations, Room 10-502, Federal Bldg., 400 N. 8th St., Richmond, Va. 23240.

No. MC 114290 (Sub-No. 83TA), filed February 28, 1977. Applicant: EXLEY EXPRESS, INC., 2610 S.E. 8th Ave., Portland, Oreg. 97202. Applicant's representative: James T. Johnson, 1610 IBM Bldg., Seattle, Wash. 98101. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pet food*, from San Diego, Calif., to Seattle, Tacoma and Auburn, Wash., and Portland, Oreg., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Van Camp Sea Food Company, a Division of Ralston Purina Company, 11555 Sorento Valley Road, San Diego, Calif. 92121. Send protests to: R. V. Dubay, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 114 Pioneer Courthouse, Portland, Oreg. 97204.

No. MC 114457 (Sub-No. 294TA), filed March 3, 1977. Applicant: DART TRANSIT, 2102 University Ave., St. Paul, Minn. 55114. Applicant's representative: James H. Wills (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Glass containers*, from Rosemount, Minn., to Milwaukee, Wis., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Brockway Glass Company, 13500 S. Robert St., Rosemount, Minn. 55063. Send protests to: Marion L. Cheney, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 414 Federal Bldg., and U.S. Courthouse, 110 S. 4th St., Minneapolis, Minn. 55401.

No. MC 115092 (Sub-No. 58TA), filed March 3, 1977. Applicant: TOMAHAWK TRUCKING, INC., P.O. Box O, Vernal, Utah 84078. Applicant's representative: Walter Kobos, 1016 Kehoe Drive, St. Charles, Ill. 60174. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, lumber mill products, lumber products and wood products* (except commodities in bulk), from points in Oregon, Washington and Idaho, to points in Colorado, Utah and Nevada, for 180 days. Supporting shipper: Georgia-Pacific Corporation, 900 SW. 5th, Portland, Oreg. 97204. Send protests to: Lyle D. Helfer, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 5301 Federal Bldg., 125 S. State St., Salt Lake City, Utah 84138.

No. MC 115730 (Sub-No. 30TA), filed March 3, 1977. Applicant: THE MICKOW CORP., P.O. Box 1774, 531 S.W. 6th St., Des Moines, Iowa 50306. Applicant's representative: Cecil L. Goettsch, 1100 Des Moines Bldg., Des Moines, Iowa 50309. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel* articles, from points in the Chicago, Ill., commercial zone, to Norfolk, Nebr., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Norfolk Iron and Metal Co., 300 Braasch Ave., Norfolk, Nebr. 68701. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Bldg., Des Moines, Iowa 50309.

No. MC 116300 (Sub-No. 28TA), filed March 3, 1977. Applicant: NANCE AND COLLUMS, INC., P.O. Drawer J, Fernwood, Miss. 39635. Applicant's representative: Harold D. Miller, Jr., P.O. Box 22567, Jackson, Miss. 39205. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fertilizer*, in bulk, from McComb, Miss., to points in Louisiana and Alabama, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Mississippi Chemical Corporation, P.O. Box 388, Yazoo City, Miss. 39194. Send protests to: Alan C. Tarrant, District Supervisor, Interstate Commerce Commission, Room 212, 145 E. Amite Bldg., Jackson, Miss. 39201.

No. MC 116763 (Sub-No. 369TA), filed March 3, 1977. Applicant: CARL SUBLER TRUCKING, INC., N. West St., Versailles, Ohio 45380. Applicant's representative: H. M. Richters (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Food and foodstuffs*, in vehicles equipped with mechanical refrigeration (except commodities in bulk, in tank vehicles), from the facilities of Kraft, Inc., at Champaign, Ill., to points in Connecticut, Delaware, Massachusetts, New Hampshire, New Jersey, Rhode Island, Maine, Virginia, Vermont, the District of Columbia, and points east of Highway 81 in Pennsylvania, New York and Maryland, restricted to the transportation of traffic originating at the named origin and destined to points in the named destination states, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Kraft, Inc., 500 Peshtigo Court, Chicago, Ill. 60609. Send protests to: Paul J. Lowry, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 5514-B Federal Bldg., 550 Main St., Cincinnati, Ohio 45202.

No. MC 117940 (Sub-No. 211TA), filed February 28, 1977. Applicant: NATIONWIDE CARRIERS, INC., P.O. Box 104, Maple Plain, Minn. 55359. Applicant's representative: Allan L. Timmerman (same address as applicant). Authority

sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Salt and salt products;* and (2) *Materials and supplies* used in agricultural, water treatment, food processing, wholesale grocery, and institutional supply industries, in mixed shipments with salt and salt products (except in bulk), from the plantsite of Diamond Crystal Salt Co., at St. Clair, Mich., to points in Connecticut, Delaware, Maryland, Massachusetts, New York (except points in the New York City Commercial Zone and Long Island), Pennsylvania, Rhode Island and the District of Columbia, for 180 days. Supporting shipper: Diamond Crystal Salt Company, 916 S. Riverside Ave., St. Clair, Mich. 48079. Send protests to: Marion L. Cheney, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 414 Federal Bldg., and U.S. Courthouse, 110 S. 4th St., Minneapolis, Minn. 55401.

No. MC 117940 (Sub-No. 212TA), filed February 28, 1977. Applicant: NATIONWIDE CARRIERS, Inc., P.O. Box 104, Maple Plain, Minn. 55359. Applicant's representative: Allan L. Timmerman (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Food and foodstuffs* (except in bulk and tank vehicles), in vehicles equipped with mechanical refrigeration, from the plantsite and warehouse facilities of Kraft, Inc., at Champaign, Ill., to points in Connecticut, Delaware, Maine, Massachusetts, New Hampshire, New Jersey, Rhode Island, Vermont, Virginia, the District of Columbia, and points east of Interstate Highway 81 in Maryland, New York, and Pennsylvania (except Allentown, Pa.), restricted to traffic originating at above named origins and destined to the above named destinations, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Kraft, Inc., 500 Peshtigo Court, Chicago, Ill 60690. Send protests to: Marion L. Cheney, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 414 Federal Bldg., & U.S. Courthouse, 110 S. 4th St., Minneapolis, Minn. 55401.

No. MC 119668 (Sub-No. 8TA), filed March 4, 1977. Applicant: FORREST RATLIFF AND AUBURN RATLIFF, doing business as RATLIFF TRUCKING SERVICE, P.O. Box 267, Oakwood, Va. 24631. Applicant's representative: Edward G. Villalon, Suite 1032 Pennsylvania Bldg., Pennsylvania Ave. and 13th St., N.W., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles*, from points in Ohio, Pennsylvania, New York, Maryland, Tennessee, Alabama, Kentucky, Illinois, Indiana and West Virginia, to the facilities of Cardinal Metals, Inc., at or near Richlands, Va., for 180 days. Supporting shipper: Cardinal Metals, Inc., P.O. Box 550, Richlands, Va. 24641. Send protests to: Danny R. Beeler, District Supervisor, Bureau of Operations, Interstate Commerce Commission, P.O. Box 210, Roanoke, Va. 24011.

No. MC 119789 (Sub-No. 328TA), filed March 2, 1977. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 6188, Dallas, Tex. 75222. Applicant's representative: Ralph W. Pulley, Jr., 4555 First National Bank Bldg., Dallas, Tex. 75202. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats and meat products*, from Dallas and Fort Worth, Tex., to Williamsburg, and Norfolk, Va.; Columbia and Charleston, S.C.; Watertown, Mass.; Landover, Md.; and Bayonne, N.J. Restriction: Restricted to traffic originating at the plantsite, warehouse and storage facilities utilized by Supreme Beef Processors, Inc., and Supreme Beef Company, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Supreme Beef Processors, Inc., 5219 Second Ave., P.O. Box 5998, Dallas, Tex. 75222. Send protests to: Opal M. Jones, Transportation Assistant, Interstate Commerce Commission, 1100 Commerce St., Room 13C12, Dallas, Tex. 75242.

No. MC 124692 (Sub-No.174TA), filed March 4, 1977. Applicant: SAMMONS TRUCKING, P.O. Box 4347 Missoula, Mont. 59801. Applicant's representative: James B. Hovland, 414 Gate City Bldg., P.O. Box 1367, Fargo, N. Dak. 58102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pre-cut and wood buildings*, knocked down, *and materials and supplies* used in the construction, installation and erection thereof, from the plantsite of Real Log Homes, Inc., located in Missoula County, Mont., to points in the United States in and west of Texas, Oklahoma, Missouri, Illinois, Indiana and Michigan (except Alaska and Hawaii), for 180 days. Supporting shipper: John D. Currens, General Manager, Real Log Homes, Inc., P.O. Box 1520, Missoula, Mont. 59807. Send protests to: Paul J. Labane, District Supervisor, Interstate Commerce Commission, 2602 First Ave., North, Billings, Mont. 59101.

No. MC 124813 (Sub-No. 168TA), filed February 28, 1977. Applicant: UMTHUN TRUCKING CO., 910 S. Jackson St., P.O. Box 166, Eagle Grove, Iowa 50533. Applicant's representative: William L. Fairbank, 1980 Financial Center, Des Moines, Iowa 50309. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lime and limestone products*, in bulk, from the facilities of Linwood Stone Products Company, Inc., at or near Davenport, Iowa, to Green Bay, Wis., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Linwood Stone Products Company, Inc., R.R. #2, Davenport, Iowa 52804. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Bldg., Des Moines, Iowa 50309.

No. MC 129068 (Sub-No. 39TA), filed March 3, 1977. Applicant: GRIFFIN TRANSPORTATION, INC., 3002 S. Douglas Blvd., Oklahoma City, Okla. 73150. Applicant's representative: Jack L. Griffin (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Trailers*, designed to be drawn by passenger automobiles, in initial movement (except recreational vehicles), *and buildings* complete or in sections mounted on wheeled undercarriages (except modular and prefabricated buildings), from Cooke County, Tex., to points in Arizona, Arkansas, Louisiana, New Mexico and Oklahoma, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Chief Industries, Inc., P.O. Box 509, Gainesville, Tex. 76240. Send protests to: Joe Green, District Supervisor, Room 240 Old Post Office Bldg., 215 N.W. Third St., Oklahoma City, Okla. 73102.

No. MC 133097 (Sub-No. 18TA), filed March 3, 1977. Applicant: SYSTEM REEFER SERVICE, INC., 4614 Lincoln Ave., Cypress, Calif. 90630. Applicant's representative: Charles E. Creager, 1329 Pennsylvania Ave., Hagerstown, Md. 21740. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in by a manufacturer of power tools, materials, supplies and equipment used in the conduct of such business, between points in the International Boundary between Canada and the United States in Michigan and New York; Hampstead and Easton, Md.; Tarboro and Fayetteville, N.C.; and Lancaster, Pa., on the one hand, and, on the other, points in Washington, Oregon, Montana, Utah, Idaho, California, Arizona, New Mexico, Nevada and Colorado, under a continuing contract with The Black & Decker Manufacturing Co., for 180 days. Supporting shipper: The Black & Decker Manufacturing Co., 701 E. Joppa Road, Towson, Md. 21204. Send protests to: Mary A. Francy, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, Room 1321 Federal Bldg., 300 N. Los Angeles St., Los Angeles, Calif. 90012.

No. MC 135874 (Sub-No. 73TA), filed March 3, 1977. Applicant: LTL PERISHABLES, INC., 550 W. 5th St., South, S. St. Paul, Minn. 55075. Applicant's representative: Samuel Rubenstein, 301 N. 5th St., Minneapolis, Minn. 55403. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Canned goods*, from Arlington and Ortonville, Minn., and Bloomer, Wis., to points in the United States (except Alaska and Hawaii), for 180 days. Supporting shipper: Big Stone Incorporated, P.O. Box 86, Chaska, Minn. 55318. Send protests to: Marion L. Cheney, Transportation Assistant, Interstate Commerce

Commission, Bureau of Operations, 414 Federal Bldg., & U.S. Courthouse, 110 S. 4th St., Minneapolis, Minn. 55401.

No. MC 138875 (Sub-No. 49TA), filed March 3, 1977. Applicant: SHOEMAKER TRUCKING CO., 11900 Franklin Road, Boise, Idaho 83705. Applicant's representative: F. L. Sighoh (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Steel buildings and component parts*, from the plantsite of American Buildings Co., at or near Atlantic, Iowa, to points in Idaho, Montana, Nevada, Oregon, Utah, Washington, Wyoming and those points in Idaho, North Dakota and Montana on the International Boundary between the United States and Canada, for 180 days. Supporting Shipper: Ronald Van Auger Construction Co., Inc., 3405 Arthur St., Caldwell, Idaho 83605. Send protests to: Barney L. Hardin, District Supervisor, Interstate Commerce Commission, 550 W. Fort St., P.O. Box 07, Boise, Idaho 83724.

No. MC 139495 (Sub-No. 206TA), filed March 4, 1977. Applicant: NATIONAL CARRIERS, INC., P.O. Box 1358, 1501 E. 8th St., Liberal, Kans. 67901. Applicant's representative: Hebert Alan Dubin, 1819 H St., N.W., Suite 1030, Washington, D.C. 20006. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Food and foodstuffs*, in vehicles equipped with mechanical refrigeration (except commodities in bulk, in tank vehicles), from the plant and warehouse facilities of Kraft, Inc., at Champaign, Ill., to points in Connecticut, Delaware, Maine, Maryland, Masschusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and the District of Columbia. Restriction: Restricted to traffic originating at the above-named origin and destined to the above-named destination points, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Kraft, Inc., 500 Peshtigo Court, Chicago, Ill. 60690. Send protests to: M. E. Taylor, District Supervisor, Interstate Commerce Commission, Suite 101 Litwin Bldg., 110 N. Market, Wichita, Kans. 67202.

No. MC 140003 (Sub-No. 7TA), filed March 3, 1977. Applicant: BALL MOTOR LINE OF APOPKA, INC., P.O. Drawer AL, Apopka, Fla. 32703. Applicant's representative: Theodore Polydoroff, 1250 Connecticut Ave., N.W., Washington, D.C. 20036. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Electronic equipment and components*, from Jackson, Mich., to Brownstown, Ind., and De Leon Springs, Fla., under a continuing contract with Sparton Indiana, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Sparton Indiana, Inc., 301 E. Bridge St., Brownstown, Ind. 47220. Send protests to: G. H. Fauss, Jr., District Supervisor, Bureau of Operations, Interstate Commerce Commission, Box 35008, 400 W. Bay St., Jacksonville, Fla. 32202.

No. MC 140829 (Sub-No. 41TA), filed February 28, 1977. Applicant: CARGO CONTRACT CARRIER CORP., P.O. Box 206, U.S. Highway 20, Sioux City, Iowa 51102. Applicant's representative: William J. Hanlon, 55 Madison Ave., Morristown, N.J. 07960. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs and bone chews*, from the plantsites and storage facilities of Sanna Division of Beatrice Foods Co., at Menominee, Vesper, Cameron, Wisconsin Rapids and Eau Claire, Wis., to points in Maine, Vermont, New Hampshire, Rhode Island, Massachusetts, Connecticut, New York, Pennsylvania, New Jersey, Maryland and Virginia. Restriction: The operations authorized above are restricted to the transportation of traffic originating at the named origins and destined to points in the above named destination states, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: James P. Zenzinger, Transportation Manager, Sanna Division, Beatrice Foods Co., 2801 W. Beltline Hwy., P.O. Box 8046, Madison, Wis. 53708. Send protests to: Carroll Russell, District Supervisor, Interstate Commerce Commission, Suite 620, 110 N. 14th St., Omaha, Nebr. 68102.

No. MC 141197 (Sub-No. 14TA), filed March 3, 1977. Applicant: FLEMING-BABCOCK, INC., 4106 Mattox Road, Riverside, Mo. 64150. Applicant's representative: Tom B. Kretsinger, 101 W. 11th St., Kansas City, Mo. 64105. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry fertilizer and fertilizer compounds, potash, urea, diammonium phosphate, triple phosphate, ammonium nitrate, phosphate blends, nitrates and nitrogen*, from Kansas City, Mo., to points in Iowa, Kansas, Missouri, Nebraska and Oklahoma, restricted to traffic moving in dump type vehicles, for 180 days. Supporting shippers: (1) Missouri Farmers Association, Inc., 201 S. 7th St., Columbia, Mo. 65201. (2) Mid West Terminal Warehouse Co., P.O. Box 11, Kansas City, Mo. and (3) Transnitro, Inc., 1211 N. Westshore Blvd., Tampa, Fla. 33607. Send protests to: Vernon V. Coble, District Supervisor, Interstate Commerce Commission, 600 Federal Bldg., 911 Walnut St., Kansas City, Mo. 64106.

No. MC 141921 (Sub-No. 4TA), filed March 2, 1977. Applicant: SAV-ON TRANSPORTATION, INC., 143 Frontage Road, Manchester, N.H. 03101. Applicant's representative: Daniel McCoy (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meat, meat products, and meat by-products and articles distributed by meat packinghouses*, as described in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766 (except hides, skins, and commodities in bulk), from the plantsite or warehouse facilities of the Sterling Colorado Beef Company, at or near Sterling, Colo., to points in Michigan, Wisconsin, Illinois, Kentucky, Ohio, New York, Pennsylvania, Massachusetts, Connecticut, Rhode Island, New Jersey, Maryland, Delaware and the District of Columbia, for 180 days. Supporting shipper: Sterling Colorado Beef Company, P.O. Box 1728, Sterling, Colo. 80751. Send protests to: Ross J. Seymour, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 425 Federal Bldg., 55 Pleasant St. Concord, N.H. 03301.

No. MC 142057 (Sub-No. 3TA), filed March 3, 1977. Applicant: WALKER EXPRESS, 4354 Twain Ave., Suite C, San Diego, Calif. 92120. Applicant's representative: William R. Daly, 8135 Binney Place, La Mesa, Calif. 92041. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Aerospace missiles or rockets*, between San Diego and Point Mugu, Calif., and Michael AAF, Utah, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: General Dynamics Corp/Convair Division, 3302 Pacific Highway, San Diego, Calif. 92138. Send protests to: Mary A. Francy, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, Room 1321 Federal Bldg., 300 N. Los Angeles St. Los Angeles, Calif. 90012.

No. MC 142059 (Sub-No. 6TA), filed March 3, 1977. Applicant: CARDINAL TRANSPORT, INC., 1830 Mound Road, P.O. Box 911, Joliet, Ill. 60436. Applicant's representative: Jack Riley (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Food and foodstuffs*, in vehicles equipped with mechanical refrigeration (except commodities in bulk, in tank vehicles), from the plant and warehouse facilities of Kraft, Inc., at Champaign, Ill., to points in Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and the District of Columbia, for 180 days. Supporting shipper: Kraft, Inc., A. P. Stefanisin, Transportation Analyst, 500 Peshtigo Court, Chicago, Ill. 60609. Send protests to: Patricia A. Roscoe, Transportation Assistant, Interstate Commerce Commission, Everett McKinley Dirksen Bldg., 219 S. Dearborn St., Room 1386, Chicago, Ill. 60604.

No. MC 142937 (Sub-No. 1TA), filed March 3, 1977. Applicant: DARREL A. CARLSON, doing business as CARLSON TRUCKING, Route No. 1, Parkers Prairie, Minn. 56361. Applicant's representative: James B. Hovland, 414 Gate City Bldg., Fargo, N. Dak. 58102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Sprinkling and irrigation systems, and parts and attachments* for sprinkling and irrigation sys-

tems, from Scotts Bluff County, Nebr., to points in Minnesota on and south of U.S. Highway 2 and on and north of a line beginning at the South Dakota-Minnesota border along State Highway 28 to its intersection with Interstate 94, thence along Interstate 94 to its intersection with State Highway 23, thence along State Highway 23 to the Minnesota-Wisconsin border, under a continuing contract with Mid-Minnesota Irrigation Supply, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Mid-Minnesota Irrigation Supply, Route 2, Box 12A, Wadena, Minn. 56482. Send protests to: Ronald R.

No. MC 142962TA, filed February 28, 1977. Applicant: CARL J. WITKIWSKI & SONS, INC., 39 Lakeshore Drive, North Fond du Lac, Wis. 54935. Applicant's representative: Nancy J. Johnson, 4506 Regent St., Suite 100, Madison, Wis. 53705. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Bones, fat, offal and hides*, in shipper-owned trailers, from Fond du Lac, and Madison, Wis., to Chicago, Ill., under a continuing contract with Darling and Company, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Darling and Company, 4650 S. Racine Ave., Chicago, Ill. Send protests to: Gail Daugherty, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, U.S. Federal Bldg., and Courthouse, 517 E. Wisconsin Ave., Room 619, Milwaukee, Wis. 53202.

No. MC 142963 (Sub-No. 1TA), filed March 4, 1977. Applicant: IRON & METAL TRUCKING, INC., 7620 Winding Way, Brecksville, Ohio 44141. Applicant's representative: Paul F. Berry, 275 E. State St., Columbus, Ohio 43215. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Flue dust*, in bulk, in dump trucks, from Cleveland, Ohio, to Saxonburg, Pa., under a continuing contract with Mid-Continent Coal & Coke Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Mid-Continent Coal & Coke Co., 20600 Chagrin, Cleveland, Ohio. Send protests to: James Johnson, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 181 Federal Office Bldg., 1240 E. 9th St., Cleveland, Ohio 44199.

No. MC 142969 (Sub-No. 1TA), filed February 28, 1977. Applicant: WESTERN DISTRIBUTING TRANSPORTATION CORP., 1800 Bassett—Unit A, P.O. Box 5542, Denver, Colo. 80217. Applicant's representative: David R. Parker, 2310 Colorado State Bank Bldg., 1600 Broadway, Denver, Colo. 80202. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Alcoholic beverages and related mixes*, from points in California; Jacksonville, Fla.; Chicago, Pekin, Peoria, and Plainfield, Ill.; Bardstown, Clermont and Frankfort, Ky.; New Orleans, La.; Detroit, Mich.; St. Louis and Weston, Mo.; Carlstadt, Carteret and Moonachie, N.J.; New York City and Scarsdale, N.Y.; Cincinnati and Silverton, Ohio; Galveston and Houston, Tex.; to Denver and Glenwood Springs, Colo. Restrictions: (1) against the transportation of commodities in bulk; (2) to traffic destined to the facilities of Western Distributing Co., and (3) to transportation under a continuing contract with Western Distributing Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Western Distributing Co., 1800 Bassett, Unit A, Denver, Colo. 80217. Send protests to: Roger L. Buchanan, District Supervisor, Interstate Commerce Commission, 721 19th St., 492 U.S. Customs House, Denver, Colo. 80202.

No. MC 142972TA, filed February 28, 1977. Applicant: LAWRENCE A. BRINK AND ROGER H. NELSEN, doing business as, BRINK'S TOWING COMPANY, 5281 E. 52nd Ave., Commerce City, Colo. 80022. Applicant's representative: Lawrence A. Brink (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wrecked and disabled motor vehicles and operative motor vehicle replacement units* (except trailers designed to be drawn by passenger automobiles), in truckaway service, between Denver, Colo., and its commercial zone, on the one hand, and, on the other, points in Wyoming, Nebraska, Kansas, Oklahoma, Texas, New Mexico, Arizona, Utah, Iowa, Missouri and Arkansas, for 180 days. Supporting shippers: Ashton Trucking Co., 4365 Hwy. 224, Commerce City, Colo. 80022. Consolidated Freightways, 5300 E. 56th Ave., Commerce City, Colo. 80022. Pacific Intermountain Express Co., 3223 E. 46th Ave., Denver, Colo. 80216. Send protests to: Herbert C. Ruoff, District Supervisor, 721 19th St., 492 U.S. Customs House, Denver, Colo. 80202.

No. MC 142973TA, filed February 28, 1977. Applicant: PEARL AND JACQUES ROBERT ENRG, 397 Carre Jean Brebeuf, Saint Jean, Quebec, Canada. Applicant's representative: S. Arnold Smith, Scraftsbury, Vt. 08526. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Laboratory animals and accessories* for them, between ports of entry on the International Boundary line between the United States and Canada at or near Highgate Springs, Vermont and Champlain, N.Y., on the one hand, and, on the other, Willington, Mass., restricted to traffic originating at or destined to St. Constant, Quebec, Canada, under a continuing contract with Canadian Breeding Farm & Laboratories, Inc., for 180 days. Supporting shipper: Canadian Breeding Farm & Laboratories, Inc., 188 LaSalle, St. Constant, Quebec, Canada. Send protests to: David A. Demers, District Supervisor, Interstate Commerce Commission, P.O. Box 548, 87 State St., Montpelier, Vt. 05602.

No. MC 142990TA, filed March 2, 1977. Applicant: MCKENZIE TANK LINES, INC., P.O. Box 1200, Tallahassee, Fla. 32302. Applicant's representative: Sol H. Proctor, 1101 Blackstone Bldg., Jacksonville, Fla. 32202. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Processed clay catalyst*, in bulk, in tank vehicles, from Attapulgus, Ga., to Sugar Creek, Mo., and Tulsa and Ponca City, Okla., under a continuing contract with Engelhard Minerals & Chemicals, for 180 days. Supporting shipper: Engelhard Minerals & Chemicals, Menlo Park, Edison, N.J. 08817. Send protests to: G. H. Fauss, Jr., District Supervisor, Bureau of Operations, Interstate Commerce Commission, Box 35008, 400 W. Bay St., Jacksonville, Fla. 32202.

No. MC 142991TA, filed March 2, 1977. Applicant: FAMILY LINES, INC., 12400 Wilmot Road, Kenosha, Wis. 53140. Applicant's representative: Richard C. Alexander, 710 N. Plankinton Ave., Milwaukee, Wis. 53203. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Candy and confectionery items* (except in bulk), *and advertising and display materials*, used in the display and sale of candy and confectionery items, in vehicles equipped with mechanical refrigeration, from the plantsites and distribution facilities of E. J. Brach & Sons, at Carol Stream, Chicago and Sullivan, Ill., to points in Arizona, California, Idaho, Nevada, Oregon, Utah and Washington, under a continuing contract with E. J. Brach & Sons, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: E. J. Brach & Sons, 4656 W. Kinzie St., Chicago, Ill. Send protests to: Gail Daugherty, Transportation Assistant, U.S. Federal Bldg., & Courthouse, 517 E. Wisconsin Ave., Room 619, Milwaukee, Wis. 53202.

No. MC 142992TA, filed March 3, 1977. Applicant: M & C TRANSFER, INC., 11325 S.W. 57th St., Miami International Airport, Miami, Fla. 33133. Applicant's representative: John P. Bond, 2766 Douglas Road, Miami, Fla. 33133. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except the transportation of said commodities in bulk, Classes A and B explosives, household goods, livestock, commodities requiring special handling and special equipment and cement), between points in Dade County, lying east of State Road 27, south of State Road 826, north of State Road 94, and west of the Atlantic Ocean; all shipments having a prior or subsequent movement by water, for 180 days. Supporting shippers: Albens International Forwarders, 9340 N.W. 13th St., Miami, Fla. 33172. Alfa Aerofreight Service, Inc., 7797 N.W. 32nd St., Miami, Fla. 33122. Sentry Air Freight Corporation, 7265 N.W. 31st St., Miami, Fla. 33122. Randy International, Ltd., Building 2141 MIAD, Miami, Fla. Security Forwarding Service, Inc., 1303 N.W. 78th Ave., Miami,

Fla. 33126. Send protests to: Joseph B. Teichert, District Supervisor, Interstate Commerce Commission, Monterey Bldg., Suite 101, 8410 N.W. 53rd Terrace, Miami, Fla. 33166.

No. MC 143002TA, filed March 3, 1977. Applicant: C.D.B. INCORPORATED, 5170 36th St., S.E., Grand Rapids, Mich. 49508. Applicant's representative: Karl L. Gotting, 1200 Bank of Lansing Bldg., Lansing, Mich. 49508. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Household and personal care products and related items and materials and supplies* used in the manufacture and distribution thereof, between Ada, Mich., on the one hand, and, on the other, Santa Ana, Los Angeles, Buena Park, Torance and La Mirada, Calif.; Portland, Oreg.; Arlington, Tex.; Atlanta, Ga.; and Dayton, Jamesburg and Secaucus, N.J., under a continuing contract with Amway Corporation, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Amway Corporation, 7575 E. Fulton Road, Ada, Mich. 49301. Send protests to: C. R. Fleming, District Supervsor, Bureau of Operations, Interstate Commerce Commission, Lansing, Mich. 48933.

PASSENGER APPLICATION

No. MC 109897 (Sub-No. 3TA), filed March 3, 1977. Applicant: GRAY LINE NEW YORK TOURS CORP., 1515 Jefferson St., Hoboken, N.J. 07030. Applicant's representative: W. L. McCracken, Greyhound Tower, Phoenix, Ariz. 85077. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Passengers*, in special operations, beginning and ending at New York, N.Y., and extending to Great Adventure Amusement Park, Jackson, N.J., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shippers: (1) Great Adventure Amusement Park, P.O. Box 120, Jackson, N.J. 08527. (2) Theatre Service Americana, Inc., 7th & 53rd St., New York, N.Y. 10019. and (3) New York Hilton Transportation Desk, 15 W. 72nd St., New York, N.Y. 10023. Send protests to: Maria B. Kejss, Transportation Assistant, Interstate Commerce Commission, 26 Federal Plaza, New York, N.Y. 10007.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8499 Filed 3-21-77;8:45 am]

[Notice No. 37]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

MARCH 15, 1977.

The following are notices of filing of applications for temporary authority under Section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

No. MC 4405 (Sub-No. 552TA), filed March 7, 1977. Applicant: DEALERS TRANSIT, INC., 522 S. Boston Ave., Enterprise Bldg., Tulsa, Okla. 74130. Applicant's representative: Leonard L. Bennett (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Electrode masts and other air correction device components;* (2) *Materials, parts and supplies* used in the manufacture of electrode masts, (1) from the plantsite of Leckenby Company of Arkansas, Fort Smith, Ark., to points in the United States (except Alaska and Hawaii); and (2) from points in the United States (except Alaska and Hawaii), to the plantsite of Leckenby Company of Arkansas, Ft. Smith, Ark., for 180 days. Supporting shipper: Leckenby Company of Arkansas, P.O. Box 1884, 2100 Wheeler Ave., Ft. Smith, Ark. 72901. Send protests to: Joe Green, District Supervisor, Room 240 Old Post Office Bldg., 215 N.W. Third St., Oklahoma City, Okla. 73102.

No. MC 9726 (Sub-No. 9TA), filed March 4, 1977. Applicant: T. F. DUNLAP TRUCKING CO., INC., 1280 Hicks Blvd., Fairfield, Ohio 45014. Applicant's representative: James R. Stiverson, 1396 W. 5th, Columbus, Ohio 43212. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Prefabricated buildings*, knocked down, in sections, or assembled in units, *and building materials*, between Denver, Colo., and Yorktown, Ind., on the one hand, and, on the other, points in the United States (except Alaska and Hawaii), under a continuing contract with Pease Company, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Pease Company, 900 Forest Ave., Hamilton, Ohio 45023. Send protests to: Paul J. Lowry, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 5514-B Federal Bldg., 550 Main St., Cincinnati, Ohio 45202.

No. MC 26396 (Sub-No. 143TA), filed March 2, 1977. Applicant: POPELKA TRUCKING CO., doing business as THE WAGGONERS, P.O. Box 990, Livingston, Mont. 59047. Applicant's representative: David Waggoner (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fleshed brine cured cattle hides*, from ports of entry located on the United States-Canada Boundary line in Montana, to Missouri, on shipments originating at Calgary and Lethbridge, Alberta, Canada, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Arnott Thomson, Superintendent, Alberta Hide Processors, Ltd., 606-5 St. S.E., Calgary, Alberta, Canada. Send protests to: Paul J. Labane, District Supervisor, Interstate Commerce Commission, 2602 First Ave., North, Billings, Mont. 59101.

No. MC 35519 (Sub-No. 2TA), filed March 7, 1977. Applicant: J. W. ATHEY, SR., AND J. W. ATHEY, JR., doing business as ATHEY TRUCKING, Route 1, Box 364, Stephens City, Va. 22655. Applicant's representative: Frank B. Hand, Jr., P.O. Box 187, Berryville, Va. 22611. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Butter and powered milk*, when moving in mixed shipments with butter, from Strasburg, Va., to Braddock, Pennsauken and Collings Lake, N.J.; Bay Shore, LI and New York, N.Y.; Coatesville, Doylestown, Hershey, and Philadelphia, Pa.; Salisbury and Pocomoke City, Md., and their commercial zones, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Valley Milk Products, a division of Beatrice Foods, Strasburg, Va. Send protests to: W. C. Hersman, District Supervisor, Interstate Commerce Commission, 12th & Constitution Ave., N.W., Room 1413, Washington, D.C. 20423.

No. MC 43685 (Sub-No. 20TA), filed March 4, 1977. Applicant: MERCER TRUCKING CO., INC., N. 1414 Fancher Road, P.O. Box 11585, Spokane, Wash. 99211. Applicant's representative: George H. Hart, 1100 IBM Bldg., Seattle, Wash. 98101. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Building stone*, from points in Park County, Mont., to points in Washington and Oregon, for 180 days. Supporting shippers: Layrite Products Company, E. 1225 Trent Ave., Spokane, Wash. 99202. Livingston Marble and Granite, Box 851, Livingston, Mont. 59407. Send protests to: L. D.

Boone, Transportation Specialist, Bureau of Operations, Interstate Commerce Commission, 858 Federal Bldg., 915 Secons Ave., Seattle, Wash. 98174.

No. MC 47662 (Sub-No. 6TA), filed March 3, 1977. Applicant: MACEVOY, INC., Milnor & Bleigh Sts., Philadelphia, Pa. 19136. Applicant's representative: Alan Kahn, 1920 Two Penn Center Plaza, Philadelphia, Pa. 19102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Scrap sheet steel and scrap tin plate*, in open top cargo containers, loaded on flat trailers, from Piscataway and Edison, N.J.; Maspeth, N.Y.; and Fogelsville, Pa., to Baltimore, Md., and Wilmington, Del., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: National Can Corp., Route 287, & S. Randolphville Road, Piscataway, N.J. 08854. Send protests to: Dieter H. Harper, District Supervisor, Interstate Commerce Commission, 428 E. State St., Room 204, Trenton, N.J. 08608.

No. MC 99539 (Sub-No. 3TA), filed March 3, 1977. Applicant: UNDERWOOD TRUCK LINES, INC., 21 S. Depot St., Brazil, Ind. 47834. Applicant's representative: Walter F. Jones, Jr., 601 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Trailers, semitrailers, trailer chasis* (except those designed to be drawn by passenger automobiles), *and parts and accessories therefor*, in initial movements, between the plantsite and storage facilities of Great Dane Trailers Indiana, Inc., located at or near Brazil, Ind., on the one hand, and, on the other, points in the United States (except Alaska and Hawaii), for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: William E. Ennis, Interstate Commerce Commission, Federal Bldg., & U.S. Courthouse, 46 E. Ohio St., Room 429, Indianapolis, Ind. 46204.

No. MC 110525 (Sub-No. 1184TA), filed March 4, 1977. Applicant: CHEMICAL LEAMAN TANK LINES, INC., 520 E. Lancaster Ave., P.O. Box 200, Downingtown, Pa. 19335. Applicant's representative: Thomas J. O'Brien (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Liquid wood preservatives*, in bulk, in tank vehicles; and (2) *Arsenic acid*, in bulk, in tank vehicles; (1) from Valparaiso, Ind., to Minneapolis, Minn.; Prairie du Chien, Wis.; Munising, Schoolcraft and St. Clair, Mich.; Washington Court House, Columbus and Orrville, Ohio; West Elizabeth, Pa., and Henry, Tenn.; and (2) from Bonham and Bryan, Tex., to Valparaiso, Ind., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Koppers Company, Inc., 850 Koppers Bldg., Pittsburgh, Pa. 15219. Send protests to: Monica A. Blodgett, Transportation Assistant, Interstate Commerce Commission, 600 Arch St., Room 3238, Philadelphia, Pa. 19106.

No. MC 113434 (Sub-No.73TA), filed March 7, 1977. Applicant: GRA-BELL TRUCK LINE, INC., 679 Lincoln Ave., Holland, Mich. 44923. Applicant's representative: Wilhelmina Boersma, 1600 First Federal Bldg., Detroit, Mich. 48226. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic bottles*, from the plantsite and facilities of Amoco Plastics Products Company, at Seymour, Ind., to Howell, Mich., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Amoco Plastic Products Company, P.O. Box 1000, Seymour, Ind. 47274. Send protests to: C. R. Flemming, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 225 Federal Bldg., Lansing, Mich. 48933.

No. MC 113651 (Sub-No. 211TA), filed March 2, 1977. Applicant: INDIANA REFRIGERATOR LINES, INC., 2404 N. Broadway, Muncie, Ind. 47303. Applicant's representative: George E. Batty (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Food and foodstuffs* in vehicles equipped with mechanical refrigeration (except commodities in bulk, in tank vehicles), from the plantsite and warehouse facilities of Kraft, Inc., at Champaign, Ill., to points in Connecticut, Delaware, Maine, Massachusetts, Maryland, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and the District of Columbia, restricted to traffic originating at the above-named origin and destined to the above-named destination points, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Kraft, Inc., 500 Peshtigo Court, Chicago, Ill. 60690. Send protests to: J. H. Gray, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 343 W. Wayne St., Suite 113, Fort Wayne, Ind. 46802.

No. MC 113855 (Sub-No. 369TA), filed March 4, 1977. Applicant: INTERNATIONAL TRANSPORT, INC., 2450 Marion Road S.E., Rochester, Minn. 55901. Applicant's representative: Michael E. Miller, 502 First National Bank Bldg., Fargo, N. Dak. 58102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Tractors;* and (2) *Parts and attachments*, when moving in mixed loads with tractors, from Portland, Oreg., and Longview, Wash., to points in Washington, Oregon, California, Nevada, Idaho, Montana, Utah and Wyoming, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: John Deere Company, Portland Branch, P.O. Box 20098, Portland, Oreg. 97220. Send protests to: Marion L. Cheney, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 414 Federal Bldg., & U.S. Courthouse, 110 S. 4th St., Minneapolis, Minn. 55401.

No. MC 114004 (Sub-No. 166TA) (Amendment), filed February 15, 1977, published in the FEDERAL REGISTER issue of March 2, 1977, and republished, as amended, this issue. Applicant: CHANDLER TRAILER CONVOY, INC., 8828 New Benton Highway, Little Rock, Ark. 72209. Applicant's representative: Winston Chandler, Jr. (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Trailers*, designed to be drawn by passenger automobiles (except travel trailers or recreational vehicles), *and buildings*, in sections, (except pre-fabricated buildings), in initial movements, in truck-away service, from Marysville and Corona, Calif.; Auburndale, Fla.; Henderson, N.C.; Caldwell, Ohio; Bend, Oreg.; Phoenix, Ariz.; Booneville, Mo.; and Ruston, La., and their respective commercial zones, to points in the United States, including Alaska, but excluding Hawaii, for 180 days. Supporting shipper: Fuqua Homes, Inc., 7100 S. Cooper, Arlington, Tex. 76015. Send protests to: William H. Land, Jr., District Supervisor, 3108 Federal Office Bldg., 700 W. Capitol, Little Rock, Ark. 72201. The purpose of this republication is to amend the territorial description in this proceeding.

No. MC 114004 (Sub-No. 167TA) (correction), filed February 15, 1977, published in the FEDERAL REGISTER issue of March 2, 1977, and republished, as corrected, this issue. Applicant: CHANDLER TRAILER CONVOY, INC., 8828 New Benton Highway, Little Rock, Ark. 72209. Applicant's representative: Winston Chandler, Jr. (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Trailers*, designed to be drawn by passenger automobiles (except travel trailers or recreational vehicles), *and buildings*, in sections (except pre-fabricated buildings), in initial movements, in truck-away service, from points in Decatur, Ala.; Casa Grande, Ariz.; Woodland and Hemet, Calif.; Ocala and Sarasota, Fla.; Goshen, Elkhart and Howe, Ind.; Arkansas City and Halstead, Kans.; Bossier City, La.; New Ulm, Minn.; Kinderhood, N.Y.; Mocksville, N.C.; McMinnville, Oreg.; Ephrata and Leola, Pa.; Holmesville and Sugarcreek, Ohio; Temple, Tex.; Brighton, Colo.; Lancaster, Wis.; and now presently under construction, Mt. Angel, Oreg., and Shaefferstown, Pa.; and points in their commercial zones, to points in the United States, including Alaska, but excluding Hawaii, for 180 days. Supporting shipper: Skyline Corporation, 2520 By-Pass Road, Elkhart, Ind. 46514. Send protests to: William H. Land, Jr., District Supervisor, 3108 Federal Office Bldg., 700 W. Capitol, Little Rock, Ark. 72201. The purpose of this republication is to correct the territorial description in this proceeding.

No. MC 114004 (Sub-No. 168TA) (amendment), filed February 17, 1977, published in the FEDERAL REGISTER issue of March 2, 1977, and republished, as amended, this issue. Applicant: CHANDLER TRAILER CONVOY, INC., 8828 New Benton Highway, Little Rock, Ark. 72209. Applicant's representative: Winston Chandler, Jr. (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Trailers*, designed to be drawn by passenger automobiles (except travel trailers), *and buildings*, in sections, mounted on wheeled undercarriages (except prefabricated buildings), from points in Colton, Woodland, and Santa Fe Springs, Calif.; Leesburg, Fla.; Rome, Ga.; Bourbon, Ind.; Ottawa, Kans.; Worthington, Minn.; Brookhaven, Miss.; Clarion, Pa.; McMinnville, Oreg.; and Texarkana, Tex., and points in their respective commercial zones, to points in the United States, including Alaska, but excluding Hawaii, for 180 days. Supporting shipper: Bendix Home Systems, Inc., 61 Perimeter Park, Atlanta, Ga. 30341. Send protests to: William H. Land, Jr., District Supervisor, 3108 Federal Bldg., 700 W. Capitol, Little Rock, Ark. 72201. The purpose of this republication is to amend the territorial description in this proceeding.

No. MC 114569 (Sub-No. 167TA), filed March 4, 1977. Applicant: SHAFFER TRUCKING, INC., P.O. Box 418, New Kingstown, Pa. 17072. Applicant's representative: N. L. Cummins (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs* (except in bulk), from the plantsite and storage facilities of Commercial Distribution Center, Inc., at or near Kansas City, Mo., to points in Maryland, Pennsylvania, Connecticut, New Jersey, New York, Massachusetts, West Virginia and Virginia, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Commercial Distribution Center, Inc., Box 477, Independence, Mo. 64051. Send protests to: Robert P. Amerine, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 278 Federal Bldg., P.O. Box 869, Harrisburg, Pa. 17108.

No. MC 114896 (Sub-No. 46TA), filed March 2, 1977. Applicant: PUROLATOR SECURITY INC., 1111 W. Mockingbird Lane, Suite 1401, Dallas, Tex. 75247. Applicant's representative: Elizabeth L. Henoch, 3333 New Hyde Park Road, New Hyde Park, N.Y. 11040. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Precious metals*, between Scottsville, N.Y., on the one hand, and, on the other, Carteret and Newark, N.J., under a continuing contract with Sabin Metal Corp., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Sabin Metal Corp., 316 Messerole St., Brooklyn, N.Y. 11222. Send protests to: Maria B. Kejss, Transportation Assistant, Interstate Commerce Commission, 26 Federal Plaza, New York, N.Y. 10007.

No. MC 117565 (Sub-No. 96TA), filed March 4, 1977. Applicant: MOTOR SERVICE COMPANY, INC., Route 3, P.O. Box 448, Coshocton, Ohio 43812. Applicant's representative: John R. Hafner (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Mobile homes*, single and double wide units, in initial movements, from Holmesville, Ohio, to points in Kentucky, Pennsylvania and West Virginia, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Skyline Corporation, Route 83, P.O. Box 127, Holmesville, Ohio 44633. Send protests to: Frank L. Calvary, District Supervisor, Interstate Commerce Commission, 220 Federal Bldg., & U.S. Courthouse, 85 Marconi Blvd., Columbus, Ohio 43215.

No. MC 117883 (Sub-No. 212TA), filed March 2, 1977. Applicant: SUBLER TRANSFER, INC., 100 Vista Drive, P.O. Box 62, Versailles, Ohio 45380. Applicant's representative: Edward J. Subler (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, and meat by-products and articles distributed by meat packinghouses*, as described in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766, from the plantsite of Elm Hill Meats, at Lexington, Ky., to points in Connecticut, Delaware, Illinois, Indiana, Iowa, Kansas, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Virginia, West Virginia, Wisconsin and the District of Columbia, restricted to traffic originating at named origin and destined to named destinations, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Elm Hill Meats, Inc., P.O. Box 469, Lisle Road, Lexington, Ky. 40501. Send protests to: Paul J. Lowry, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 5514-B Federal Bldg., 550 Main St., Cincinnati, Ohio 45202.

No. MC 123502 (Sub-No. 47TA), filed March 7, 1977. Applicant: FREE STATE TRUCK SERVICE, INC., P.O. Box 760, Glen Burnie, Md. 21061. Applicant's representative: W. Wilson Corroum (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Crude Rubber*, in bulk, in dump vehicles, from Belle Mead and Somerville, N.J., to Baltimore, Md., for 90 days. Supporting shipper: Edwin W. Burchess, Exec. Vice President, International Briquetting Corp., 2805 Light St., Baltimore, Md. 21230. Send protests to: William L. Hughes, District Supervisor, Interstate Commerce Commission, 814-B Federal Bldg., Baltimore, Md. 21201.

No. MC 124078 (Sub-No. 716TA), filed March 2, 1977. Applicant: SCHWERMAN TRUCKING COMPANY, 611 S. 28th St., Milwaukee, Wis. 53246. Applicant's representative: Richard H. Prevette (same address as applicant). Authority sought to operate as a *Common carrier*, by motor vehicle, over irregular routes, transporting: *Dry clay*, in bulk, in tank vehicles, from Bath, S.C., to Wooster, Ohio, for 180 days. Supporting shipper: Rubbermaid Inc., 1147 Akron Road, Wooster, Ohio 44691. Send protests to: Gail Daugherty, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, U.S. Federal Bldg., & U.S. Courthouse, 517 E. Wisconsin Ave., Room 619, Milwaukee, Wis. 53202.

No. MC 124078 (Sub-No. 717TA), filed March 2, 1977. Applicant: SCHWERMAN TRUCKING COMPANY, 611 S. 28th St., Milwaukee, Wis. 53246. Applicant's representative: Richard Prevette (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Cement*, in bulk, from Hartford, Conn., to points in New York, Massachusetts, New Hampshire and Vermont, restricted to traffic having an immediate prior movement by railroad, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Consolidated Rail Corporation, Room 450, 6 Penn Center Plaza, Philadelphia, Pa. 19104. Send protests to: Gail Daugherty, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, U.S. Federal Bldg., & Courthouse, 517 E. Wisconsin Ave., Room 619, Milwaukee, Wis. 53202.

No. MC 124221 (Sub-No. 59TA), filed March 2, 1977. Applicant: HOWARD BAER, P.O. Box 27, Route 98 W., Morton, Ill. 61550. Applicant's representative: Robert W. Loser, 1009 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Bakery products*, from Roanoke, Va., to Savannah, Ga.; and (2) *Merchandise*, as is dealt in by wholesale, retail and chain grocery and food business houses, and in connection therewith, equipment, materials, and supplies used in the conduct of such business (except commodities in bulk), in vehicles equipped with mechanical refrigeration, from Cincinnati, Ohio, to Savannah, Ga. Restrictions: Restricted in Parts (1) and (2) above: (1) Restricted to the transportation of traffic originating at or destined to a facility of The Kroger Company; (2) Restricted to movements in vehicles equipped with mechanical refrigeration; and (3) Limited to a transportation service to be performed under a continuing contract with The Kroger Company, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: The Kroger Co., Henry B. deHamel, Manager of Distribution Systems, 1014 Vine St., Cincinnati, Ohio

45201. Send protests to: Patricia A. Roscoe, Transportation Assistant, Interstate Commerce Commission, Everett McKinley Dirksen Bldg., 219 S. Dearborn St., Room 1386, Chicago, Ill. 60604.

No. MC 124679 (Sub-No. 74TA), filed March 2, 1977. Applicant: C. R. ENGLAND & SONS, INC., 975 W. 2100 South, Salt Lake City, Utah 84119. Applicant's representative: Daniel E. England, P.O. Box 2465, Salt Lake City, Utah 84110. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, meat by-products and articles* distributed by meat packinghouses, from the plantsite and storage facilities of Joe Doctorman and Son, Inc., at or near Salt Lake City, Utah, to Denver and Colorado Springs, Colo.; Hillsboro, Oreg., and points in California and Nevada, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Joe Doctorman & Son, Inc., 2900 S. 300 East, Salt Lake City, Utah 84110. Send protests to: Lyle D. Helfer, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 5301 Federal Bldg., 125 S. State St., Salt Lake City, Utah 84138.

No. MC 129086 (Sub-No. 24TA), filed February 18, 1977. Applicant: SPENCER TRUCKING CORPORATION, Rt. 2, Box 254A, Keyser, W. Va. 26726. Applicant's representative: Edward N. Button, 1329 Penna. Ave., P.O. Box 1417, Hagerstown, Md. 21740. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Cullet*, between Cleveland, Ohio and its commercial zone, on the one hand, and, on the other, points in West Virginia, Pennsylvania and New Jersey; and (2) Cullet, from points in Virginia to points in West Virginia, Pennsylvania and New Jersey, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Bassichis Co., 2323 W. 3rd St., Cleveland, Ohio 44100. Send protests to: J. A. Niggemyer, District Supervisor, Interstate Commerce Commission, 416 Old Post Office Bldg., Wheeling, W. Va. 26003.

No. MC 133119 (Sub-No. 114TA), filed March 4, 1977. Applicant: HEYL TRUCK LINES INC., 200 Norka Drive, P.O. Box 206, Akron, Iowa 51001. Applicant's representative: A. J. Swanson, P.O. Box 81849, Lincoln, Nebr. 68501. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Processed meats*, from Booneville, Miss., and its commercial zone, to the port of entry on the International Boundary at or near Sweetgrass, Mont., restricted to the transportation of traffic moving in foreign commerce to points in Alberta. Applicant intends to tack at Alberta Provincial Authority, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Larry Wood, Office Manager, American Packing Company, a subsidiary of East Asiatic Company, Inc., 101 E. Chambers, P.O. Box 429, Booneville, Miss. 38829. Send protests to: Carroll Russell, District Supervisor, Interstate Commerce Commission, 110 N. 14th St., Omaha, Nebr. 68102.

No. MC 133562 (Sub-No. 22TA) (correction), filed January 31, 1977, published in the FR issue of February 11, 1977, and republished as corrected this issue. Applicant: HOLIDAY EXPRESS CORPORATION, P.O. Box 115, Estherville, Iowa 51334. Applicant's representative: Edward A. O'Donnell, 1004 29th St., Sioux City, Iowa 51104. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, meat by-products and articles distributed by meat packinghouses*, as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of Spencer Foods, Inc., at or near Spencer and Hartley, Iowa, to points in Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia and the District of Columbia, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Spencer Foods, Inc., P.O. Box 1228, Spencer, Iowa 51301. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Bldg., Des Moines, Iowa 50309. The purpose of this republication is to correct the territorial description in this proceeding.

No. MC 134064 (Sub-No. 4TA), filed March 4, 1977. Applicant: INTERSTATE TRANSPORT, INC., 1820 Atlanta Highway, Gainesville, Ga. 30501. Applicant's representative: Charles M. Williams, 350 Capitol Life Center, 1600 Sherman St., Denver, Colo. 80203. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Prepared flour mixes and frosting mixes*, from the plantsite and storage facilities of Chelsea Milling Co., at or near Chelsea, Mich., to points in Alabama, Georgia, North Carolina and South Carolina, restricted to traffic originating at the plantsite and storage facilities of Chelsea Milling Co., at or near Chelesa, Mich., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Chelsea Milling Company, North St., Chelsea, Mich. 48118. Send protests to: Sara K. Davis, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, 1252 W. Peachtree St., N.W., Room 546, Atlanta, Ga. 30309.

No. MC 135797 (Sub-No. 68TA), filed March 2, 1977. Applicant: J. B. HUNT TRANSPORT, INC., P.O. Box 200, U.S. Highway 71, Lowell, Ark. 72745. Applicant's representative: Don Garrison, 204 Highway 71 North, Suite 3, Springdale, Ark. 72764. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Canned juices* (except in bulk), on traffic originating at the facilities of or used by Texsun Corporation, at or near Trafalgar, Ind., and Weslaco, Tex., from Trafalgar, Ind., to points in Missouri; and from Weslaco, Tex., to points in Mississippi and Tennessee, for 180 days. Applicant has also filed an underlying ETA seking up to 90 days of operating authority. Supporting shipper: Texsun Corporation, P.O. Box 327, Weslaco, Tex. 78596. Send protests to: William H. Land, Jr., District Supervisor, 3108 Federal Office Bldg., 700 W. Capitol, Little Rock, Ark. 72201.

No. MC 136343 (Sub-No. 104TA), filed March 4, 1977. Applicant: MILTON TRANSPORTATION, INC., P.O. Box 355, R.D. No. 1, Milton, Pa. 17847. Applicant's representative: George A. Olsen, 69 Tonnele Ave., Jersey City, N.J. 07306. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs* (except frozen and in bulk), from the plantsite and storage facilities of American Home Foods, Division of American Home Products Corporation, at or near Milton, Pa., to points in North Carolina and Tennessee, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: American Home Foods, Division of American Home Products Corporation, 685 Third Ave., New York, N.Y. 10017. Send protests to: Robert P. Amerine, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 278 Federal Bldg., P.O. Box 869, Harrisburg, Pa. 17108.

No. MC 136987 (Sub-No. 14TA), filed March 4, 1977. Applicant: REMINGTON FREIGHT LINES, INC., P.O. Box 315, Remington, Ind. 47977. Applicant's representative: William H. Towle, 180 N. LaSalle St., Chicago, Ill. 60601. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Beverage preparations*, from Momence, Ill., to points in Massachusetts, Connecticut, New Jersey, Georgia, Pennsylvania, Michigan, Indiana, Nebraska, California, Oregon, Washington, Tennessee, Missouri, Kansas, Iowa, Maine and Maryland, under a continuing contract with Ko-Pac, Inc., and restricted to shipments originating at the facilities of Ko-Pac, Inc., and destined to points in the named destination states, under a continuing contract with Ko-Pac, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Ko-Pac, Inc., P.O. Box 201, Momence, Ill. 60954. Send protests to: J. H. Gray, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 343 W. Wayne St., Suite 113, Fort Wayne, Ind. 46802.

No. MC 138000 (Sub-No. 27TA, filed March 4, 1977. Applicant: ARTHUR H. FULTON, P.O. Box 86, Stephens City, Va. 22655. Applicant's representative: Charles E. Creager, 1329 Pennsylvania Ave., P.O. Box 1417, Hagerstown, Md. 21740. Authority sought to operate as a *common carrier*, by motor vehicle, over

irregular routes, transporting: *Malt beverages,* from Detroit, Mich., and its commercial zone, to points in Alabama, Georgia, Maryland, North Carolina and South Carolina, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: The Stroh Brewery Company, 909 E. Elizabeth, Detroit, Mich. Send protests to: W. C. Hersman, District Supervisor, Interstate Commerce Commission, 12th & Constitution Ave., NW., Room 1413, Washington, D.C. 20423.

No. MC 139193 (Sub-No. 57TA) (correction), filed January 28, 1977, published in the FR issue of February 16, 1977, and republished as corrected this issue. Applicant: ROBERTS & OAKE, INC., 527 E. 52nd St. North, P.O. Box 1356, Sioux Falls, S. Dak. 57101. Applicant's representative: Jacob P. Billig, Suite 300, 2033 K St., NW., Washington, D.C. 20006. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Meats, meat products, meat by-products, dairy products, and articles distributed by meat packinghouses,* as described in Sections A, B and C of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766 (except hides and liquid commodities in bulk), from Estherville and Sioux City, Iowa, to points in Georgia and Tennessee, under a continuing contract with John Morrell & Co., for 180 days. Supporting shipper: John Morrell & Co., 208 S. LaSalle St., Chicago, Ill. 60604. Send protests to: J. L. Hammond, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 369 Federal Bldg., Pierre, S. Dak. 57501. The purpose of this republication is to correct the authority sought in this proceeding.

No. MC 139269 (Sub-No. 10TA) (correction), filed February 4, 1977, published in the FR issue of February 17, 1977, and republished as corrected this issue. Applicant: C. P. CRASKA, Inc., 207 Cosby Manor Road, Utica, N.Y. 13501. Applicant's representative: Murray J. S. Kirshtein, 118 Bleeker St., Utica, N.Y. 13501. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Foodstuffs,* in mechanically temperature controlled vehicles, from Philadelphia, Pa., to points in New York (except New York City and Long Island), for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Samuel Fareri, Vice-President, Northwestern Products, Inc., 1401 N. Delaware Ave., Philadelphia, Pa. 19125. Vita Food Products, Inc., 3650 S. Galloway St., Philadelphia, Pa. 19148. Send protests to: Morris H. Gross, District Supervisor, Interstate Commerce Commission, U.S. Courthouse & Federal Bldg., 100 S. Clinton St., Room 1259, Syracuse, N.Y. 13202. The purpose of this republication is to add another supporting shipper.

No. MC 139495 (Sub-No. 205TA), filed March 2, 1977. Applicant: NATIONAL CARRIERS, INC., P.O. Box 1358, 1501 E. 8th St., Liberal, Kans. 67901. Applicant's representative: Herbert Alan Dubin, 1819 H St., N.W., Suite 1030, Washington, D.C. 20006. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Pottery and pottery products,* from Marshall and Palestine, Tex., to points in Illinois, Indiana, Michigan, Iowa, Kansas, Maryland, Massachusetts, Missouri, New Jersey, New York, Ohio, Pennsylvania Virginia, Vermont, Wisconsin and the District of Columbia, for 180 days. Supporting shipper: Marshall Pottery, Inc., 1400 Lake St., Marshall, Tex. 75670. Send protests to: M. E. Taylor, District Supervisor, Interstate Commerce Commission, Suite 101 Litwin Bldg., 110 N. Market, Wichita, Kans. 67202.

No. MC 141867 (Sub-No. 2TA), filed March 7, 1977. Applicant: SPECIALIZED TRUCKING SERVICE, INC., 1523 18th N.E., Puyallup, Wash. 98371. Applicant's representative: Jack R. Davis, 1100 IBM Bldg., Seattle, Wash. 98101. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: (1) *Glass bottles, jars and containers;* and (2) *Covers, stoppers, etc.,* for (1) above, from points of entry on the Canada-United States Border in the state of Washington, to points in Washington and California, serving the provinces of British Columbia and Alberta, Canada, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Comglas Ltd., 8650 20th Ave., Burnaby, British Columbia V3N 1C8. Send protests to: L. D. Boone, Transportation Specialist, Bureau of Operations, Interstate Commerce Commission, 858 Federal Bldg., Seattle, Wash. 98174.

No. MC 142895 (Sub-No. 1TA), filed February 15, 1977. Applicant: EIGHTY EIGHT ENTERPRISES, INC., 8100 S. 100 East, Sandy, Utah 84070. Applicant's representative: Irene Warr, 430 Judge Bldg., Salt Lake City, Utah 84111. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Lumber, millwork, wood products, reinforcing steel, and building materials,* from points in Oregon, Washington, Idaho, Montana, California, Arizona, Colorado, Texas; Oklahoma City and Tulsa, Okla., to Salt Lake City, Ogden, Provo and Midvale, Utah, under a continuing contract with Gene's Building Materials, Inc., for 180 days. Supporting shipper: Gene's Building Materials, Inc., 313 Windsong Ave., Sandy, Utah 84070. Send protests to: Lyle D. Helfer, District Supervisor, Interstate Commerce Commission, 5301 Federal Bldg., Bureau of Operations, 125 S. State St., Salt Lake City, Utah 84138.

No. MC 142939 (Sub-No. 1TA), filed March 2, 1977. Applicant: BERNARD HARGER, doing business as HARGER TRUCKING, P.O. Box 1631, Gardena, Calif. 90249. Applicant's representative: Bernard Harber (same address as applicant). Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in by distributors of paper products, from the facilities of the La Salle Paper Company, at Los Angeles and Pomona, Calif., to points in Clark County, Nev., under a continuing contract with La Salle Paper Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: La Salle Paper Co., 215 W. Colorado Ave., Las Vegas, Nev. 89102. Send protests to: Mary A. Francy, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, Room 1321, Federal Bldg., 300 N. Los Angeles St., Los Angeles, Calif. 90012.

No. MC 142971TA, filed March 2, 1977. Applicant: F & W TRANSPORT CO., INC., 37 River Road, Camden, N.J. 08105. Applicant's representative: Robert B. Pepper, 168 Woodbridge Ave., Highland Park, N.J. 08904. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Wooden and plastic cabinets and materials and supplies* used in the manufacturing, sale and installation thereof (except in bulk), between Lakewood, N.J., on the one hand, and, on the other, points in New York, Connecticut, Delaware, Maryland, Maine, Massachusetts, New Hampshire, Pennsylvania, Rhode Island, Vermont and the District of Columbia, under a continuing contract with Excel Wood Products Co., Inc., for 180 days. Supporting shipper: Excel Wood Products Co., Inc., P.O. Box 819, Lakewood, N.J. 08701. Send protests to: Dieter H. Harper, District Supervisor, Interstate Commerce Commission, 428 E. State St., Room 204, Trenton, N.J. 08608.

No. MC 142993TA, filed March 4, 1977. Applicant: LONG LAKE TOWING SERVICE, 818 E. State St., Olympia, Wash. 98501. Applicant's representative: Anthony Eugene Carpenter (same address as applicant). Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Wrecked or disabled vehicles,* between Portland, Oreg., Olympia, Tacoma and Seattle, Wash., restricted to autos moving between salvage pools and auto wrecking yards, for 180 days. Supporting shippers: There are approximately 10 statements of support attached to the application, which may be examined at the Interstate Commerce Commission in Washington, D.C., or copies thereof which may be examined at the field office named below. Send protests to: L. D. Boone, Transportation Specialist, Bureau of Operations, Interstate Commerce Commission, 858 Federal Bldg., 915 Second Ave., Seattle, Wash. 98174.

No. MC 142994TA, filed March 4, 1977. Applicant: VIRGINIA COURIER SERVICE, INC., P.O. Box 287, Harrisonburg, Va. 22801. Applicant's representative: Chester A. Zyblut, 1030 15th St., NW., Washington, D.C. 20005. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Business papers, notes, checks, records and audit and accounting media,* between Harrisonburg, Va., and its commercial zone, on the one

hand, and, on the other, points in Hampshire, Mineral, Grant, Hardy, Pendelton, Preston, Taylor, Barbour, Upshur, Webster, Berkley, Jefferson, Pocahontas, Randolph, Greenbrier, Tucker and Morgan Counties, W. Va., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Data Corp. of Virginia, Inc., Harrisonburg, Va. 22801. Send protests to: Danny R. Beeler, District Supervisor, Interstate Commerce Commission, Bureau of Operations, P.O. Box 210, Roanoke, Va. 24011.

No. MC 143003TA, filed March 7, 1977. Applicant: GEORGE L. MORROW TRUCKING COMPANY, INC., P.O. Box 916, Raymondville, Tex. 78580. Applicant's representative: George L. Morrow (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Citrus pulp and pellets*, in bulk, between points in Hidalgo and Cameron Counties, Tex., for 180 days. Supporting shipper: I. S. Joseph Company, Inc., P.O. Box 567, Mission, Tex. 78572. Send protests to: Richard H. Dawkins, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Room B-400 Federal Bldg., 727 E. Durango, San Antonio, Tex.

No. MC 143004TA, filed March 4, 1977. Applicant: GORDON L. PETERSEN AND GWYNETH A. PETERSEN doing business as, CLOVIS MOVING & STORAGE, 700 E. Tatum Ave., Clovis, N. Mex. 88101. Applicant's representative: Alan F. Wohlstetter, 1700 K St., NW., Washington, D.C. 20006. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Used household goods, between* points in Guadalupe, Quay, De Baca, Curry and Roosevelt Counties, N. Mex., restricted to the transportation of traffic having a prior or subsequent movement, in containers, and further restricted to the performance of pickup and delivery service in connection with packing, crating and containerization or unpacking, uncrating and decontainerization of such traffic, for 180 days. Supporting shippers: Smith Alecander, Manager, InterIntra Forwarding, Inc., 7192 Kalanianaole Highway, Honolulu, Hawaii 96825. Samuel Klein, Vice President, Allstates Van Lines Corp., 50-18 97th Place, Corona, N.Y. 11368. D. C. Morrow, Executive Vice President, Swift International Forwarders, P.O. Box 3128, Irving, Tex. 75061. William M. Bunnell, General Manager, Lyon Household Shipping, Inc., 3416 S. La Cienega Blvd., Los Angeles, Calif. 90016. Send protests to: John H. Kirkemo, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 1106 Federal Office Bldg., 517 Gold Ave., S.W., Albuquerque, N. Mex. 87101.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8500 Filed 3-21-77;8:45 am]

[Notice No. 139]

MOTOR CARRIER TRANSFER PROCEEDINGS

MARCH 22, 1977.

Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212a(b) and Transfer Rules, 49 CFR Part 1132:

No. MC-FC 77026. By application filed March 8, 1977, JENSEN CHARTERS, INC., 155 So. 1st Street, St. Helens, OR 97223, seeks temporary authority to lease the operating rights of Kelso Ocean Beach Stage Lines, 204 So. 7th, P.O. Box 746, West Kelso, WA 98626, under section 210a(b). The transfer to Jensen Charters, Inc., of the operating rights of Kelso Ocean Beach Stage Lines, is presently pending.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8501 Filed 3-21-77;8:45 am]

[Notice No. 136]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act.

Each application (except as otherwise specifically noted) contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application.

Protests against approval of the application, which may include a request for oral hearing, must be filed with the Commission within 30 days after the date of this publication. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representative(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the Act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

No. MC-FC-76834, filed March 7, 1977. Transferee: CASAZZA TRUCKING CO., 1250 Glendale Avenue, Sparks, Nevada 89431. Transferor: C. H. Miller, doing business as C. H. Miller Transportation, P.O. Box 1776, Oroville, California 96965. Applicants' representatives: Raymond A. Greene, Jr., 100 Pine Street, Suite 2550, San Francisco, California 94111. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC 116881 (Sub-No. 2) and Certificate of Registration Nos. MC 116881 (Sub-No. 3) and MC 116881 (Sub-No. 4), issued December 4, 1962, July 25, 1969, and March 5, 1971 respectively, as follows: MC 116881 (Sub-No. 2)—General Commodities, Between points in San Francisco, California; Commodities requiring special handling by reason of their unusual size or weight, and in connection therewith, parts when included in the same shipment, Between recognized water terminals located on San Francisco Bay, at or South of San Francisco and Richmond, California, on the one hand, and, on the other, points within 100 miles of San Francisco, including San Francisco; Between railroad and inland water terminals within 100 miles of San Francisco, California, including those in San Francisco, on the one hand, and, on the other, points within 50 miles of such terminals; Between points in San Francisco, San Mateo, Santa Clara, Solano, Marin, Contra Costa, Sonoma, and Alameda Counties, California; MC 116881 (Sub-No. 3)—Lumber and forest products as described in Item No. 660 of Original Pages 52 and 53 of Minimum Rate Tariff No. 2, between the points and over the following routes: A. To, from and between points in Butte County, California and over the following routes: 1. Over U.S. Highway 99, 99 West and 99 East, within the confines of Butte County. 2. Points in Butte County 10 miles south of Vina. 3. Points in Butte County between Chico and the junction of State Highways 32 and 36 via State Highway 32. B. Between those points and over those routes, in Butte County as hereinabove specified in A. 1, 2 and 3 on the one hand, and on the other, the following named points and routes:

1. Over U.S. Highway 99, 99W and 99E between the California-Oregon State line and Modesto. 2. Over U.S. Highway 97 between the California-Oregon State line and U.S. Highway 99. 3. Over State Highway 96 between U.S. Highway 99 and U.S. Highway 299. 4. Over U.S. Highway 101 between the California-Oregon State Line and its junction with State Highway 36. 5. Over U.S. Highway 199 between California-Oregon State line and Crescent City. 6. Over an unnumbered road between Callahan and Tower House. 7. Over U.S. Highway 299 between U.S. Highway 101 and Alturas. 8. Over State Highway 89 between its junction with State Highway 44 and U.S. Highway 99. 9. Over State Highway 44 between Redding and its junction with State Highway

89. 10. Over State Highway 36 to a point thereon approximately one mile northeasterly of Westwood, thence over an unnumbered road, between U.S. Highway 101 and Westwood. 11. Over U.S. Highway 40 between Sacramento and San Francisco. 12. Over U.S. Highway 50 between Stockton and San Francisco. 13. Over State Highway 12 between U.S. Highway 40 and Napa. 14. Over State Highway 37 to Sears Point, thence over State Highway 48, between U.S. Highway 101 and U.S. Highway 40. 15. Over U.S. Highway 101 and 101 By-Pass between Ukiah and San Jose. 16. Over State Highway 17 between Oakland and San Jose. 17. Over an unnumbered road via San Francisco Bay Toll Bridge, between State Highway 17 and U.S. Highway 101. 18. With the right to serve all points embraced within the following laterals to the above-described routes: a Thirty-five miles north of Corning and Vina, and b. Ten miles south of Corning and Vina, and 19. Intermediate points within the above-described routes and laterals. c. Between those points and over those routes in Butte County as hereinabove specified in A. 1, 2 and 3 on the one hand, and, on the other hand, the following named points and routes:

1. Between Sacramento and Berkeley via State Highway 24. 2. Between San Jose and the California-Mexican border via U.S. Highway 101 and 101 Alternate. 3. Between Modesto and the California-Mexican border via U.S. Highway 99 to Los Angeles, U.S. Highway 60 to Riverside, U.S. Highway 395 to San Diego, U.S. Highway 80 to El Centro, and U.S. Highway 99 to the California-Mexican border. 4. Between U.S. Highway 50, at its junction with State Highway 33 three miles easterly of Tracy, and Ventura, via State Highway 33 and U.S. Highway 399. 5. Between Bakersfield and the California-Mexican border via U.S. Highway 466 to its junction with U.S. Highway 395, thence via U.S. Highway 395 to its junction with U.S. Highway 99, thence via U.S. Highway 99 to the California-Mexican border. 6. Between Chico and the junction of State Highways 32 and 36 via State Highway 32. 7. Between Sacramento and the California-Nevada State Line via U.S. Highway 40. 8. Between Sacramento and the California-Nevada State Line via U.S. Highway 50. 9. With the right to serve points adjacent to the above routes located within 35 miles laterally thereof; and 10. Between intermediate points. II. The commodities set forth in B. below: A. Between all points and places and over the routes specified, including all off-route points located within a radius of 10 miles laterally of the named highways, as follows:

1. Marysville and Susanville via Alternate U.S. Highway 40 and California State Highways 89 and 36. 2. Marysville, Sierraville, and junction U.S. Highway 395, via California State Highways 20, 49, 89 and Alternate U.S. Highway 40. 3. Susanville and junction Alternate U.S. Highway 40 via U.S. Highway 395. 4. Unnumbered highways and roads between Susanville, Walkermine, Cascade, Gibsonville, Taylorville, Mohawk, Portola, Calpine, Challenge, La Porte, Bangor, Marysville, Honcut, Enterprise, Janesville, Englemine, Genesee, Quincy, and Indian Falls. B. Commodities authorized are: Building or Paving Materials, Miscellaneous, and listed under that heading in Items Nos. 15860 through 16870. Conduits, Drain Tile, Sewer Pipe, or Related Articles, Clay, Concrete or Earthen, as listed under that heading in Items Nos. 28980 through 29210. Conduits, Pipe, Smokestacks, Tubing or Fittings, Other Than Clay, Concrete or Earthen, as listed under that heading in Items Nos. 29220 through 30440. Electrical applicances or equipment, or parts named, as listed under that heading in Items Nos. 34020 through 35425. Iron and steel articles, as listed under that heading in Items Nos. 53610 through 52290. Machinery or machines or parts named, as listed under that heading in Items Nos. 58470 through 67392. Outfits, as listed under that heading in Items Nos. 73380 through 74240. Railway material or equipment, as listed under that heading in Items Nos. 80835 through 82950. Vehicles, motor, as listed under that heading in Items Nos. 93315 through 93440. Vehicle parts, as listed under that heading in Items Nos. 93445 through 94790. Miscellaneous commodities, viz: Cement, hydraulic, masonry, mortar, natural or Portland. Culverts, Mine props or timbers, Ties, railroad, Tunnel segments.

NOTE.—The term "Items" as used above refers to the specified items as listed in Western Classification No. 77, J. P. Hackler, Tariff Publishing Officer, on the issue date thereof. This certificate of registration evidences a right to engage in operations, in interstate or foreign commerce, as described, only insofar as such operations do not duplicate those authorized in Certificate No. MC-116881 (Sub-No. 2) issued by the Interstate Commerce Commission. MC-116881 (Sub-No. 4).

I. (A) Property necessary or incidental to the establishment, maintenance or dismantling of oil, gas or water wells, pipe lines, refineries and cracking or casing head plants. (B) Material and equipment used in the construction of roads, dams and bridges. (C) Material and equipment used in the construction of and destined for power and compressor plants. Over and along the following routes within the Counties of Alpine, Amador, Calaveras, El Dorado, Fresno, Imperial, Inyo, Kern, Kings, Los Angeles, Madera, Mariposa, Merced Mono, Monterey, Nevada, Orange, Placer, Riverside, San Benito, San Bernardino, San Diego, San Luis Obispo, Santa Barbara, Sierra, Tulare, Tuolumne, and Vertura; (1) U.S. 101 and U.S. 101 By-Pass between Oregon-California State line and California-Mexico Line; (2) U.S. 99, 99-E and 99-W between Oregon-California State Line and Mexican Border; (3) U.S. 395 between the Oregon-California State Line and the California-Nevada State Line, via Alturas and Johnstonville; (4) State Highway 20 between Marysville, California, and Junction U.S. 40; (5) U.S. 40 between San Francisco and California-Nevada State Line; (6) U.S. 50 Between Sacramento, California, and California-Nevada State Line; (7) U.S. 395 between California-Nevada State Line at Topaz Lake and Junction U.S. 66; (8) U.S. 66 between Los Angeles and Needles, California; (9) U.S. 60 between Los Angeles, California, and California-Arizona State Line; (10) U.S. 91 and 466 between Barstow and Nevada-California State Line; (11) U.S. 80 between San Diego and California-Arizona State Line; (12) State Highway 127 between Baker and Nevada-California State Line; with the right to make lateral departures therefrom within a radius of 50 miles of such routes insofar as they authorize transportation within the above California Counties.

II. That the certificate herein granted is subject to the following conditions and limitations; (A) Carrier shall not transport any shipment which shall carry a charge lower than applicable to a shipment of 10,000 pounds. (B) Applicants shall not transport any shipments of lumber and forest products except in connection with the transportation referred to in paragraph I (A) hereof. (C) Carrier shall not transport any shipments of iron and steel articles and tin plate, having their origin or destination at Pittsburg, California. (D) Transportation performed under the authority herein granted shall be limited to commodities originating at or destined to an oil-well site, construction site or storage yard. Transferee is presently authorized to operate as a common carrier under Certificate No. MC-133828. Transferee has filed a conversion application in connection with the above-described certificates of registration and has been docketed MC-133828 (Sub-No. 6). Transferee proposes to tack the rights to be acquired herein with its presently held rights at Truckee and Roseville California. Application has not been filed for temporary authority.

No. MC-FC-76916, filed January 7, 1977. Transferee: MARIPOSA EXPRESS, INC., 201 West 15th Street, Merced, California 95340. Transferor: Jack Armas and Jean Armas, A Partnership, doing business as Mariposa Express, 201 West 15th Street, Merced, California 95340. Applicant's representative: Eugene A. Mash, Attorney at Law, 728 West 19th Street, Merced, California 95340. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate of Registration No. MC-96793 (Sub-No. 1), issued March 25, 1970, and Certificate No. MC-96793 (Sub-No. 2), issued April 12, 1972, as follows: General freight over a specified route between Merced and Mid Pines, California and General commodities with the usual exceptions over a specified regular route between Merced, Calif. and all points in Yosemite National Park, Calif. serving specified intermediate points.

Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76945, filed January 24, 1977. Transferee: FORWARDERS TRANSPORT, INC., P.O. Box 1073, Secaucus, New Jersey 07094. Transferor: C. G. Potter, an individual, d.b.a. Maumee Express, P.O. Box 1073, Secaucus, New Jersey 07094. Applicants' representative: Charles J. Williams, Attorney at Law, 1815 Front St., Scotch Plains, New Jersey 07076. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificates No. MC-71593 and subnumbers 2 and 3, issued March 12, 1975, December 8, 1976, and December 8, 1976, as follows: General commodities, (with exceptions), From Newark, N.J., to points

in that part of the New York, N.Y., Commercial Zone, as defined in *Commercial Zones and Terminal Areas*, 53 M.C.C. 451, within which local operations may be conducted pursuant to the partial exemption of Section 203(b)(8) of the Interstate Commerce Act (the "exempt" zone), also From New York, N.Y., to points in Union, Hudson, Essex, Bergen, and Passaic Counties, N.J. also Between points in that portion of the New York, N.Y., Commercial Zone, as defined in the fifth supplemental report in *Commercial Zones and Terminal Areas*, 53 M.C.C. 451, within which local operations may be conducted pursuant to the partial exemption of Section 203(b)(8) of the Interstate Commerce Act (the exempt zone) and Newark, N.J., on the one hand, and, on the other, Cleveland, Toledo, Columbus, and Cincinnati, Ohio, Louisville, Ky., Detroit Mich., and Indianapolis, Ind. with restrictions. also Between points in that part of the New York, N.Y., Commercial Zone as defined in the fifth supplemental report in *Commercial Zones and Terminal Areas*, 53 M.C.C. 451, within which local operations may be conducted under the exemption provided by Section 203(b)(8) of the Act (the "exempt" zone), and Newark, N.J., on the one hand, and, on the other, Chicago, Ill., St. Louis, Mo., and Milwaukee, Wis. with restrictions. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76958, filed February 2, 1977. Transferee: WINTER TRUCK LINES, INC., Mahnomen, Minnesota 56557. Transferor: Leo Winter, an individual, d/b/a Winter Truck Line, Mahnomen, Minnesota 56557. Applicant's representative: Clayton E. Schott, C.P.A., P.O. Box 68, Detroit Lakes, Minnesota 56501. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC-135764 Sub-2, issued July 12, 1972, as follows: Malt beverages, over irregular routes, from Milwaukee, Wis., to Mahnomen, Minn. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76959, filed January 31, 1977. Transferee: W. B. & L. TRUCKING & CARTAGE CO., INC., 404 N. Midler Avenue, Syracuse, New York 13206. Transferor: Gordon Jackson, an individual, d/b/a Case Express, 200 Fairview Avenue, Manlius, New York 13104. Applicant's representative: Joseph M. Kelley, Attorney at Law, 812 Syracuse-Kemper Bldg., Syracuse, New York 13202. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC-60175, issued June 12, 1941, as follows: General commodities (with exceptions) between Syracuse, N.Y., and Manlius, N.Y.: From Syracuse over New York Highway 5 to Fayetteville, N.Y., thence over New York Highway 92 to Manlius, and return over the same route. Service is authorized to and from all intermediate points. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76974, filed February 11, 1977, Transferee: HARRIS TRANSPORTATION CO., a Corporation, 14860 Seventh St. (Rear), Victorville, California 92392. Transferor: Ralph L. Harris, Florence L. Harris, Glenn M. Harris, and Roberta S. Harris, a Co-partnership, dba. Harris Transportation Company, 14860 Seventh St. (Rear), Victorville, California 92392. Applicant's representative: R. Y. Schureman, Attorney at Law, 1545 Wilshire Blvd., Los Angeles, California 90017. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate of Registration No. MC-121300 Sub 1, and Certificate No. MC-121300 Sub 3, issued August 13, 1969, and September 6, 1974, respectively as follows: General commodities, with exceptions, between points in the specified Los Angeles Basin Territory. Also Bastnasite ore concentrate, with restriction, in bulk, over irregular routes, from the facilities of the Molybdenum Corporation of America at or near Mountain Pass, Cal. to points in San Bernardino County, Cal. Transferee presently holds no authority fron. this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76982, filed February 17, 1977. Transferee: SAYRE TRUCKING COMPANY, A Corporation, 6101 S. Narragansett Ave., Chicago, Illinois 60638. Transferor: Chester Pucilowski, dba, Sayre Fast Freight, 6101 S. Narragansett Ave., Chicago, Illinois 60638. Applicant's representative: Philip A. Lee, Attorney-at-law, 120 W. Madison St., Chicago, Illinois 60602. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate of Registration No. MC-99935 Sub-1, issued October 31, 1963, which authorizes transportation to be conducted solely within the state of Illinois as follows: Roofing supplies, sheet steel, light machinery, bakery and confectionery products, household articles, packaged and crated freight within a radius of fifty (50) miles from 5531 SOUTH SAYRE AVENUE, CHICAGO 38, ILLINOIS, and to transport such property to or from any point outside of said authorized area of operation, for a shipper or shippers within such area. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76991, filed February 28, 1977. Transferee: ARTHUR E. PAMIN, JR. AND STEVEN V. BIDLAKE, doing business as Molitor Trucking, 6450 Highway 10 West, Missoula, Mo. 59801. Transferor: M. S. Molitor, doing business as Molitor Trucking, P.O. Box 259, Boulder, MT 59632. Applicants' representative: Charles A. Murray, Jr., Attorney-at-Law, Room 207A Behner Building, 2822 Third Avenue North, Billings, MT 59101. Authority sought for purchase by transferee of the operating rights of transferor set forth in Certificates Nos. MC-135846 (Sub-No. 1), and MC-135846 (Sub-No. 3), issued March 8, 1973, and October 12, 1976, respectively, as follows: Malt Beverages, in containers, from San Francisco, Calif., to points in Idaho, Montana, Nevada, Oregon, Utah, and Washington, and from Vancouver, Wash., to points in Idaho, Montana, Utah, and Washington; empty containers and container tops and related packaging material, between San Francisco, Calif., Vancouver, Wash., and Portland, Oreg.; malt beverages, in containers, from Azusa and Los Angeles, Calif., and points in its commercial zone as defined by the Commission, to points in Montana; and juicies and mixes, from Hayward and Sacramento, Calif., to Billings, Bozeman, Butte, Helena, Livingston, and Missoula, Mont. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

No. MC-FC-76992, filed February 24, 1977. Transferee: SINDALL TRANSPORT INC., 15 Lewis Road, Guelph, Ontario, Canada. Transferor: Donald M. Sindall and Glenn J. Yantzi, doing business as Don M. Sindall Transport, 15 Lewis Road, Guelph, Ontario, Canada. Applicants' representative: S. Harrison Kahn, Attorney-at-Law, Suite 733 Investment Building, Washington, D.C. 20005. Authority sought for purchase by transferee of the operating rights of transferor set forth in Certificates Nos. MC-115078 and MC-115078 (Sub-No. 6), issued January 15, 1960 and April 26, 1974, respectively, as follows: Agricultural machinery, implements, and parts, other than hand (except commodities the transportation of which, because of size or weight, require the use of special equipment), from New Holland, Mountville, Belleville, Intercourse and Lancaster, Pa., to the ports of entry on the United States-Canada Boundary line in New York, New Hampshire, and Vermont, restricted to traffic moving to points in Canada; rough sawed lumber, from the United States-Canada Boundary line, at Buffalo and Niagara Falls, N.Y., to points in New York and Pennsylvania, and from points in Pennsylvania, to the United States-Canada Boundary line, at Buffalo and Niagara Falls, N.Y.; and (1) agricultural, industrial, and construction machinery and equipment, and attachments for and equipment designed for use with such machinery and equipment, (2) such machinery and equipment as is dealt in by lawn and garden dealers, and trailers designed for the transportation of such machinery, and (3) attachments, accessories, parts, and supplies used in and for the manufacture, repair, and assembly of the commodities described in (1) and (2) above in mixed loads with the commodities described in (1) and (2) above, from the plant sites of the New Holland Division, Sperry Rand Corporation, at New Holland, Mountville, and Belleville, Pa., to ports of entry

on the United States-Canada Boundary line, located at points in New York, New Hampshire, and Vermont, restricted against the transportation of commodities which because of their size and weight require the use of special equipment. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8503 Filed 3-21-77;8:45 am]

[Notice No. 135]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

MARCH 21, 1977.

Synopses of orders entered by Division 3 of the Commission pursuant to sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 1132), appear below:

Each application (except as otherwise specifically noted) filed after March 27, 1972, contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application. As provided in the Commission's General Rules of Practice any interested person may file a petition seeking reconsideration of the following numbered proceedings on or before April 11, 1977. Pursuant to section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC-FC-75879. By order entered February 24, 1977, Division 3, acting as an Appellate Division, granted the authority sought by Hughes Refrigerated Express, Inc., to tack the various individual portions of the authorities previously evidenced by certificates No. MC 105782 (Sub-Nos. 3, 4, and 7), and now evidenced by Certificate No. MC 105782 (Sub-No. 3), in order to perform through motor common carrier service. The authority set forth in Certificate No. MC 105782 (Sub-No. 3) is as follows:

IRREGULAR ROUTES

Frozen foods, and *fresh, cold-packed, and partially frozen fruits, berries, and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: Between Philadelphia and Doylestown, Pa., Camden, Beach Haven, and Brant Beach, N.J., and Crisfield, Md., between Crisfield, Md., on the one hand, and, on the other, points in New Jersey, New York, and Pennsylvania; between Philadelphia and Doylestown, Pa., Camden, Beach Haven, and Brant Beach, N.J., on the one hand, and, on the other, points in Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Virginia, Tennessee, Wisconsin, and the District of Columbia.

Frozen fruits and frozen fruit purees, and fresh, cold-packed, and partially frozen fruits, berries, and vegetables when transported in the same vehicle and at the same time with the preceding commodities: From Cincinnati, Ohio, and points in that part of Kentucky and Tennessee on and west of a line beginning at Louisville, Ky., and extending along U.S. Highway 31-E to junction U.S. Highway 31, and thence along U.S. Highway 31 to the Tennessee-Alabama State line, to points in Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Ohio, Maryland, Virginia, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized; from points in Arkansas, to points in New York, New Jersey and Pennsylvania, with no transportation for compensation on return except as otherwise authorized.

Frozen fruits and fresh, cold-packed, and partially frozen fruits, berries, and vegetables when transported in the same vehicle and at the same time with the preceding commodities: From Chicago, Ill., Lafayette, Ind., and points in the Lower Peninsula of Michigan, to points in Massachusetts, Connecticut, New York, New Jersey, Pennsylvania, Maryland, Virginia, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized; from Erie, North East, Greencastle, and Hanover, Pa., to New York, N.Y., and Newark, Woodbridge, and Haddonfield, N.J., with no transportation for compensation on return except as otherwise authorized; from points in that part of New York on and west of a line beginning at Oswego, N.Y., and extending along U.S. Highway 104 to junction New York Highway 38, thence south along New York Highway 38 to Auburn, N.Y., thence west along U.S. Highway 20 to Geneva, N.Y., and thence south along New York Highway 14 to the New York-Pennsylvania State line, to New York, N.Y., and points in Pennsylvania and New Jersey, with no transportation for compensation on return except as otherwise authorized.

Frozen vegetables, and fresh, cold-packed, and partially frozen fruits, berries, and vegetables when transported in the same vehicle and at the same time with the preceding commodities: From Erie, North East, Greencastle, Hanover, and Biglerville, Pa., to New York, N.Y., and Newark and Haddonfield, N.J., with no transportation for compensation on return except as otherwise authorized; from points in that part of New York on and west of a line beginning at Oswego, N.Y., and extending along U.S. Highway 104 to junction New York Highway 38 thence south along New York Highway 38 to Auburn, N.H., thence west along U.S. Highway 20 to Geneva, N.Y., and thence south along New York Highway 14 to the New York-Pennsylvania State line to New York, N.Y., and points in Pennsylvania, New Jersey, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized; from Hanover, Pa., to Landover and Baltimore, Md., and points in New Jersey and the District of Columbia, with no transportation for compensation on return except as otherwise authorized; From Bay City, Mich., to points in New Jersey, Pennsylvania, New York, Connecticut, Massachusetts, Maryland, Virginia, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized; from Rockland and Camden, Maine, to New York, N.Y., Haddonfield and Newark, N.J., and points in Pennsylvania, with no transportation for compensation on return except as otherwise authorized; from Southhampton, Pa., to Portland, Maine, Watertown and Springfield, Mass., Providence, R.I., New London and New Haven, Conn., Ossining, Milton, New York, White Plains, Newburgh, Syracuse, Rochester, and Albany, N.Y.; Camden, Newark, Jersey City, and Bayonne, N.J., Baltimore, Md., Washington, D.C., Richmond and Norfolk, Va., Jacksonville, Fla., Chicago, Ill., Detroit, Mich., and Kansas City, Mo., with no transportation for compensation on return except as otherwise authorized.

Frozen strawberries, and *fresh, cold-packed, and partially frozen fruits, berries, and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: From Plant City, Fla., to Paterson and Newark, N.J., and New York, Utica, and Nyack, N.Y., with no transportation for compensation on return except as otherwise authorized.

Frozen peaches, and *fresh, cold-packed and partially frozen fruits, berries and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: From Fort Valley and Montezuma, Ga., Spartanburg, S.C., and Hamlin, N.C., to Paterson and Newark, N.J., and New York, Utica, and Nyack, N.Y., with no transportation for compensation on return except as otherwise authorized.

Frozen applies, and *fresh, cold-packed and partially frozen fruits, berries, and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: From Winchester, Va., to Paterson and Newark, N.J., and New York, Utica and Nyack, N.Y., with no transportation for compensation on return except as otherwise authorized; from Corzet, Va., to Paterson and Newark, N.J., New York, Utica, and Nyack, N.Y., and Boston and Brockton, Mass., with no transportation for compensation on return except as otherwise authorized.

Frozen fruit purees, and *fresh, cold-packed, and partially frozen fruits, berries, and vegetables*, when transported in the same vehicle and at the same with the preceding commodities: From Baltimore, Md., to Paterson and Newark, N.J., and New York, Utica, and Nyack, N.Y., with no transportation for compensation on return except as otherwise authorized.

Frozen fruits, frozen vegetables, frozen purees, and *mincemeat,* and *fresh, cold-packed, and partially frozen fruits, berries, and vegetables* when transported in the same vehicle and at the same time with the preding commodities: From Haddonfield and Gloucester, N.J., to Chicago, Ill., Miami and Jacksonville, Fla., Wilmington, Del., Portland, Maine, Charlotte, N.C., Atlanta, Ga., Kansas City and St. Louis, Mo., and points in Maryland, Virginia, Ohio, Pennsylvania, New York, Connecticut, Massachusetts, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized, from Lemoyne, Pa., to points in New Jersey, and Haddonfield and Gloucester, N.J., Chicago, Ill., Miami and Jacksonville, Fla., Wilmington, Del., Portland, Maine, Charlotte, N.C., Atlanta, Ga., Kansas City and St. Louis, Mo., and points in Maryland, Virginia, Ohio, New York, Connecticut, Massachusetts, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized.

Frozen fruits, frozen vetetables, and *frozen fruit purees,* and *fresh, cold-packed, and partially frozen fruit, berries, and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: From Braddock, N.J., to Miami and Jacksonville, Fla., Knoxville, Tenn., Winston-Salem and Charlotte, N.C., Atlanta, Ga., Richmond and Charlottesville, Va., Landover and Baltimore, Md., Columbus, Martins Ferry, Cleveland and Akron, Ohio, Uniontown, Washington, and Pittsburgh, Pa., New York, Rochester, and Schenectady, N.Y., and Cambridge, Boston, and Worcester, Mass., and the District of Columbia, with no transportation for compensation on return except as otherwise authorized.

Frozen meat pies, frozen chicken pies, frozen fish pies, and *frozen chicken croquettes,* and *fresh, cold-packed, and partially frozen fruits, berries, and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: From Plumsteadville, Pa., to Baltimore, Salisbury, and Landover, Md., Milford and Wilmington, Del., Cleveland and Youngstown, Ohio, Providence, R.I., and points in New Jersey, New York, Connecticut, Massachusetts, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized.

Frozen berries, and fresh, cold-packed, and partially frozen fruits, berries, and vegetables when transported in the same vehicle and at the same time with the preceding commodities: From points in the Lower Peninsula of Michigan, to points in Massachusetts, Connecticut, New York, New Jersey, Pennsylvania, Maryland, Virginia, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized.

Frozen hors d'oeuvres and *frozen pastry products,* and *fresh cold-packed, and partially frozen fruits, berries, and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: From Jersey City, N.J., to Boston, Cambridge, and Worcester, Mass., New Haven, Wallingford, Bridgeport, and Norwalk, Conn., Buffalo, Rochester, Syracuse, Albany, Elmira, Troy, and West Point, N.Y., Harrisburg, Philadelphia, Pittsburgh, Carnegie, Easton, and Wilkes-Barre, Pa., Baltimore, Md., Washington, D.C., Miami and Tampa, Fla., Cleveland and Cincinnati, Ohio, Detroit, Mich., Chicago, Ill., South Bend, Ind., and Milwaukee, Wis., with no transportation for compensation on return except as otherwise authorized.

Frozen potato products, and *fresh, cold-packed, and partially, frozen fruits, berries, and vegetables* when transported in the same vehicle and at the same time with the preceding commodities: From Philadelphia, Pa., to Providence, R.I., Miami, Fla., Cleveland, Ohio, Buffalo, N.Y., Detroit, Mich., Syracuse, N.Y., Indianapolis, South Bend, and Fort Wayne, Ind., and St. Louis, Mo., with no transportation for compensation on return except as otherwise authorized.

Frozen fruits frozen berries, and *frozen vegetables;* between points in Pennsylvania; from points in Tennessee, to points in New York, with no transportation for compensation on return except as otherwise authorized; from points in Delaware, Michigan, and New York, to points in Pennsylvania, with no transportation for compensation on return except as otherwise authorized; from points in Michigan, to New York, N.Y., and Washington, D.C., with no transportation for compensation on return except as otherwise authorized; from points in New York, to Baltimore, Md., Washington, D.C., and Camden, N.J., with no transportation for compensasion on return except as otherwise authorized.

Frozen fruits, frozen berries, and *frozen vegetables,* and when moving in the same vehicle and at the same time with frozen fruits and frozen berries, frozen vegetables, or *bananas, seafood* and *seafood products* the transportation of which is exempt from economic regulation under the Interstate Commerce Act; from points in Pennsylvania, to Denver, Colo., Milton, Del., Washington, D.C., Chicago, Ill., Detroit, Mich. and Providence R.I., and to points in Connecticut, Maryland, Massachusetts, New Jersey, New York, Ohio, Virginia, and points in that part of West Virginia on the west of U. S. Highway 119, with no transportation for compensation on return except as otherwise authorized.

Bananas: From Philadelphia, Pa., to Chicago, Ill., Boston, Mass., Cleveland, Ohio, and Utica, N.Y., with no transportation for compensation on return except as otherwise authorized.

Frozen foodstuffs, in containers, in vehicles equipped with mechanical refrigeration: From the facilities of Stouffer Foods, Division of Litton Industries at or near Cleveland, Ohio, to Points in Pennsylvania, Maryland, New Jersey, New York, Connecticut, Massachusetts, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized; from the facilities of Stouffer Foods, Division of Litton Industries, at King of Prussia, Pa., to the facilities of Stouffer Foods, Division of Litton Industries at or near Cleveland, Ohio, and Syracuse, N.Y., and to points in New Jersey, Maine, Massachusetts, Connecticut, Rhode Island, Maryland, and the District of Columbia, with no transportation for compensation on return except as otherwise authorized.

RESTRICTION

The authority granted under the two territory descriptions next-above are restricted to the transportation of shipments originating at the facilities of Stouffer Foods, Division of Litton Industries at King of Prussia, Pa., or at or near Cleveland, Ohio.

Any interested person may file a petition for within 30 days of the date of this notice.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8504 Filed 3-21-77;8:45 am]

[Notice 137]

MOTOR CARRIER TRANSFER PROCEEDINGS

MARCH 22, 1977.

Application filed for temporary authority under Section 210a(b) in connection with transfer application under Section 212a(b) in connection with transfer application under Section 212a(b) and Transfer Rules, 49 CFR Part 1132.

No. MC-FC 77022. By application filed March 11, 1977, INTERNATIONAL TRAILER TRANSPORT, INC., 796 Frelinghuysen Avenue, P.O. Box 4067, Newark, N.J. 07112, seeks temporary authority to transfer a portion of the operating rights of L.J.P. Truck Lines, Inc., 273 Meserole Street, Brooklyn, N.Y. 11222, under section 210a(b). The transfer to International Trailer Transport, Inc., of a portion of the operating rights of L.J.P. Truck Lines, Inc., is presently pending.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-8493 Filed 3-21-77;8:45 am]

[Notice 138]

MOTOR CARRIER TRANSFER PROCEEDINGS

MARCH 22, 1977.

Application filed for temporary authority under Section 210a(b) in connection with transfer application under Section 212a(b) in connection with transfer application under Section 212a (b) and Transfer Rules, 49 CFR Part 1132:

No. MC-FC 77024. By application filed March 15, 1977, FROST TRUCK LINES, INC., 14751 Boyle Avenue, Fontana, CA 92335, seeks temporary authority to transfer the operating rights of

MARY FROST, (Secured party in foreclosure of Tiger Transportation Inc. MC–140186), 2321 21st Street W., Billings, MT 59102, under section 210a(b). The transfer to FROST TRUCK LINES, INC., of the operating rights of MARY FROST (Secured party in foreclosure of Tiger Transportation Inc. MC–140186), is presently pending.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77–8494 Filed 3–21–77;8:45 am]

[No. 36478]

NORTH CAROLINA INTRASTATE RAIL FREIGHT RATES AND CHARGES—1976

Petition for Investigation of Rates

In the matter of petition for investigation of intrastate freight rates and charges within the State of North Carolina.

By joint petition authorized under section 13(3) of the Interstate Commerce Act, filed November 18, 1976, petitioners Class I rail carriers [1] subject to Part I of the Interstate Commerce Act, and also operating in intrastate commerce in the State of North Carolina, request that this Commission institute an investigation of their North Carolina intrastate freight rates and charges, under section 13(4), 13(5), and 15a of the Interstate Commerce Act, wherein they will seek an order authorizing them to increase such rates and charges in the same amounts approved for interstate application by this Commission in Ex Parte No. 318, Increased Freight Rates and Charges—1976.

By tariff filed on April 14, 1976, with the North Carolina Utilities Commission, petitioners sought to make the increases granted in Ex Parte 318, supra, applicable on North Carolina intrastate traffic, effective May 20, 1976. Following a hearing regarding said tariff, the North Carolina Utilities Commission on October 27, 1976, issued an order denying the increases.

Petitioners contend that present interstate freight rates from, to, and within North Carolina are just and reasonable and that the proposed intrastate rates will not exceed a just and reasonable level; that transportation conditions for intrastate traffic in North Carolina are not more favorable than for interstate traffic; that traffic moving under present North Carolina intrastate rail freight rates and charges fails to provide its fair share of earnings; and, that the present North Carolina intrastate rail freight rates and charges create undue and unreasonable advantage, preference, and prejudice between persons and localities in intrastate commerce within North Carolina and interstate and foreign commerce, and result in undue, unreasonable, and unjust discrimination against and an undue burden on interstate commerce in violation of section 13 and 15a of the Interstate Commerce Act to the extent that they do not include the increases authorized in Ex Parte No. 318, supra.

Under section 13(4) and 13(5) of the Interstate Commerce Act, this Commission is directed to institute an investigation into the lawfulness of intrastate rail freight rates and charges upon filing of a petition by the railroads pursuant to section 13(3) of the Act, after the appropriate State agency has reached a final decision or has failed to act within 120 days after a carrier by railroad has filed with such appropriate state body a change in an intrastate rate, fare, or charge for the purpose of adjusting such rate, fare, or charge to the rate charged on similar traffic moving in interstate or foreign commerce. This Commission may act notwithstanding the laws or constitution of any State, or the pendency of any proceeding before any State court or other State authority. We note the failure of the North Carolina Utilities Commission to act within 120 days after filing by petitioners for an appropriate change in intrastate rates, vesting our jurisdiction.

Wherefore, and good cause appearing therefor;

It is ordered, That the petition be, and it is hereby, granted; and that an investigation, under sections 13 and 15a of the Interstate Commerce Act, be, and it is hereby, instituted to determine whether the North Carolina intrastate rail freight rates in any respect cause any unjust discrimination against or any undue burden on interstate or foreign commerce, or cause undue or reasonable advantage, preference, or prejudice as between persons and localities in intrastate commerce and those in interstate or foreign commerce, or are otherwise unlawful, by reason of the failure of such rates and charges to include the full increases authorized for interstate application by this Commission in Ex Parte No. 318, supra; and to determine if any rates or charges, or maximum or minimum charges, or discrimination, undue burden, or other violation of law, found to exist.

It is further ordered, That all common carriers by railroad operating in the State of North Carolina, subject to the jurisdiction of the Commission, be, and they are hereby, made respondents to this proceeding.

It is further ordered, That all persons who wish to actively participate in this proceeding and to file and receive copies of pleadings shall make known that fact by notifying the Office of Proceedings, Room 5342, Interstate Commerce Commission, Washington, D.C. 20423, on or before April 6, 1977. Although individual participation is not precluded, to conserve time and to avoid unnecessary expense, persons having common interests should endeavor to consolidate their presentations to the greatest extent possible. The Commission desires participation of only those who intend to take an active part in the proceeding.

It is further ordered, That as soon as practicable after the date of indicating a desire to participate in the proceeding has passed, the Commission will serve a list of names and addresses of all persons upon whom service of all pleadings must be made and that thereafter this proceeding will be assigned for oral hearing or handling under modified procedure.

And is is further ordered, That a copy of this order be served upon each of the petitioners herein; that the State of North Carolina be notified of the proceeding by sending copies of this order of the instant petition by certified mail to the Governor of the State of North Carolina and the North Carolina Utilities Commission; and that further notification of this proceeding be given to the public by depositing a copy with the Director, Office of the Federal Register, for publication in the FEDERAL REGISTER.

This is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969.

Dated at Washington, D.C., this 9th day of March, 1967.

By the Commission, Commissioner Hardin.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77–8493 Filed 3–21–77;8:45 am]

[1] Carolina, Clinchfield and Ohio Railway; Louisville and Nashville Railroad Company; Norfolk and Western Railway Company; Norfolk Southern Railway Company; Seaboard Coast Line Railroad Company; and Southern Railway Company.

federal register

TUESDAY, MARCH 22, 1977

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education

■

SCHOOL ASSISTANCE IN FEDERALLY AFFECTED AREAS

Final Rules and Proposed Rules

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education

[45 CFR Part 115]

SCHOOL ASSISTANCE IN FEDERALLY AFFECTED AREAS

Proposed Rulemaking

Interim regulations for treatment of payments under State equalization programs were published in the FEDERAL REGISTER on June 25, 1976 (41 FR 26320). A notice of proposed rulemaking was published in the same document (41 FR 26330) proposing an alternate qualifying test based on the principle of fiscal neutrality. Interested parties were invited to comment on the proposed rule. Due to complexities of interpreting the proposed rule as it relates to a wide variety of public school financing programs, the proposed rule is being republished with additional clarifying detail for additional public comment simultaneously with the publication of final regulations.

A. SUMMARY OF STATUTORY AMENDMENT AND FINAL REGULATIONS

1. *Effect of Pub. L. 93-380.* Section 305 (a)(2) (effective for Fiscal Year 1976 and thereafter) of Pub. L. 93-380 amended section 5(d) of Pub. L. 81-874 to permit States to take into account payments under Title I of that Act in determining the relative financial resources available to local educational agencies and relative financial need of those agencies if the State has in effect a program of State aid for free public education designed to equalize expenditures among local educational agencies in the State. However, Pub. L. 81-874 payments may be so taken into account only in the proportion that local revenues covered by those programs are of total local revenues for education. This proposed rule establishes an alternate qualifying test for determining whether a State has in effect such a program.

2. *Proposed additional qualifying standard.* It was apparent from a number of inquiries that the proposed fiscal neutrality standard was not well understood and that a substantial amount of clarifying detail should be added. Additional detail is added to § 115.64 and also to the appendix. The purpose of the standard, however, remains the same. As stated in the preamble to the proposed rule, that purpose was and still is "* * * to measure those school finance systems such as so-called power equalizing programs, which allow for variances in educational expenditures based on local choice but not on local wealth."

One change was to modify the title to a more accurately descriptive term "wealth neutrality". Additional detail was provided regarding how "leeway" or local unmatched funds are analyzed for wealth neutrality, how the matched or equalized portion is analyzed, and how other State funds are analyzed. Also included are provisions which are designed to measure the effects of unequal budget and expenditure restraints which prevent full participation by some districts in the equity features of the program. Additional interpretative items have been added to the appendix along with examples of how analyses will be made.

In view of the fact that the removal of local taxable wealth by the Federal acquisition of real property is one of the primary reasons for payments under the Act, the well researched principle that differences in local expenditures for education are significantly related to differences in local wealth, and that differences in student needs and local choice may require significantly different expenditures, the Commissioner feels that a test of the degree to which a State has removed local taxable wealth advantages or disadvantages is fair and appropriate alternative test under section 5(d)(2) of the Act.

A basic notion underlying the "power equalizing" type of school financing program is that of giving to each local educational agency the same power to raise revenues for education. Stated another way, the same local tax effort should yield the same revenues for education. This equal effort-equal yield principle is the essential feature of any such program with equal yield interpreted as an equal educational opportunity which may or may not mean equal dollars depending on possible differences in student needs or differences in costs of equal opportunities.

To measure the degree to which this equal effort-equal yield principle is in effect in a program, not only must the yields and efforts of local educational agencies be analyzed but any restraint on effort which makes equal yields impossible must also be considered. Thus, the standard is designed to measure as not wealth neutral both revenues which represent unequal yields for equal effort and revenues not obtainable by some local educational agencies but obtained by others, because of budget and expenditure constraints imposed by the State.

The wealth neutrality standard is set at 85 percent. While most authorities who have studied educational finance agree that substantial expenditure differences, because of differences in student needs and costs, may be necessary in order to provide equal educational opportunity, there is near consensus that differences in local educational agency taxable wealth should not be allowed to determine large differences in educational expenditures. Three national groups in recent years, the National Education Finance Project, the Advisory Council on Intergovernmental Relations, and the President's Commission on School Finance, suggested that a modest leeway, based on local wealth, is reasonable. Based on an average $1200 expenditure per pupil and 85 percent wealth neutrality, no more than $180 per pupil, on the average, could be realized by a local wealth advantage. As dicussed above, this difference is unlikely to cause significant differences in the quality of an educational program. It is possible under a program meeting the neutrality standard for a few expenditure differences to be substantially greater than the average. Such differences could only affect a small portion of the pupils in a State. Even these would necessarily be on the high side. As noted above, factors such as sparsity, unusual cost factors, etc. may justify substantial differences in a few cases. The consideration of State imposed restraints in § 115.64 will prevent a State from meeting the standard if even one local agency is denied a reasonably equitable opportunity to realize educational revenue comparable to most other agencies in the State.

Further examination of data from several States indicates that less than a quarter of the States will be able to meet either the expenditure disparity or wealth neutrality standard at the present time. Thus, taken together the standards are carefully constructed exceptions as intended by the Congress and will protect local educational agencies from unfair treatment by States concerning payments received under the Act.

B. SUMMARY OF COMMENTS, RESPONSES, AND CHANGES IN THE PROPOSED RULE

The comments received concerning the proposed alternate standard were essentially the same as those received concerning the original proposed rules. In the previous section, the rationale for the appropriateness of, and the reasonableness of, the specific levels is provided. Comments are discussed below on an individual basis. After the summary of each comment, a response is set forth stating changes which have been made to the proposed rule in light of the comment, or the reasons why no change is deemed necessary.

Comment: Four commenters were in favor of adding a fiscal neutrality test but suggested that the percentage of leeway be increased; one suggested 15% and three suggested 20%.

Response: The percentage has been increased to 15 percent. At least four large educational finance studies conducted by nationally recognized experts in school finance during recent years have indicated that this percentage would fall within the range of a reasonable leeway differential. In addition, a preliminary examination of data indicates that a small number of additional States may qualify under the modified wealth neutrality standard while a large majority cannot. It is believed that the wealth neutrality and expenditure disparity standards constitute fair and reasonable alternative tests, which, in keeping with the law and its legislative history, will allow those States with a high degree of equity in their financing programs to qualify while excluding others.

Comment: Two commenters opposed the neutrality test as an alternate test.

Response: Section 5(d)(2) requires the Commissioner to provide regulations for determining when a program of State aid is "designed to equalize expenditures." A program meeting the requirements of

such regulations is exempted from the general prohibition of considering payments under the Act as local resources in determining State aid. One of the obvious ways to judge a program "designed to equalize expenditures" is to measure directly the extent to which expenditures among districts are equal. The expenditure disparity test does that. In the preamble to the proposed fiscal neutrality standard, a rationale was stated for an alternative test for programs which allow for variances in educational expenditures based on local choice but not on local wealth. A wealth neutrality test is considered to be a fair and reasonable measure of a State's efforts to equalize educational opportunity while allowing a large degree of local determination. In addition, the extent to which a State has neutralized the effects of local taxable wealth in determining revenues for a local district, to that extent the State has shifted to the State as a whole one of the primary burdens of Federal activity for which Pub. L. 81-874 payments are made (loss of local revenue due to Federal acquistion of real property).

C. OTHER CHANGES

A number of typographical and technical corrections have been made. The revised proposed rule defines what wealth neutralized revenues are instead of defining unequalized revenues Additional operational rules for making calculations and additional examples have been supplied in an appendix.

D. OPPORTUNITY FOR PUBLIC COMMENT

Parties interested in commenting on the proposed rule should submit comments to the U.S. Office of Education, Bureau of Elementary and Secondary Education, Room 2069, 400 Maryland Avenue, S.W. Washington, D.C. 20202, Attention: Mr. William Stormer.

All written and oral comments must be received not later than May 6, 1977. Comments and suggestions submitted in writing will be available in the above office between the hours of 8:30 a.m. and 4 p.m. Monday through Friday of each week.

The Office of Education has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

(Catalog of Federal Domestic Assistance No. 13.478, School Assistance in Federally Affected Areas-Maintenance and Operation.)

Dated: January 17, 1977.

EDWARD AGUIRRE,
Commissioner of Education.

Approved: March 11, 1977.

JOSEPH A. CALIFANO, Jr.
Secretary of Health, Education, and Welfare.

It is proposed to amend Subpart G of Part 115, Title 45 of the Code of Federal Regulations, by adding § 115.64 and by revising §§ 115.62, 115.65, and the Appendix to read as follows:

§ 115.62 General qualifying standard for State aid programs.

* * * * *

(a) *General standard.* * * *

(4) Meets the standards of §§ 115.63, 115.64 or 115.65 of this subpart.

* * * * *

§ 115.64 Wealth neutrality test.

(a) *General rule.* (1) For any Fiscal Year for which a determination is made under this subpart, the Commissioner will consider a State aid program to have met the requirement of § 115.62(a)(4) if no less than 85 percent of the total State, intermediate, and local revenues for current expenditures for all local educational agencies in the State are wealth neutral revenues for the Fiscal Year for which a determination is made under this subpart.

(2) Paragraph (b) of this section sets forth rules for determining which State, intermediate, and local revenues are "wealth neutral revenues."

(b) *Categories of wealth neutral revenues.* Except as excluded under each paragraph of this section, the revenues described below are "wealth neutral revenues."

(1) *Local leeway revenues.* Wealth neutral revenues are revenues from local or intermediate sources which are not taken into consideration under any part of the State aid program designed to equalize expenditures among local educational agencies in the State, except for:

(i) Any of those revenues derived from taxes which exceed the amount of revenues that each agency would realize from its tax effort if it were the local educational agency with the least taxable wealth per pupil in the State;

(ii) Any of those revenues derived from taxes which are realized from any portion of each agency's tax effort which exceeds the maximum tax effort permitted the local educational agency in the State which, because of limitations under State law regarding the exercise of tax effort, is restricted to the least amount of per pupil revenue from State, intermediate, and local sources. These State limitations are those which are imposed on budget, expenditure, or local tax effort increases over prior year levels. However, any revenues already taken into consideration under paragraph (b)(1)(i) of this section may not be considered under this clause; and

(iii) Any of those revenues not derived from taxes which exceed the least amount per pupil of these non-tax revenues realized by any local educational agency in the State.

(2) *Local and State equalization funds.* Except as provided in paragraphs (b)(2) (i), (ii), and (iii) of this section, wealth neutral revenues are revenues realized or taken into consideration under any part of the State aid program designed to equalize expenditures among local educational agencies in the State. This includes revenues realized from State and intermediate as well as local sources. It also includes local or intermediate revenues taken into consideration for a local educational agency which does not receive State aid under any equalized part of the State aid program because the amount realized by the agency from those sources exceeds the amount of revenues guaranteed by the State aid formula.

(i) If an equalized part of a State aid program requires that local educational agencies exercise a uniform local tax effort, this category of wealth neutralized revenues does not include those revenues realized by any agency from State, intermediate, and local sources which exceed the least amount of those revenues realized per unit of need under the equalized part of the State aid program by any other agency. However, any of these excess revenues which are attributable to the special educational costs considered in § 115.61(b)(3) of this part are still regarded as wealth neutral revenues.

(ii) If an equalized part of a State aid program permits local educational agencies to exercise different local tax efforts and guarantees a uniform yield per unit of need for each unit of tax effort, this category of wealth neutral revenues does not include any revenues realized per unit of need by an agency from State, intermediate or local sources which exceed the amount of guarantee per unit of effort. However, any of these excess revenues which are attributable to the special educational costs considered in § 115.61(b)(3) of this part are still regarded as wealth neutral revenues.

(iii) If an equalized part of a State aid program subjects local educational agencies, in the exercise of tax efforts, to limitations based on prior year budget, expenditure or tax effort levels, then this category of wealth neutralized revenues does not include those revenues for any local educational agency which exceed the least amount of revenues per unit of need that could be realized by any local agency if it were exercising its maximum tax effort as permitted under those State limitations.

(3) *Other State funds.* All revenues from State sources which were not considered under paragraph (b)(2) as realized or taken into consideration under an equalized part of the State aid program. However, this category of wealth neutralized revenues does not include any revenues designed to guarantee State aid to local educational agencies with relatively high taxable wealth per pupil.

(c) The method required for calculating the percentage of wealth neutral revenues for a State is set out in the Appendix to this subpart.

§ 115.65 Consideration for exceptional circumstances.

(a) *General requirements.* A State program which does not conform to the standards of either § 115.63 or § 115.64 of this subpart may, nevertheless, qualify under this section if the Commissioner determines on the basis of information submitted by the State, that:

(1) A decision not to apply the exact disparity standard specified in § 115.63 to the program submitted by the State would be justifiable because of exceptional circumstances within the State related to disparities in current expenditures or revenue per pupil for education;

(2) A decision not to apply the wealth neutrality standard in § 115.64 would be justifiable because of exceptional circumstances related to the coverage of educational expenditures by the State equalization program;

(3) Current expenditures or revenues for education in that State will be more equalized if payments under the Act are taken into consideration under this subpart than if they are not; and

(4) The program meets the requirements of paragraph (a)(3) of this section.

(b) *Determination of "more equalized."* For purposes of paragraph (a)(3) of this section, current expenditures or revenues for education within a State are considered "more equalized" if the distribution around the mean per pupil expenditure for all local educational agencies within the State is less when payments under the Act are taken into consideration in conformity with § 115.64 of this part than when they are not, as calculated according to accepted statistical methods appropriate to the circumstances.

(c) *Specific program requirements.* A program of State aid considered under this is not considered a program designed to equalize expenditures among local educational agencies in the State unless the Commissioner finds that, in addition to meeting the requirements of the preceding paragraphs—

(1) The amount of the revenue available to local educational agencies in the State is not predominantly a function of the wealth of individual local educational agencies;

(2) The program is designed to ensure the provision of financially adequate educational programs and supportive services for every pupil in the State who is enrolled in public schools;

(3) In the determination of the relative financial need of local educational agencies, that program (i) makes provision for identifying those pupils with special educational needs (such as handicapped children, economically disadvantaged children, children with limited English-speaking ability), (ii) takes into consideration the additional costs of providing free public education for such children or categories of children; and (iii) takes into consideration the costs of providing education which might be associated with such factors as sparsity or density of population, cost of living, and socio-economic characteristics of the local educational agencies; except that nothing in this clause shall be construed to require any particular system of weighting of pupils.

(4) Such program involves a substantial percentage of school revenues;

(5) Such program is designed to provide systems and procedures for evaluating the degree to which the program is achieving its stated objectives.

(20 U.S.C. 240(d)(2); S. Rep. No. 763, 93d Cong., 2d Sess. 56 (1974); H.R. Rep. 805, 93d Cong., 2d Sess. 42–44 (1974); 102 Cong. Rec. S 8604–8607 (daily ed., May 20, 1974); *Id.*, H 7401 (daily ed., July 31, 1974); Congressional Research Service, *Public Law 874 and State Equalization Plans* 30–34 (H.R. Comm. on Education and Labor Print (March 1974))

APPENDIX

* * * * *

2. Determinations of wealth neutrality standard compliance under § 115.64.

(a) The determination of the percent of wealth neutral revenues in a State program is made by:

(1) Calculating the total amount of neutral and non-neutral revenue for each category of revenues described in § 115.64(b) for each local educational agency in the State;

(2) Calculating the total neutral and non-neutral revenue for all local educational agencies in the State; and

(3) Dividing the total of neutral revenues by the total of all State, intermediate, and local revenues.

(b) In cases where per pupil amounts are necessary to make comparisons for calculations under paragraph (a) of this section, those calculations are made on the following bases:

(1) Except as provided in paragraph (b)(2), per pupil amounts of revenues are computed on the basis of the total number of pupils as determined in accordance with whatever standard measurement of pupil count is used in the State.

(2) If a State aid program uses a "weighted" pupil or other designated unit of need in determining allocations of State aid which reflect special cost differentials, a computation of per pupil revenue under paragraph (a) may be made on the basis of the "weighted" pupils or other unit of need.

There are two allowable categories of special cost differentials: (i) those associated with pupils having special educational needs, such as handicapped children, economically disadvantaged children, non-English speaking children, and gifted and talented children; and (ii) those associated with sparsity or density of population, cost of living, or special socioeconomic characteristics.

Example 1. State A has an equalization program under which each LEA is guaranteed $900 per pupil less the LEA contribution derived from a uniform required tax. A minimum of $100 per pupil is paid even if the required tax produces more than $900. Each LEA is permitted to levy additional local taxes. Additional categorical State aid is made available for special cost programs. The State has no limitations on budget, expenditure or local tax effort increases. The State is composed of three LEAs with data as shown.

	LEA No. 1	LEA No. 2	LEA No. 3
Taxable wealth per pupil	$30,000	$60,000	$20,000
Enrollment	2,000	1,000	1,000
Yield per pupil from required local tax	$700	$950	$500
Equalized State aid per pupil	200	100	400
Additional local tax per pupil	100	300	70
Additional State aid per pupil	160	150	155
Total State, intermediate, and local revenues per pupil	1,160	1,500	1,125

LEA No. 1

The $700 per pupil derived from the required local tax rate and the $200 per pupil in State equalization aid are neutral since $900 per pupil was the least amount realized by any LEA for the same required tax effort. See § 115.64(b)(2)(i). One third of the $100 per pupil from the additional local tax is not neutral since the least wealthy LEA #3 could only realize two-thirds of the revenue that LEA #1 could at any tax rate. See § 115.64(b)(1)(i). The $160 per pupil of State categorical aid is neutral. See § 115.64(b)(3). Thus, $1127 per pupil ($700+$200+⅔ of $100+$160) is wealth neutral and $33 per pupil is not neutral.

LEA No. 2

Of the $950 per pupil derived from local required effort $900 is neutral since that was the least amount realized by any LEA for the required local tax rate. The $50 per pupil above the guarantee and the $100 per pupil minimum State equalization aid are not neutral since they exceed the least amount realized by another agency. See § 115.64(b)(2)(i). Two thirds of the $300 per pupil realized on the additional local tax $200 is not neutral since the last wealthy, LEA #3, could only realize one-third of the revenue that LEA #2 could at any rate. See § 115.64(b)(1)(i). The $150 per pupil of State categorical aid is neutral. Thus, $1150 per pupil ($900+⅓ of $300+$150) is wealth neutral and $350 per pupil is not neutral.

LEA No. 3

The $500 per pupil derived from the required local tax rate and the $400 per pupil in State equalization aid are neutral since $900 is the least amount realized under the equalization program. See § 115.64(b)(2)(i). All of the $70 per pupil realized from the additional local tax is neutral since LEA #3 is the least wealthy in the State. See § 115.64(b)(1)(i). The $155 per pupil of State categorical aid is neutral. Thus, all of the $1125 per pupil is neutral.

The calculation of the percentage of wealth neutral funds for State A is as follows:

	Total revenues	
	Neutral	Not neutral
LEA No. 1	$1,127 per pupil ×2,000 pupils	$33 per pupil ×2,000 pupils
	$2,254,000	$66,000
LEA No. 2	$1,150 per pupil ×1,000 pupils	$350 per pupil ×1,000 pupils
	$1,150,000	$350,000
LEA No. 3	$1,125 per pupil ×1,000 pupils	None.
	$1,125,000	
Total neutral revenues	$4,529,000	
Total State, intermediate, and local revenues	$4,945,000	=91.6 pct neutral

Thus, State A qualifies under § 115.64(a).

Example 2. State B in the prior year had an equalization program which required a 5 mill effort and allowed 5 mills additional leeway. For the required 5 mill effort each LEA was granted $600 per pupil. LEA #1, on a wealth base of $60,000 per pupil, levied the full 10 mills producing $300 per pupil of State basic aid, received $300 per pupil of State aid, and with the $300 per pupil leeway yield, had revenues of $900 per pupil. LEA #2, on a wealth base of $160,000 per pupil, also levied the full 10 mills producing $800 per pupil which exceed the guarantee and thus received no State basic aid. The leeway yielded an additional $800 per pupil for a total of $1,600 per pupil.

The State has instituted a new program raising the guarantee to $900 per pupil with a 10% budget increase limitation. LEA #1, (with 2,000 pupils), now realizes $300 per pupil from its required effort, receives $600 of State equalization aid, and can levy only 1.5 mills for a yield of $90 per child because of its budget restraint of $990 per child. ($900 per child plus 10%). LEA #2 (with 1000 pupils), realizes $800 per pupil from its required effort, receives $100 per pupil in State equalization aid, levies 5 mills leeway for another $800 per pupil for a total of $1,700 per pupil which is still within its budget increase limitation of $1,760 per pupil.

Assuming that no other LEA is restrained below the $900 per pupil guarantee and that LEA #1 is the most restrained at $90 per pupil leeway then all of the revenues of LEA #2 above the level are not neutral since it is the most restricted LEA. (See § 115.64 (b)(1)(ii)).

The percentage of neutrality is calculated in the same way as in Example 1. Assuming there are no other LEAs, the percentage of wealth neutral revenues is 80.7, and State B does not qualify under § 115.64(a).

Example 3. State C has an equalization program under which each LEA is guaranteed $900 per weighted pupil or 110 percent of the prior year's per weighted pupil revenue under the program, whichever is less, minus the LEA contribution derived from a required tax which is uniform for all LEA's guaranteed $900 per pupil and proportionately less for those LEA's guaranteed lesser amounts per pupil. No additional local leeway taxes are allowed. LEA #1 received $850 per pupil under the program in the prior year while LEA #2 received $800 per pupil under the program in the prior year. LEA #1 is limited to the $900 guarantee since 110 percent of its prior year's expenditure exceeds the $900 guarantee. LEA #2 qualifies for an $880 guarantee since 110 percent of $800 equals $880. LEA #2's required tax effort is also proportionately less.

Assuming that neither LEA realizes revenues in excess of the guarantees for LEA #1 (with 10,000 pupils), $880 of the $900 per pupil revenue is wealth neutral and for LEA #2 (with 2,000 pupils), all $880 in per pupil revenue is wealth neutral. (See § 115.64(b)(2)(iii)).

The percentage of neutrality of the revenues would be calculated as in Example 1. If there are no other LEA's, the percentage of wealth neutral revenues is 98.2 and the State qualifies under § 115.64(a).

Example 4. State D has an equalization program which permits different local tax efforts from 1 mill to 10 mills and which guarantees $100 per pupil for each mill levied. LEA #1 taxes at 5 mills and realizes $300 per pupil. Since the guarantee level for 5 mills is $500 per pupil, State D gives LEA #1 $200 in equalization aid. LEA #2 also taxes at 5 mills, but realizes $800 per pupil. Since the guarantee for 5 mills is only $500 per pupil, LEA #2 receives no equalization aid. LEA #3 taxes at 8 mills and realizes $400 per pupil. Since the guarantee at 8 mills is $800 per pupil, LEA #3 receives $400 in equalization aid. LEA #4 taxes at 8 mills, but realizes $100 per pupil. Since the guarantee for 8 mills is only $800 per pupil, LEA #4 receives no equalization aid. All of the funds LEA #1 realized under the equalization program are neutral since there is no excess over the guaranteed amount for 5 mills. $300 per pupil of the funds realized by LEA #2 are not neutral, because that is the amount in excess of the amount guaranteed for a 5 mill tax effort under the equalization program, and is attributable to the greater wealth of LEA #2.

All of the funds realized by LEA #3 under the equalization program are neutral since there is no excess over the guaranteed amount for an 8 mill tax effort. $200 per pupil realized by LEA #4 is not neutral, because that is the amount in excess of the guaranteed amount for an 8 mill tax effort under the equalization program and is attributable to the greater wealth of LEA #4. See § 115.64(b)(2)(ii).

Example 5. State E has a foundation-type equalization program under which each LEA receives funds for a teacher salary, based on a salary schedule, for each 25 pupils in average daily attendance with additional teacher units allocated for small or sparsely populated districts, and special education programs such as handicapped and vocational classes. Each district also receives under the program a set amount of dollars per teacher unit for expenses other than salaries. Each LEA must make a tax effort of 10 mills to qualify for the foundation equalization aid. The yield from the 10 mills tax is deducted from the amount of the equalization guarantee. There are no State restrictions on budget, expenditure or tax effort increases over prior years. No LEAA in the State realizes more than the equalization amount for the 10 mills effort. All of the funds realized by all LEAs under the foundation equalization program are neutral. Any excess in the amount of revenues realized by any agency over that realized by any other are attributable to differences in the designated needs. (See § 115.61(b)(3) and § 115.64(b)(2)(i)).

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Title 45—Public Welfare

CHAPTER I—OFFICE OF EDUCATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 115—ASSISTANCE FOR LOCAL EDUCATIONAL AGENCIES IN AREAS AFFECTED BY FEDERAL ACTIVITIES AND ARRANGEMENTS FOR EDUCATION OF CHILDREN WHERE LOCAL EDUCATIONAL AGENCIES CANNOT PROVIDE SUITABLE FREE PUBLIC EDUCATION

Final Regulations for Treatment of Payments Under State Equalization Programs

A notice of proposed rulemaking was published in the FEDERAL REGISTER on May 1, 1975 (40 FR 19114) setting forth proposed regulations for the treatment of Pub. L. 81–874 payments under State equalization programs as provided for in section 5(d)(2) of that Act.

Following comments on the proposed rules, interim regulations and a proposed amendment were published in the FEDERAL REGISTER on June 25, 1976 (41 FR 26320 and 26330). Additional comments were invited on the interim regulations.

Elsewhere in this issue of the FEDERAL REGISTER, an alternative standard to §§ 115.63 and 115.65 of these regulations has been published in a notice of proposed rulemaking related to section 5(d), Pub. L. 81–874. That notice proposes an amendment to § 115.62 of these final regulations and the addition of § 115.64, which is reserved under these regulations. A notice of proposed rulemaking was previously published for that amendment on June 25, 1976 (41 FR 26330); however, because clarifying language has been added to the amendment it is being published a second time as a proposed rule. These regulations, however, will become effective irrespective of when that proposed rule is finally adopted.

A. SUMMARY OF STATUTORY AMENDMENT AND FINAL REGULATIONS

1. *Effect of Pub. L. 93–380.* Section 305(a)(2) (effective for Fiscal Year 1976 and thereafter) of Pub. L. 93–380 amended section 5(d) of Pub. L. 81–874 to permit States to take into account payments under Title 1 of that Act in determining the relative financial resources available to local educational agencies and relative financial need of those agencies if the State has in effect a program of State aid for free public education designed to equalize expenditures among local educational agencies in the State. However, Pub. L. 81–874 payments may be so taken into account only in the proportion that local revenues covered by those programs are of total local revenues for education. As mandated by the statute, these regulations implement the amendments to Pub. L. 81–874 by establishing standards for determining whether a State has in effect such a program, by defining certain terms, by establishing procedures for determinations pursuant to section 5(d)(2), and by setting forth the procedure for a hearing regarding those determinations.

2. *Effect of Pub. L. 94–482.* Section 330(a) of Pub. L. 94–482 amended section 5(d)(2) of Pub. L. 81–874 to provide that no payments may be withheld from or repayment required of any State or local educational agency for any period prior to promulgation of final regulations, or, if the State is not in conformance with such regulations until July 1, 1977. Therefore, if any State desires to take into consideration payments under Pub. L. 81–874 after July 1, 1977 and desires an advance determination of whether its program qualifies under these regulations, it should initiate proceedings as provided in § 115.68 as early as practical so that a determination can be completed prior to that date.

3. *General rules.* Under § 115.61(b)(1), only a State whose program of State aid meets the standards set forth in §§ 115.62 and 115.63 or 115.65 may be excepted from the operation of section 5(d)(1) of the Act. However, these States may take into consideration only the proportion of Pub. L. 81–874 funds as permitted under § 115.66. In light of the many recent cases in State courts concerning the validity of State systems of school finance, § 115.61(b)(2) states that no State aid programs may qualify under these regulations if a State court has ruled that such a program violates law and the final ruling is not under appeal.

4. *Definitions.* Four terms have been defined: "State aid," "equalize expenditures," "current expenditures," and "revenue." The second of the foregoing is defined by reference to other sections of the regulations which set forth the qualifying standards for equalization programs.

5. *Qualifying standard.* Sections 115.62, 115.63 and 115.65 establish standards under which the Commissioner shall determine, for purposes of section 5(d)(2) of the Act, whether a State has a program of State aid designed to equalize expenditures among local educational agencies within that State. These standards have been developed in light of the legislative history of section 5(d) of the Act, which indicates that the Commissioner should promulgate regulations which afford only a limited and carefully constructed exception to the existing rule under section 5(d). (See, for example, the Congressional Record, daily edition, May 20, 1974, S 8607 and July 31, 1974, H 7401, 7412). In particular, the House Committee on Education and Labor print, Pub. L. 81–874 and State Equalization Plans (March 1974), specifically mentioned in House Report 93–805, has been used as a reference in establishing the evaluative standards.

Any State aid program in effect which apportions payments on a relative shared-cost basis among local educational agencies in the State will be considered an equalization type of program to which these regulations may be applied. An expenditure disparity alternative test or standard is available for making determinations as to whether or not programs qualify.

If there is a disparity of no more than 25 percent in revenues per pupil (or other unit of pupil need used in the State program) available to the 95th and 5th percentile school districts (those with the 95th and 5th percentiles of the total number of pupils after being ranked in order of revenue per pupil), the program would be deemed to qualify under section 5(d)(2). A disparity standard has been chosen because it is a method of evaluating school finance programs in terms of equalization that has been used both by the courts and authorities in the field of school finance, and because it is believed that the phrase "equalize expenditures" focuses upon the relative availability of funds to local educational agencies for educating the children within their school systems. "Revenue" data, as an alternative to "expenditure" data, is permitted because revenues generally reflect the amounts of funds available for expenditure in a school district and because revenue data is more accessible for current fiscal year evaluation. In calculating the disparity, revenues or expenditures attributable to capital expenditures are likely to fluctuate considerably from year to year. The exclusion of the upper and bottom 5 percentile school districts is based upon the accepted principle of statistical evaluation that such percentiles usually represent unique or noncharacteristic situations.

An exception clause in § 115.65 provides that State programs which cannot be fairly evaluated under the above tests may still be considered for the exemption if certain other conditions are fulfilled. This clause then provides for a determination by the Commissioner in reference to specified evaluative criteria. These criteria, while judgmental in nature, have been selected as reasonable parameters of a truly equalizing State aid program. Consideration under this clause is further conditioned upon the requirement that educational expenditures be more equalized within a State as a result of any offsetting of Pub. L. 81–874 payments. It is expected that this exception will be rarely used, if at all.

6. *Proportionality determination.* Under this amendment to section 5(d), a State is limited as to how much of Pub. L. 81–874 payments going to a school district may be taken into consideration. Section 115.66 sets forth the statutory formula for determining what proportion local revenues under a State equalization program are of total local revenues for education. The amendments to section 5(d) prohibit a State from taking Pub. L. 81–874 payments into account in excess of this proportion. The phrase "local revenues covered under a State equalization program" and "total local revenues" are clarified in the regulation to distinguish among various revenues available for current expenditure that a school district might receive.

7. *Assurances.* A number of assurances are required of both State and local educational agencies with regard to the taking into consideration of Pub. L. 81–874 payments under a State aid program. Under § 115.67, a local educational agency will be required to assure that the State in which it is situated is acting in compliance with section 5(d) of the Act

as regards that agency. A State educational agency will be required to assure that it is acting in conformity with section 5(d) of the Act and these regulations, and that the State will restore to a school district any State aid not paid because of consideration of Pub. L. 81–874 payments not actually received. A failure on the part of either agency to provide these assurances will cause determination proceedings to be initiated under this subpart, but will not itself require suspension of payments under the Act.

8. *Determination procedures.* Provision is made in § 115.68 for proceedings to obtain determinations by the Commissioner under section 5(d)(2) at the initiation of an affected State or local educational agency or at the initiation of the Office of Education. Where the State educational agency, for example, desires an authoritative determination by the Commissioner whether and the extent to which section 5(d) permits it to take into consideration Pub. L. 81–874 payments in determining State aid, it may file with the Office of Education a submission seeking a determination. Also, where a local educational agency is adversely affected by a State taking into consideration Pub. L. 81–874 payments, it may seek a determination as to the status of such a State practice under section 5(d). The adverse effect contemplated in this case would be the loss of State aid monies which the local agency would have received but for the State's action. (In such a situation, the concerned State agency would, of course, be asked to respond.) Finally, the Office of Education itself, where it believes that a State may be acting in noncompliance with section 5(d), may initiate proceedings leading to an appropriate determination. Determinations will be applicable only for the fiscal years in issue.

At the same time, the regulation provides that a determination by the Office of Education that taking into consideration Pub. L. 81–874 payments under section 5(d)(2) is authorized would not have to be obtained before a State could commence such an action, if it were done in compliance with section 5(d)(2). For example if a State, since the effective date of section 5(d)(2), has been taking into consideration these payments under a State equalization program which qualifies under section 5(d)(2) and the regulations, and this State action is in the appropriate proportion for each local educational agency in the State, the fact that a determination by the Commissioner on the legality of this practice was not obtained in advance would not defeat the operation of section 5(d)(2) in providing an exception for the State. This rule, however, would not preclude the Commissioner from determining that a State had been in noncompliance with section 5(d)(2) during the time it acted without an advance determination.

In addition, provision is made for advance consultation with the Office of Education for States contemplating the adoption of equalization programs which would take into consideration Pub. L. 81–874 payments.

9. *Hearing procedures.* Section 115.69 establishes what parties may request a hearing, the time and place of hearings, the right to counsel for all parties, the conduct of the hearing, and the procedure for a final decision by the Commissioner. It further provides that there shall be no reduction or termination of Pub. L. 81–874 payments prior to a final decision and that, if a State which is found to be in noncompliance will cease and desist in its improper action and will make appropriate restitution to any local educational agency adversely affected by such an action, there will be no reduction or termination of Pub. L. 81–874 payments.

10. *Appendix.* An appendix has been added to these regulations setting forth the different methods for making certain computational determinations established under these regulations. Each description is accompanied by one or more illustrative examples.

B. SUMMARY OF COMMENTS, RESPONSES, AND CHANGES IN THE REGULATIONS

The comments received concerning the interim regulations were essentially the same as those received concerning the proposed rules. In the previous section, substantial detail of the rationale for the appropriateness of and the reasonableness of the specific levels is provided. Comments are discussed below on an individual basis. After the summary of each comment, a response is set forth stating changes which have been made to the regulations in light of the comment, or the reasons why no change is deemed necessary.

Comment: Two commenters opposed excluding the upper and lower 5% in applying the expenditure disparity test.

Response: No change has been made in the regulations. It is common practice when analyzing the effects of a general rule over an extremely wide range of data to exclude highly atypical data from consideration. It is deemed that the exclusion of the upper and lower 5 percent is appropriate in this case. Extremely small and remote districts, nonoperating districts, special purpose cooperative schools, privately supplemented public schools, and voucher programs are examples of conditions which can produce atypical data.

Comment: One commenter suggested that a standard based on a high proportion of State support should be added to the regulations.

Response: No change has been made in the regulations. Section 5(d)(2) of the Act specified that a qualifying program must be "* * * designed to equalize expenditures. * * *" The degree of equity of expenditures and the degree of wealth neutrality is not necessarily related to the proportion of State support. For example, if a State modified district boundaries so that taxable wealth per pupil was equal in all districts and all districts levied the same tax rate, equal expenditures and wealth neutrality could occur with no State support. Thus, a regulation concerning the proportion of State support would not necessarily affect the degree of expenditure equity. This is not to dispute the contention that increases in State support usually do decrease the expenditure disparity.

Comment: One commenter felt that the omission of concern for the ratio of assessed value to actual value in the regulations is a serious defect.

Response: No change has been made in the regulations. The degree of equity of expenditures is not necessarily related to the ratio of assessed value to actual value. For example, tax rates can be adjusted to negate differences in the ratios of assessed value to actual value. In fact, some States employ such a method for adjusting unequal assessments among districts when calculating State aid. While equity in assessment practices is encouraged, a regulation on this issue would not be consistent with the provisions of section 5(d)(2) of the Act.

Comment: One commenter objected to the weighting of attendance figures by cost of living multipliers, average teacher's salary factors, social and economic characteristics, and other "non-educationally related" variations.

Response: No change has been made in the regulations. The Commissioner is required by the Act to define "State Aid" and "equalize expenditures" but not in such a way as to have an adverse effect on programs which take into consideration the additional cost of programs for particular groups or categories of children. In making these definitions, the Act does not prohibit the Commissioner from similar treatment of other factors for which States may provide additional resources. The additional factors in the interim regulations describe other cost differentials known to be in use in State aid programs in some States. It is expected that calculations under these regulations will use those cost differentials or pupil weightings established under State law in each State.

Comment: One commenter expressed concern that § 115.65(c)(3) requires identification and categorical support within impact aid programs and that § 115.65(c)(5) requires evaluation of these programs and that Federal inspection and reporting will thereby be promulgated upon local districts.

Response: No change is needed in the regulations. Section 115.60(b) states that the sole purpose of subpart G of these regulations is to determine whether or not a State has a program designed to equalize expenditures and, if so, to determine what portion of payments to a district under Pub. L. 81–874 may be taken into consideration in determining State aid to that district. The criteria in § 115.65(c) is for the above purpose only and does not apply to the use of Pub. L. 81–874 funds within a local district.

Comment: One commenter expressed the belief that the regulations were meaningless since few, if any, States could pass either the disparity or the proposed neutrality test.

Response: The expenditure disparity standard was developed in light of the history of the legislation which is cited in the preamble to the interim regula-

tions. The qualifying test is intended to be limited and carefully constructed exception to the general rule contained in section 5(d)(1) of the Act against consideration of Pub. L. 81–874 payments in determining State aid. However, it is recognized that the majority of States may not qualify under the regulations.

Comment: Five commenters expressed the view that the 25 percent expenditure disparity standard was not restrictive enough while three indicated it was still too stringent.

Response: No change has been made in the regulation. A preliminary perusal of data from several States following the publication of proposed rules in May, 1975 indicated that only 2 or possibly 3 States might qualify under the 20 percent disparity standard proposed. A too strict standard would nullify the intent of the amendment. A standard set at 25 percent is believed to be a fair one which will allow those States with the better equity features in their plans to qualify while a large majority of States cannot qualify without significant changes to their programs.

Comment: One commenter objected to revenues for capital outlay being excluded from the definitions of total local revenues.

Response: No change has been made in the regulation. The exclusion is based on the fact that Pub. L. 81–874 is a current expenditure program and, as a consequence, it would be inconsistent to incorporate into a test of program qualification and into procedures for program operation measures of classes of expenditures which are unrelated to the purposes of the program in question. Additionally, expenditures for capital outlay and debt service are likely to fluctuate considerably from year to year and might act unfairly in the application of the qualifying standard.

Comment: One commenter expressed concern that once a State program qualified under these regulations that it could take into account Pub. L. 81–874 payments to all local districts and suggested that districts with low resources be exempted.

Response: No change has been made in the regulations. If a State program qualifies, the Act clearly gives that State the right to take into account payments under the Act in determining State aid limited only by the proportion calculation as set forth in § 115.66. A State can exempt low spending districts if it decides to do so. To require such an exemption, however, is deemed to be beyond the rulemaking authority of the Commissioner. It is agreed that greater equity might be obtained by exempting districts with high tax efforts and low expenditures. However, this is a matter for State decision.

Comment: One commenter suggested a one year additional delay in the regulations and one suggested they be withdrawn until they can be reviewed through the active participation of representatives from school districts throughout the country.

Response: The Commissioner does not believe that additional delay in promulgating regulations will serve the purposes of the amendment. Representatives of local school districts have had ample opportunity to review the interim regulations. Prior to publication of proposed rules, four regional meetings were held where the legislation was discussed. A presentation was made to a national organization of districts receiving payments under Pub. L. 81–874 and at other conferences including a special conference of eight States in February, 1975. Proposed rules were published May 1, 1975 and the public was invited to comment. Interim regulations were published June 25, 1976 and again comments were invited. Other comments have been made through letters and telephone communication. It is believed that adequate opportunity has been provided for interested parties to review and comment on these regulations.

Comment: One commenter said that, despite numerous requests, local school districts were not consulted during the development of the interim final regulations.

Response: See response to preceding comment.

Comment: One commenter expressed concern that the interim regulations reflect significant changes from earlier proposed rules and that further opportunity for comment should be afforded.

Response: The second paragraph of the preamble to the interim regulations stated that the purpose of the publication of interim regulations was to allow additional comment. Thus, the suggestion has already been granted.

C. OTHER CHANGES

1. A number of typographical and technical corrections have been made.

2. The regulations have been reorganized and renumbered to facilitate understanding and use of them.

3. Clarifying language has been added to § 115.63(b) regarding the procedure for calculating an expenditure disparity in those States operating local educational agencies of different grade levels of instruction.

4. Section 115.6(d) has been modified to include in the expenditures disparity calculation, all Federal funds received by a local educational agency for which the agency is not accountable to the Federal Government for their use. Payment under such funds are considered to be reimbursements or payments in lieu of taxes and as such are appropriately counted as local funds.

5. Section 115.66(b)(2) has been modified to permit a State to consider up to 100 percent of a local educational agency's Pub. L. 81–874 receipts in the computation of the proportion in the case where there are no local revenues for current expenditures and the State provides all of those revenues on behalf of the agency. The modification was necessary in order to carry out the intention of the proportion provision which is to reflect the relative burden which the State and an agency share of any Federal activity in that agency. If all of an agency's non-Federal funds are provided by the State, then the burden of any Federal activity within that district is borne by the State as a whole.

6. Section 115.69(h)(2) and (3) has been modified to specify a 30 day period for the provision of satisfactory assurances that State aid which was denied agencies because of Pub. L. 81–874 receipts will be restored. The modified language was added in order to facilitate the timely and effective administration of the provision.

7. Additional examples have been incorporated into the Appendix in order to illustrate the calculation of a weighted average under the provisions of § 115.63(b) and to further illustrate the calculation of the proportions under the provisions of § 115.66.

D. ADOPTION OF REGULATIONS

Effective date: Pursuant to section 431(d) of the General Education Provisions Act, as amended (20 U.S.C. 1232(d)), these regulations have been transmitted to the Congress concurrently with the publication of this document in the FEDERAL REGISTER. These regulations are effective July 1, 1977, subject to the provisions in section 431(d) concerning Congressional action.

The Office of Education has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11281 and OMB Circular A–107.

(Catalog of Federal Domestic Assistance No. 13.478—School Assistance in Federally Affected Areas—Maintenance and Operations.)

Dated: January 17, 1977.

EDWARD AGUIRRE,
Commissioner of Education.

Approved: March 11, 1977.

JOSEPH A. CALIFANO, Jr.,
Secretary of Health, Education, and Welfare.

Subpart G—Determinations Under Section 5(d) (1) and (2)

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APPENDIX

Subpart G—Determinations Under Section 5(d)

§ 115.60 Scope and purpose.

(a) *Scope.* This subpart applies to determinations made by the Commissioner pursuant to section 5(d) of the Act as amended by Pub. L. 93–380, Pub. L. 94–482.

(b) *Purpose.* The sole purpose of the regulations in this subpart is to implement the provisions of section 5(d)(2) of the Act. The definitions and standards contained herein have been developed with respect to the particular intent of the amendment made to section 5(d) of the Act by sections 304(c) and 305(a)(2) of Pub. L. 93-380 and section 330(a) of Pub. L. 94-482 and should not be construed as establishing definitions and standards for any other purpose.

(20 U.S.C. 240(d); secs. 304(c), 305(a)(2), Pub. L. 93-380, 88 Stat. 484; 120 Cong. Rec. S8505, 8507 (daily ed. May 20, 1974).)

§ 115.61 Treatment of State Aid Programs in General.

(a) *Statutory provisions.* (1) Section 5(d)(1) of the Act provides that, except in section 5(d)(2), no payment may be made to any local educational agency within a State which takes into consideration payments under section 5 of the Act in determining the eligibility of any agency for State aid, or the amount of that aid, with respect to free public education during the fiscal year of those payments or the preceding fiscal year, or which makes aid available in such a manner as to result in less State aid to any agency which is eligible for payments under the Act than that agency would receive if it were not so eligible.

(2) Section 5(d)(2) of the Act provides that, if a State has in effect a program of State aid for free public education for any fiscal year, which is designed to equalize expenditures for free public education among the local educational agencies of that State, payments under the Act may be taken into consideration by that State in determining (i) the relative financial resources available to local educational agencies in that State and (ii) the relative financial need of those agencies for the provision of free public education for children served by those agencies, subject to the provisions in that section.

(3) Section 5(d)(2)(A)(ii) of the Act provides that, if a State takes payments under the Act into consideration in accordance with section 5(d)(2), the State may do so only to the extent of the proportion that the local revenues of a local educational agency covered under the equalization part of a State aid program are of that agency's total local revenues for education.

(4) Section 5(d)(2)(C) of the Act, as added by Pub. L. 94-482 provides that no payment under the Act may be withheld from and no repayment may be required of any State or local educational agency because of any noncompliance with section 5(d)(2)(A) of the Act or this subpart prior to July 1, 1977 if that State had a program of State aid whose procedures were designed to equalize expenditures for free public education among those agencies in effect on October 12, 1976.

(20 U.S.C. 240(d); H.R. Rep. No. 94-1701, 235 (1976))

(b) *General rules.* (1) Except as provided in paragraph (b)(2) of this section, a State may take into consideration payments under the Act in allocating State aid if that State has a program of State aid which qualifies under § 115.62. However, those payments may be taken into consideration for each affected local educational agency only in the proportion described in § 115.66.

(2) No program of State aid may qualify under this subpart if a court of that State has determined by final order, not under appeal, that the program fails to equalize expenditures for free public education among local educational agencies within the State or otherwise violates law.

(3) The Commissioner will not interpret any of the provisions of §§ 115.62, 115.63, and 115.65 so as to consider any part of a State aid program which allocates funds for the additional cost of providing free public education for children with special educational needs as disequalizing expenditures for free public education. For the purposes of this subpart, children with special educational needs are handicapped children, non-English speaking children, economically disadvantaged children, gifted and talented children and the like.

(20 U.S.C. 240(d)(2); 20 U.S.C. 242(b))

(c) *Data for determinations.* Determinations under this subpart requiring the submission of financial or school population data may be made either (i) On the basis of data for the fiscal year preceding the fiscal year of determination if the same program was then in effect; or (ii) On the basis of estimates of data for the fiscal year of determination. Data submitted must be the most currently available and complete data, whether based on revenues or current expenditures. Estimates submitted by a State educational agency or other appropriate State agency must set forth the assumptions upon which such estimates are founded, must be accompanied by an assurance as to their accuracy, and must be adjusted by actual data for the fiscal year of determination as soon as available for the purpose of verification.

(20 U.S.C. 240(d); 242(b))

(d) *Definitions.* For the purposes of this subpart, the following terms shall have the meanings indicated below:

(1) "State aid" means any contribution, no repayment for which is expected, which is made by a State to or on behalf of local educational agencies within the State for current expenditures in the provision of free public education;

(2) "Equalize expenditures" means to meet the standards set forth in § 115.62;

(3) "Current expenditures" means the total charges incurred for the benefit of the school year in an elementary or secondary school program, exclusive of capital outlay and debt service for capital outlay.

(4) "Revenue" means an addition to assets which does not increase any liability, does not represent the recovery of an expenditure, does not represent the cancellation of certain liabilities without a corresponding increase in other liabilities or a decrease in assets, and does not represent a contribution of fund capital in food service or pupil activity funds. Furthermore, for the purposes of this subpart, the term "revenue" includes only revenue for current expenditures.

(20 U.S.C. 240 (d)(2))

§ 115.62 General qualifying standard for State Aid programs.

(a) *General standard.* For the purposes of section 5(d)(2) of the Act, the Commissioner will consider a program of State aid to be designed to equalize expenditures for free public education among local educational agencies in that State if the program—

(a) Is authorized by State law in effect for the fiscal year for which the determination under this subpart is made;

(b) Provides for the apportionment of State aid among local educational agencies in the State in order to carry out the objectives of the program;

(c) Provides that in determining the amount to be apportioned to each local educational agency in the State, the State will take into consideration the relative financial resources available to local educational agencies in that State for the program; and

(d) Meets the standard of either § 115.63, § 115.64 or § 115.65 of this subpart.

(20 U.S.C. 240(d)(2))

§ 115.63 Disparity standard.

(a) *25 percent disparity limitation.* The Commissioner will consider a program of State aid to have fulfilled the requirement of § 115.62(a)(4) of this subpart if the disparity in the amount of current expenditures or revenue per pupil for free public education among local educational agencies in the State is no more than 25 percent for the fiscal year for which a determination is made under this subpart. The method for calculating the percentage of that disparity in a State is set out in the Appendix to this subpart.

(b)(1) *Weighted average disparity for different grade level groups.* If a State requests it, the Commissioner will make separate disparity computations for different groups of local educational agencies in the State which have similar grade levels of instruction.

(2) In those cases, the weighted average disparity, based on the proportionate number of pupils in each group, may not be more than 25 percent for all the groups. The method for calculating the weighted average disparity percentage is set out in the Appendix to this subpart.

(c) *Per pupil figure computations.* In calculating the current expenditures or revenue disparities under this section, computations of per pupil figures are made on the following bases:

(1) Except as provided in paragraph (c)(2) of this section, the per pupil amount of current expenditures or revenue for a local educational agency is computed on the basis of the total number of pupils receiving free public education in the schools of the agency. The total number of pupils is determined in accordance with whatever standard

measurement of pupil count is used in the State.

(2) If a State aid program uses a "weighted pupil," a "classroom," "instructional unit," or other designated unit of need in determining allocations of State aid in order to take account of special cost differentials, the computation of per pupil revenue or current expenditures may be made on those bases. There are two allowable categories of special cost differentials: (i) Those associated with pupils having special educational needs, such as handicapped children, economically disadvantaged children, non-English speaking children, and gifted and talented children; and (ii) those associated with sparsity or density of population, cost of living, or special socioeconomic characteristics within the area served by an agency.

(d) *Revenues and current expenditures included in determinations.* The following revenues or current expenditures must be included for each local educational agency in the State in determining the percentage of disparity under paragraph (a) of this section:

(1) All revenues or current expenditures from State sources, except those applied or contributed outside any equalized part of the State aid program which are designated for special cost differentials of the type specified in paragraph (c)(2) of this section.

(2) All revenues for current expenditures from local or intermediate sources, except those taken into consideration under any equalized part of the State aid program which are designated for special cost differentials of the type specified in paragraph (c)(2) of this section.

(3) Pub. L. 81-874 funds received by the agency under sections 2, 3 and 4 of the Act, except to the extent that (i) they are not taken into consideration under the State aid program, and (ii) they exceed the proportion of those funds that the State would be allowed to take into consideration under § 115.66 of this subpart; and

(4) Any other Federal funds received by the agency for which the agency is not accountable to the Federal Government for their use such as Federal Forest Reserve funds (16 U.S.C. 500).

(20 U.S.C. 240(d)(2))

§ 115.64 [Reserved]

§ 115.65 Consideration for exceptional circumstances.

(a) *General requirements.* A State program which does not conform to the standards of either § 115.63 of this subpart may, nevertheless, qualify under this section if the Commissioner determines on the basis of information submitted by the State, that:

(1) a decision not to apply the exact disparity standard specified in § 115.63 to the program submitted by the State would be justifiable because of exceptional circumstances within the State related to disparities in current expenditures or revenue per pupil for education

(2) current expenditures or revenues for education in that State will be more equalized if payments under the Act are taken into consideration under this subpart than if they are not, and

(3) The program meets the requirements of paragraph (c)(3) of this section.

(b) *Determination of "mere equalized."* For purposes of paragraph (c)(1)(3) of this section, current expenditures or revenues for education within a State are considered "more equalized" if the distribution around the mean per pupil expenditure for all local educational agencies within the State is less when payments under the Act are taken into consideration in conformity with § 115.6 of this part than when they are not, as calculated according to accepted statistical methods appropriate to the circumstances.

(c) *Specific program requirements.* A program of State aid considered under this is not considered a program designed to equalize expenditures among local educational agencies in the State unless the Commissioner finds that, in addition to meeting the requirements of the preceding subparagraphs—

(1) The amount of the revenue available to local educational agencies in the State is not predominantly a function of the wealth of individual local educational agencies;

(2) The program is designed to ensure the provision of financially adequate educational programs and supportive services for every pupil in the State who is enrolled in public schools;

(3) In the determination of the relative financial need of local educational agencies, that program (i) makes provision for identifying those pupils with special educational needs (such as handicapped children, economically disadvantaged children, children with limited English-speaking ability), (ii) takes into consideration the additional costs of providing free public education for such children or categories of children; and (iii) takes into consideration the costs of providing education which might be associated with such factors as sparsity or density of population, cost of living, and socio-economic characteristics of the local educational agencies; except that nothing in this clause shall be construed to require any particular system of weighting of pupils.

(4) Such program involves a substantial percentage of school revenues;

(5) Such program is designed to provide systems and procedures for evaluating the degree to which the program is achieving its stated objectives.

(20 U.S.C. 240(d)(2); S. Rep. No. 763, 93d Cong., 2d Sess. 56 (1974); H.R. Rep. 805, 93d Cong., 2d Sess. 42-44 (1974); 102 Cong. Rec. S 8604-8607 (daily ed., May 20, 1974); *Id.*, H 7401 (daily ed., July 31, 1974); Congressional Research Service, *Public Law 874 and State Equalization Plans* 30-40 (H.R. Comm. on Education and Labor Print (March 1974))

§ 115.66 Proportion of funds that may be taken into consideration.

(a) *Provision of law.* Section 5(d)(2)(A)(ii) of the Act provides that, in allocating State aid a State may consider as local resources funds received under the Act only in proportion to the share that local revenues covered under a State equalization program are of total local revenues. That determinations of proportionality must be made on a case-by-case, school district by school district basis, for each local educational agency affected and not on the basis of a general rule to be applied throughout a State.

(20 U.S.C. 240(d)(2)(A)(ii); S. Rep. No. 1026, 93d Cong., 2d Sess., 163 (1974))

(b) *Computation of proportion.* (1) In computing the share that local revenues covered under a State equalization program are of total local revenues for a local educational agency with respect to a program qualifying under § 115.62, the proportion is obtained by dividing (i) the amount of local revenues covered under the equalization program by (ii) the total local revenues attributable to current expenditures for free public education within such agency.

(2) In cases where there are no local revenues for current expenditures and the State provides all of those revenues on behalf of the local educational agency, the State may consider up to 100 per cent of the funds received under the Act by that agency in allocating State aid.

(20 U.S.C. 240(d)(2)(A)(ii); 102 Cong. Rec. H. 7403 (daily ed., July 31, 1974)

(c) *Local revenues.* For the purposes of this section—

(1) "Local revenues covered under a State equalization program" means those revenues for current expenditures produced within the boundaries of a local educational agency contributed to or taken into consideration in a program of State aid subject to a determination under this subpart, but excluding all revenues from State and Federal sources.

(2) "Total local revenues" means all revenues for current expenditures of a local educational agency, including revenues for education programs for children needing special services, vocational education, transportation, and the like during the period in question but excluding all revenues from State and Federal sources.

(3) Revenues received by a local educational agency which are produced within the boundaries of an intermediate school district or other local governmental instrumentality will be counted as local revenues.

(d) *Application of proportion to payments under the Act.* (1) The proportion established under this section (or a lesser proportion) for any local educational agency receiving payments under the Act may be applied by a State to actual receipts of those payments or to the prorated entitlements provided for under section 5 of the Act and § 115.24 of this subpart.

(2) That proportion may not be applied to any portion of a payment under the Act made to a local educational agency on the basis of low-rent public housing pupils or handicapped children after July 1, 1975.

(20 U.S.C. 240(d)(2); 102 Cong. Rec. H7412 (daily ed., July 31, 1974))

§ 115.67 Assurances in applications.

(a) *By applicants.* Each applicant for financial assistance under the Act must set forth an assurance in its application either (1) that the State in which it is situated is not taking payments to such applicant under the Act into consideration with regard to a program of State aid, or (2) that, if the State is taking such payments into consideration with regard to its program of State aid, the State is doing so, for that applicant, in conformity with § 115.66 of this subpart.

(b) *By State educational agencies.* Each State educational agency which certifies an application for financial assistance under the Act, as provided for in § 115.10 of this part, must submit to the Commissioner an assurance with such application either (1) that the State is not taking payments under the Act into consideration with regard to a program of State aid, or (2) that the State is taking such payments into consideration with regard to a program of State aid in conformity with section 5(d)(2) of the Act and this subpart.

(c) *State guarantee of certain payments.* A further assurance is required of any State which does not take into consideration payments under the Act in allocating State aid to local educational agencies. The State must assure, for each application it certifies in accordance with § 115.10 of this part, that it will reimburse any local educational agency the amount of any of those payments taken into consideration but not in fact received by the agency by the time of final payment under the Act for the year of determination. The State must also include this assurance as part of any submission for determination under § 115.68 of this subpart.

(d) *Failure to provide assurances.* A failure on the part of any local or State educational agency to set forth the assurances required by this section constitutes sufficient cause for an initiation of proceedings by the Commissioner, as provided for in § 115.68 of this subpart. However, the Commissioner will not, because of a failure to provide these assurances, suspend or terminate payments under the Act with respect to such agencies prior to the rendering of a final decision under this subpart.

(20 U.S.C. 240(d); S. Rep. No. 1026, 93d Cong., 2d Sess. 163 (1974))

§ 115.68 Submissions and consultations.

(a) *Initiation.* (1) A proceeding under this subpart leading to a determination by the Commissioner as to whether, or the extent to which a State may take into consideration payments under the Act in determining relative financial resources or need under a program of State aid may be initiated (i) by the State educational agency or other appropriate agency of the State; (ii) by a local educational agency which is or would be adversely affected by that State action; or (iii) by the Commissioner, if the Commissioner has reason to believe that the State's action is in violation of section 5(d) of the Act and that payments to local educational agencies in the State should therefore be terminated under section 5(d) of the Act.

(2) Whenever a proceeding under this subpart is initiated, the party initiating the proceeding shall give adequate notice to all State and local agencies which might be adversely affected by a determination. Those agencies will be accorded a right of intervention in the determination proceedings.

(3) Nothing in this subpart shall be construed to prohibit a State which has not obtained a prior determination from the Commissioner under this subpart from taking into consideration payments under the Act as provided for in section 5(d)(2) of the Act if that action is in conformity with §§ 115.62 and 115.66 of this subpart.

(20 U.S.C. 240(d)(2); H.R. Rep. No. 805, 93d Cong., 2d Sess., 42–43 (1974))

(b) *Submission.* (1) A submission by a State or local educational agency under this section must be made in the manner requested by the Commissioner and must contain such information and assurances as may be required by the Commissioner in order to reach a determination under section 5(d) of the Act and this subpart.

(2) A State educational agency in a submission must (i) demonstrate how its program of State aid comports with the criteria and standards in § 115.62 and (ii) indicate for each local educational agency receiving funds under the Act the proportion of those funds which will be taken into consideration in accordance with § 115.66.

(3) A local educational agency in a submission must demonstrate how it is affected by (i) the action of the State and (ii) the applicability of the standards set forth in this subpart to such action.

(4) Whenever a proceeding is initiated under this subpart, the Commissioner may request from a State the data deemed necessary to make a determination. A failure on the part of a State to comply with that request within a reasonable period of time shall result in a summary determination by the Commissioner that the program of State aid of that State does not comport with the regulations under this subpart.

(c) *Advance consultation.* States may upon request consult with the Office of Education regarding the possible application of the requirements of this subpart to relevant proposed legislation (such as legislation providing for taking into account funds under the Act in determining the amount of State aid) prior to the adoption of the legislation.

(20 U.S.C. 240(d))

§ 115.69 Notice and opportunity for hearing.

(a) *General requirements.* The Commissioner will afford reasonable notice of a determination under this subpart and opportunity for a hearing to any State educational agency or local educational agency adversely affected by the determination. The Commissioner will afford the notice and opportunity for a hearing and the hearing (if requested) shall take place prior to the implementation by the Commissioner of any determination. The notice shall set forth the reasons for the determination in sufficient detail to enable the agencies to respond.

(b) *Requests for hearing.* (1) A State or local educational agency which is adversely affected by a determination under section 5(d) of the Act and this subpart and which desires a hearing regarding that determination must submit a written request for a hearing within 30 days after the Commissioner gives appropriate notice. The time within which a request must be filed will not be extended unless the time for filing the request is extended in writing by the Commissioner or the Commissioner's designee at the time notice of the determination is given.

(2) A request for a hearing in accordance with this section must specify the issues of fact and law to be considered.

(3) If a local educational agency requests a hearing it must furnish a copy of the request to the appropriate State educational agency. If a State requests a hearing, it must furnish a copy of the request to all local educational agencies whose payments under the Act are or would be taken into consideration in the allocation of State aid.

(c) *Time and place of hearing.* The hearing shall be held at a time and place fixed by the Commissioner or the Commissioner's designee (with due regard to the mutual convenience of the parties).

(d) *Counsel.* In all proceedings under this section, all parties shall have the right to be represented by counsel.

(e) *Proceedings.* The Commissioner may refer the matter in controversy to a hearing officer or to a hearing panel designated by the Commissioner for such purpose. The hearing officer or hearing panel may consist of or include persons who are employees of the Department, employees of other Federal departments and agencies, and persons who are not Federal employees.

(f) *Procedural rules.* (1) If in the opinion of the hearing officer or panel no dispute exists as to a material fact the resolution of which would be materially assisted by oral testimony, the hearing officer or panel shall afford each party to the proceeding an opportunity for presenting its case at the option of the hearing officer or panel (i) in whole or in part in writing or (ii) in an informal conference which shall afford each party sufficient notice of the issues to be considered (where such notice has not previously been afforded).

(2) With respect to hearings involving a dispute as to a material fact the resolution of which would be materially assisted by oral testimony, the hearing officer or panel shall afford each party, in addition to the notice of issues required by paragraph (f)(1)(ii) of this section, the following:

(i) An opportunity for a record of the proceedings;

(ii) An opportunity to present witnesses on the party's behalf; and

(iii) An opportunity to cross-examine other witnesses either orally or through written interrogatories.

(g) *Decisions.* When a hearing officer or panel is designated to consider the matter, the officer or panel shall make an initial decision based upon written findings, which shall be forwarded to the Commissioner. The Commissioner may, by appropriate notification to the parties, determine to review it or certify it as the final decision of the Commissioner without further proceedings. Written notice of the initial decision shall be sent to all parties. In any case in which the Commissioner modifies or reverses the initial decision, a notice of that action shall be accompanied by a written statement of the grounds for the reversal or modification. Notice of the final decision of the Commissioner shall be served upon all parties to the hearing, the hearing panel and any local educational agency which may be adversely affected thereby.

(h) *Effect on payments.* (1) When an appropriate request for a hearing under this section has been made the Commissioner will not suspend or terminate payments to a local educational agency under the Act on the basis of section 5(d)(1) of the Act until a final decision with respect to the matter in controversy has been made under this subpart.

(2) If a State has been finally determined, after notice and opportunity for hearing, to have been taking into consideration payments under the Act in violation of sections 5(d) (1) and (2) of the Act, the Commissioner shall terminate payments under the Act to all local educational agencies in that State unless the State provides satisfactory assurances within thirty (30) days after receiving notice of a final decision, that it will restore to all affected local agencies any State aid which was denied the agencies because of those payments.

(3) If a State has been finally determined, after notice and opportunity for a hearing, to have been taking into consideration payments under the Act in excess of the proportion computed under § 115.66 of this subpart, the Commissioner shall terminate payments under the Act to all local educational agencies in that State, unless the State provides satisfactory assurances, within thirty (30) days after receiving notice of a final decision, that it will reimburse all affected local educational agencies for the excess amount of payments taken into consideration in the allocation of State aid and that thereafter it will only take into consideration payments under the Act in the proportion permitted.

(4) During the thirty days provided under paragraphs (h) (2) and (3) for a State to provide satisfactory assurances, the Commissioner will suspend payments under the Act to all local educational agencies in the State. However, if during that time the State does provide the assurances required, the Commissioner will lift the suspension of payments.

(20 U.S.C. 240(d), 242(b); S. Rep. No. 1026, 93d Cong., 2d Sess. 163 (1974).)

APPENDIX

[Pub. L. 81-874, Section 5(d)]

ASSISTANCE FOR LOCAL EDUCATIONAL AGENCIES IN AREAS AFFECTED BY FEDERAL ACTIVITIES; METHODS OF CALCULATIONS FOR TREATMENT OF PAYMENT UNDER STATE EQUALIZATION PROGRAMS

The following paragraphs describe the methods for making certain calculations in conjunction with determinations made under various requirements of the regulations set forth in this subpart. These methods shall be the only methods used in making these calculations.

1. *Determinations of disparity standard compliance under § 115.63.*

The determination of disparity in current expenditures or revenue per pupil is made by:

(a) Ranking all local educational agencies having similar grade levels within the State on the basis of current expenditures or revenues per pupil with respect to the fiscal year for which data has been submitted in accordance with these regulations;

(b) Identifying those local agencies in each ranking which fall at the 95th and 5th percentiles of the total number of pupils in attendance in the schools of these agencies; and

(c) Subtracting the lower current expenditure or revenue per pupil figure from the higher for those agencies identified in paragraph (b) and dividing the difference by the lower figure.

Example: In State X, after ranking all local educational agencies organized on a grade 9-12 basis in order of the expenditures per pupil, for the fiscal year in question, it is ascertained by counting the number of pupils in attendance in these agencies in ascending order of expenditure that the 5th percentile of student population is reached at LEA A with a per pupil expenditure of $820, and that the 95th percentile of student population is reached at LEA B with a per pupil expenditure of $1000. The percentage disparity between the 95th and 5th local educational agencies is 22 percent ($1000—$820=$180 ; $820). The program would be deemed to qualify.

(d) In cases under § 115.63(b), where separate computations are made for different groups of local educational agencies, the disparity percentage for each group is obtained in the manner described in paragraphs (a), (b) and (c) above. Then the weighted average disparity percentage as for the State as a whole is determined by:

(i) Multiplying the disparity percentage for each group by the total number of pupils receiving free public education in the schools in that group;

(ii) Summing the figures obtained in (i); and

(iii) Dividing the sum obtained in (ii) by the total number of pupils for all the groups.

Example: For State Y three groups of local educational agencies were considered. Group #1 (grades 1-6) had a disparity percentage of 18 percent and 80,000 pupils. Group #2 (grades 7-12) had a disparity percentage of 22 percent and 100,000 pupils. Group #3 (grades 1-12) had a disparity percentage of 35 percent and 20,000 pupils. The figure obtained under (i) is 14,400 for group #1, 22,000 for group #2, and 7000 for group #3. The sum of these figures under (ii) is 43,400. Dividing that number by the total number of pupils for all three groups (200,000) gives a weighted average percentage of 21.7 percent. State Y meets the requirement of § 115.63(b).

2. *Determination under § 115.63(b) as to maximum proportion of Pub. L. 81-874 payments that may be taken into consideration by a State under an equalization program.* The proportion that local revenues covered under a State equalization program are of total local revenues for a particular local educational agency is obtained by dividing: (a) the amount of local revenues covered under the equalization program by (b) the total local revenues attributable to current expenditures for education within the agency.

Examples.

Example 1. State A has an equalization program under which each LEA is guaranteed $900 per pupil less the LEA contribution based on a uniform tax levy. LEA X contributes $700 per pupil and the State contributes the $200 difference. No other local revenues are applied to current expenditures for education by LEA X. The percentage of funds under the Act which may be taken into consideration by State A for LEA X is 100% (700/700). If LEA X receives $100 per pupil in Public Law 81-874 funds, $100 per pupil may be taken into consideration by State A in determining LEA X's relative financial resources and needs under the program. LEA X is regarded as contributing $800 and State A would now contribute the $100 difference.

Example 2. The initial facts are the same as in Example 1, except that LEA X, under a permissible additional levy outside the equalization program, raises an additional $100 per pupil. The percentage of Pub. L. 81-874 funds which may be taken into consideration is 87.5% (700/800). If LEA X receives $100 per pupil in Pub. L. 81-874 funds, $87.50 per pupil may be taken into consideration. LEA X is now regarded as contributing $787.50 per pupil under the program and State A would now contribute $112.50 per pupil as the difference.

Example 3. State B has an equalization program in which each participating LEA is guaranteed a certain per pupil revenue at various levels of tax rates. For an 8 mill rate the guarantee is $500, for 9 mills $550, for 10 mills $600. LEA Y levies a 10 mill rate and realizes $300 per pupil. Furthermore, it levies an additional 10 mills under a local leeway option, realizing another $300 per pupil. The percentage of Pub. L. 81-874 which may be taken into consideration is 50% (300/600). If LEA Y receives $100 per pupil in Pub. L. 81-874 funds, $50 per pupil may be taken into consideration. LEA Y may be regarded as contributing $350 per pupil under the program and State B would now contribute $250 as the difference.

Example 4. The initial facts are the same as in Example 3, except that LEA Z in State B, while taxing at the same 10 mill rate for both the equalization program and leeway allowance as LEA Y, realizes $550 per pupil for each tax. As with LEA Y, the percentage of Pub. L. 81-874 funds which may be taken into consideration for LEA Z is 50% (550/1100). If LEA Z receives $150 per pupil in Pub. L. 81-874 funds, then up to $75 per pupil normally could be taken into consideration. However, since LEA Z would have received only $50 per pupil in State aid, only $50 on the allowable $75 could be taken into consideration. Thus, LEA Z may be regarded as contributing $600 per pupil under the program and State B would not contribute any State aid.

Example 5. The initial facts are the same as in Example 4, except that LEA Z realizes $600 per pupil from each of the 10 mill taxes. Since LEA Z is regarded as contributing $600 to the equalization program and receives no State aid, no Pub. L. 81-874 funds are taken into consideration under the program.

[FR Doc.77-8032 Filed 3-21-77;8:45 am]

federal register

TUESDAY, MARCH 22, 1977

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

REORGANIZATION AND REPUBLICATION

Title 21—Food and Drugs

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

SUBCHAPTER A—GENERAL

[Recodification Docket No. 17; Docket No. 77N-0032]

REORGANIZATION AND REPUBLICATION

The Food and Drug Administration (FDA) is reorganizing and republishing all of Subchapter A of the general regulations, effective March 22, 1977.

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for FDA, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the 17th and final document in a series of recodification documents that include all regulations administered by FDA; this document reorganizes existing Parts 1 through 9 and transfers § 200.18 from Subchapter C to reorganized Subchapter A, Parts 1 through 99.

The following table shows the relationship of the Code of Federal Regulations under former section numbers under Subchapter A and the newly assigned numbers under the subchapter:

Old Section	New Section
1.1	1.1
1.1a	1.23
1.1b	1.20
1.1c	1.24
1.1d	1.35
1.1e	1.31
1.2	1.3
1.3	1.21
1.4	7.12
1.5	7.13
1.315	1.83
1.316	1.90
1.317	1.91
1.318	1.94
1.319	1.95
1.320	1.96
1.321	1.97
1.322	1.99
1.700	2.10
2.1	10.1
2.3	10.3
2.4	10.10
2.5	10.20
2.6	10.25
2.7	10.30
2.8	10.33
2.9	10.35
2.10	10.40
2.11	10.45
2.12	10.50
2.13	10.55
2.14	10.60
2.15	10.65
2.16	10.70
2.17	10.75
2.18	10.80
2.19	10.85
2.20	10.90
2.21	10.95
2.22	10.100
2.23	10.105
2.24	10.110
2.25	10.19
2.100	12.1
2.110	12.20
2.111	12.21
2.112	12.22
2.113	12.24
2.114	12.26
2.115	12.28
2.116	12.30
2.117	12.32
2.118	12.35
2.119	12.37
2.120	12.38
2.130	12.40
2.131	12.45
2.135	12.50
2.140	12.60
2.141	12.62
2.142	12.70
2.143	12.75
2.144	12.78
2.150	12.89
2.151	12.82
2.152	12.83
2.153	12.85
2.154	12.87
2.155	12.89
2.156	12.90
2.157	12.91
2.158	12.92
2.159	12.93
2.160	12.94
2.161	12.95
2.162	12.96
2.163	12.97
2.164	12.98
2.165	12.99
2.170	12.100
2.171	12.105
2.172	12.110
2.173	12.115
2.180	12.120
2.181	12.125
2.182	12.130
2.183	12.139
2.190	12.140
2.191	12.159
2.200	13.1
2.201	13.5
2.202	13.10
2.203	13.15
2.204	13.20
2.205	13.25
2.206	13.30
2.207	13.40
2.208	13.45
2.209	13.50
2.300	14.1
2.301	14.40
2.302	14.55
2.303	14.5
2.304	14.25
2.305	14.20
2.306	14.30
2.307	14.22
2.308	14.31
2.309	14.39
2.310	14.33
2.311	14.35
2.312	14.29
2.313	14.60
2.314	14.61
2.315	14.70
2.316	14.75
2.317	14.65
2.318	14.27
2.319	14.7
2.320	14.10
2.321	14.15
2.322	14.19
2.330	14.80
2.331	14.82
2.332	14.84
2.333	14.86
2.334	14.90
2.335	14.95
2.340	14.100
2.350	14.120
2.351	14.122
2.352	14.125
2.353	14.127
2.354	14.130
2.360	14.140
2.361	14.142
2.362	14.145
2.363	14.147
2.364	14.155
2.370	14.160
2.371	14.171
2.372	14.174
2.373	14.172
2.400	15.1
2.401	15.20
2.402	15.21
2.403	15.39
2.404	15.25
2.405	15.40
2.406	15.45
2.500	16.1
2.501	16.5
2.502	16.42
2.505	16.40
2.506	16.42
2.510	16.22
2.511	16.24
2.512	16.60
2.513	16.80
2.514	16.85
2.515	16.95
2.516	16.119
2.520	16.120
2.600	19.1
2.610	19.5
2.611	19.6
2.612	19.10
2.613	19.21
2.620	19.55
2.621	19.45
2.700	7.1
2.703	7.3
2.705	7.84
2.706	7.85
2.707	7.87
3.13	2.25
3.73	2.5
3.89	2.19
3.700	2.110
4.1	20.1
4.2	20.2
4.3	20.3
4.20	20.20
4.21	20.21
4.22	20.22
4.23	20.23
4.24	20.24
4.25	20.25
4.26	20.26
4.27	20.27
4.28	20.28
4.29	20.29
4.30	20.30
4.31	20.31
4.32	20.32
4.40	20.40
4.41	20.41
4.42	20.42
4.43	20.43
4.44	20.44
4.45	20.45
4.46	20.46
4.47	20.47
4.48	20.48
4.49	20.49
4.50	20.50
4.51	20.51
4.52	20.52
4.53	20.53
4.60	20.60
4.61	20.61
4.62	20.62
4.63	20.63
4.64	20.64
4.80	20.80
4.81	20.81
4.82	20.82
4.83	20.83
4.84	20.84
4.85	20.85
4.86	20.86
4.87	20.87
4.88	20.88
4.89	20.89
4.90	20.90
4.91	20.91
4.100	20.100
4.101	20.101
4.102	20.102
4.103	20.103
4.104	20.104
4.105	20.105
4.106	20.106
4.107	20.107
4.108	20.108
4.109	20.109
4.110	20.110
4.111	20.111
4.112	20.112
4.113	20.113
4.114	20.114
4.115	20.115
4.116	20.116
4.117	20.117
4.118	20.118
4.119	20.119
5.1	5.1
5.20	5.20
5.21	5.30
5.22	5.45
5.23	5.22
5.24	5.23
5.25	5.64
5.26	5.73
5.27	5.76
5.28	5.83
5.29	5.84
5.30	5.80
5.31	5.82
5.32	5.75
5.33	5.21
5.34	5.35
5.35	5.36
5.36	5.25
5.37	5.78
5.38	5.61
5.39	5.71
5.40	5.63
5.41	5.66
5.42	5.37
5.43	5.86
5.44	5.87
5.45	5.88
5.46	5.89
5.47	5.46
5.48	5.90
5.49	5.91
5.50	5.92
5.51	5.68
5.52	5.70
5.53	5.26
5.100	5.100
5.105	5.105
5.110	5.110
5.115	5.115
6.1	25.1
6.2	25.20
6.3	25.25
6.4	25.5
6.5	25.10
6.6	25.30
7.1	21.1
7.3	21.3
7.10	21.10
7.20	21.20
7.21	21.21
7.30	21.30
7.31	21.31
7.32	21.32
7.33	21.33
7.40	21.40
7.41	21.41
7.42	21.42
7.43	21.43
7.44	21.44
7.45	21.45
7.50	21.50
7.51	21.51
7.52	21.52
7.53	21.53
7.54	21.54
7.60	21.60
7.61	21.61
7.65	21.65
7.70	21.70
7.71	21.71
7.72	21.72
7.73	21.73
7.74	21.74
7.75	21.75
8.1	70.3
8.2	70.11
8.3	70.10
8.4	71.1
8.5	71.2
8.6	71.20
8.7	71.4
8.8	71.6
8.9	71.15
8.10	71.22
8.11	70.45
8.12	70.51
8.15	71.25
8.16	70.57
8.17	70.58
8.18	71.18
8.19	71.30
8.22	80.21
8.23	80.22
8.24	80.37
8.25	80.38
8.26	80.39
8.27	80.31
8.28	80.34
8.29	80.32
8.30	80.35
8.31	70.20
8.32	70.25
8.33	71.37
8.34	70.40
8.35	70.42
8.36	70.50
8.37	70.55
8.50	70.19
8.51	80.10
8.101	70.5
8.201	74.302
8.202	74.250
8.206	74.101
8.242	74.303
8.244	74.340
8.275	74.705
8.300	73.1
8.301	73.275
8.302	73.90
8.303	73.85
8.304	73.95
8.305	73.30
8.306	73.295
8.307	73.340
8.308	73.345
8.309	73.600
8.310	73.615
8.311	73.500
8.313	73.250
8.314	73.260
8.315	73.140
8.316	73.575
8.317	73.100
8.318	73.170
8.319	73.50
8.320	73.160
8.321	73.40
8.322	73.315
8.323	73.450
8.324	73.300
8.325	73.200
8.326	73.75
8.501	81.1
8.502	81.10
8.503	81.25
8.505	81.27
8.510	81.30
8.515	81.32
8.4021	74.1101
8.4022	74.1102
8.4023	74.1104
8.4026	74.1045
8.4039	74.1109
8.4069	74.1205
8.4070	74.1206
8.4072	74.1208
8.4102	74.1303
8.4103	74.1304
8.4104	74.1340
8.4116	74.1317
8.4125	74.1331
8.4128	74.1334
8.4132	74.1339
8.4152	74.1602
8.4175	74.1705
8.4177	74.1707
8.4178	74.1707a
8.4179	74.1708
8.4182	74.1711
8.6000	73.1001
8.6001	73.1200
8.6002	73.1085
8.6003	73.1030
8.6004	73.1095
8.6005	73.1575
8.6006	73.1400
8.6009	73.1100
8.6010	73.1015
8.6011	73.1010
8.6012	73.1070
8.6013	73.1550
8.6014	73.1125
8.6015	73.1075
8.6016	73.1150
8.6017	73.1375
8.6018	73.1025
8.7034	74.2104
8.7061	74.2151
8.7102	74.2208
8.7163	74.2304

Old Section	New Section	Old Section	New Section
8.7179	74.2317	9.131	82.1708
8.7192	74.2331	9.133	82.1710
8.7195	74.2334	9.151	82.1306
8.7201	74.2340	9.152	82.1307
8.7222	74.2602	9.153	82.1308
8.7223	74.2602a	9.154	82.1309
8.7255	74.2705	9.155	82.1310
8.7257	74.2707	9.156	82.1311
8.7258	74.2707a	9.157	82.1312
8.7259	74.2708	9.158	82.1313
8.7262	74.2711	9.162	82.1317
8.8001	73.2575	9.164	82.1319
8.8002	73.2190	9.166	82.1321
8.8003	73.2400	9.167	82.1322
8.8004	73.2125	9.172	82.1327
8.8005	73.2150	9.173	82.1328
8.8006	73.2120	9.175	82.1330
8.8007	73.2725	9.176	82.1331
8.8008	73.2775	9.178	82.1333
8.8009	73.2250	9.179	82.1334
8.8010	73.2180	9.181	82.1336
9.1	82.3	9.182	82.1337
9.2	82.5	9.201	82.1254
9.3	82.6	9.202	82.1255
9.20	82.50	9.207	82.1260
9.23	82.203	9.208	82.1261
9.40	82.705	9.214	82.1267
9.41	82.706	9.240	82.1104
9.62	82.303	9.242	82.1106
9.63	82.304	9.270	82.1602
9.80	82.101	9.280	82.1051
9.81	82.102	9.300	82.2050
9.100	82.51	9.301	82.2701a
9.101	82.1050	9.307	82.2707a
9.103	82.1205	9.400	82.2201
9.104	82.1206	9.449	82.2051
9.130	82.1707	200.18	2.35

The changes being made are nonsubstantive; for this reason, notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of reorganized Subchapter A is set forth below.

Dated: March 14, 1977.

JOSEPH P. HILO,
Associate Commissioner for Compliance.

Subchapter A—General

Part
1 General regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.
2 General administrative rulings and decisions.
5 Delegations of authority and organization.
7 Enforcement policy.
10 Administrative practices and procedures.
12 Formal evidentiary public hearing.
13 Public hearing before a public board of inquiry.
14 Public hearing before a public advisory committee.
15 Public hearing before the Commissioner.
16 Regulatory hearing before the Food and Drug Administration.
19 Standards of conduct and conflicts of interest.
20 Public information.
21 Protection of privacy.
25 Environmental impact considerations.
70 Color additives.
71 Color additive petitions.
73 Listing of color additives exempt from certification.
74 Listing of color additives subject to certification.
80 Color additive certification.
81 General specifications and general restrictions for provisional color additives for use in foods, drugs, and cosmetics.
82 Listing of certified provisionally listed colors and specifications.

PART 1—GENERAL REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

Subpart A—General Provisions

Sec.
1.1 General.
1.3 Definitions.

Subpart B—General Labeling Requirements

1.20 Presence of mandatory label information.
1.21 Failure to reveal material facts.
1.23 Procedures for requesting variations and exemptions from required label statements.
1.24 Exemptions from required labeling.
1.31 Package size savings.
1.35 "Cents-off," or other savings representations.

Subparts C & D—[Reserved]

Subpart E—Imports and Exports

1.83 Definitions.
1.90 Notice of sampling.
1.91 Payment for samples.
1.94 Hearing on refusal of admission.
1.95 Application for authorization to relabel and recondition.
1.96 Granting of authorization to relabel and recondition.
1.97 Bonds.
1.99 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

AUTHORITY: Secs. 4, 6, 80 Stat. 1297, 1299, 1300, secs. 403, 602, 701, 52 Stat. 1047, 1050, 1054, 1055–1056 as amended; 15 U.S.C. 1453, 1455, 21 U.S.C. 343, 352, 362, 371, unless otherwise noted.

Subpart A—General Provisions

§ 1.1 General.

(a) The provisions of regulations promulgated under the Federal Food, Drug, and Cosmetic Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in regulations promulgated under that act.

(c) The definition of "package" in § 1.20 and of "principal display panel" in §§ 101.1, 201.60, 501.1, 701.10 and 801.60 of this chapter; and the requirements pertaining to uniform location, lack of qualification, and separation of the net quantity declaration in §§ 101.105(f), 201.62(e), 501.105(f), 701.13(f) and 801.62(e) of this chapter to type size requirements for net quantity declaration in §§ 101.105(i), 201.62(h), 501.105(i), 701.13(i) and 801.62(h) of this chapter, to initial statement of ounces in the dual declaration of net quantity in §§ 101.105 (j) and (m), 201.62 (i) and (k), 501.105 (j) and (m), 701.13 (j) and (m) and 801.62 (i) and (k) of this chapter, to initial statement of inches in declaration of net quantity in §§ 201.62(m), 701.13 (o) and 801.62(m) of this chapter, to initial statement of square inches in declaration of net quantity in §§ 201.62(n), 701.13(p) and 801.62(n) of this chapter, to prohibition of certain supplemental net quantity statements in §§ 101.105(o), 201.62(o), 501.105(o), 701.13(q) and 801.62(o) of this chapter, and to servings representations in §§ 101.8 and 501.8 of this chapter are provided for solely by the Fair Packaging and Labeling Act. The other requirements of this part are issued under both the Fair Packaging and Labeling Act and the Federal Food, Drug, and Cosmetic Act, or by the latter act solely, and are not limited in their application by section 10 of the Fair Packaging and Labeling Act.

§ 1.3 Definitions.

(a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(b) "Label" means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

(Secs. 4, 6, 80 Stat. 1297, 1299, 1300, secs. 403, 602, 52 Stat. 1047, 1050, 1054; 15 U.S.C. 1453, 1455, 21 U.S.C. 343, 352, 362.)

Subpart B—General Labeling Requirements

§ 1.20 Presence of mandatory label information.

The term "package" means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

(a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or

(c) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231–233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234–236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251–256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257–257i).

(d) Containers used for tray pack displays in retail establishments.

(e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part.

A requirement contained in this part that any word, statement, or other information appear on the label shall

not be considered to be complied with unless such word, statement, or information also appears on the outer container or wrapper of the retail package of the article, or, as stated in paragraph (e) of this section, such information is easily legible by virtue of the transparency of the outer wrapper or container. Where a consumer commodity is marketed in a multiunit retail package bearing the mandatory label information as required by this part and the unit containers are not intended to be sold separately, the net weight placement requirement of § 101.105(f) applicable to such unit containers is waived if the units are in compliance with all the other requirements of this part.

§ 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are:

(1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or

(2) Material with respect to consequences which may result from use of the article under (i) the conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

(b) Affirmative disclosure of material facts pursuant to paragraph (a) of this section may be required, among other appropriate regulatory procedures, by

(1) Regulations in this chapter promulgated pursuant to section 701(a) of the act; or

(2) Direct court enforcement action.

(c) Paragraph (a) of this section does not:

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act.

(2) Permit a statement of differences of opinion with respect to the effectiveness of a drug unless each of the opinions expressed is supported by substantial evidence of effectiveness as defined in sections 505(d) and 512(d) of the act.

(Secs. 201(n), 403(a), 502 (a) and (f), 505, 512, 602(a), 701(a), 52 Stat. 1041, 1047, 1050, 1052–1053 as amended by 76 Stat. 781–785, 1054–1055, 82 Stat. 343–351 (21 U.S.C. 321(n), 343(a), 352 (a) and (f), 355, 360b, 362(a), 371(a)).)

§ 1.23 Procedures for requesting variations and exemptions from required label statements.

Section 403(e) of the act (in this Part 1, the term "act" means the Federal Food, Drug, and Cosmetic Act) provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 403(i) of the act provides for the establishment by regulation of exemptions from the required declaration of ingredients where such declaration is impracticable, or results in deception or unfair competition. Section 502(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 602(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 5(b) of the Fair Packaging and Labeling Act provides for the establishment by regulation of exemptions from certain required declarations of net quantity of contents, identity of commodity, identity and location of manufacturer, packer, or distributor, and from declaration of net quantity of servings represented, based on a finding that full compliance with such required declarations is impracticable or not necessary for the adequate protection of consumers, and a further finding that the nature, form, or quantity of the packaged consumer commodity or other good and sufficient reasons justify such exemptions. The Commission, on his own initiative or on petition of an interested person, may propose a variation or exemption based upon any of the foregoing statutory provisions, including proposed findings if section 5(b) of the Fair Packaging and Labeling Act applies, pursuant to Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 1.24 Exemptions from required label statements.

The following exemptions are granted from label statements required by this part:

(a) *Foods.* (1) While held for sale, a food shall be exempt from the required declaration of net quantity of contents specified in this part if said food is received in bulk containers at a retail establishment and is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

(2) Random food packages, as defined in § 101.105(j) of this chapter, bearing labels declaring net weight, price per pound or per specified number of pounds, and total price shall be exempt from the type size, dual declaration, and placement requirements of § 101.105 of this chapter if the accurate statement of net weight is presented conspicuously on the principal display panel of the package. In the case of food packed in random packages at one place for subsequent shipment and sale at another, the price sections of the label may be left blank provided they are filled in by the seller prior to retail sale. This exemption shall also apply to uniform weight packages of cheese and cheese products labeled in the same manner and by the same type of equipment as random food packages exempted by this paragraph (a)(2) except that the labels shall bear a declaration of price per pound and not price per specified number of pounds.

(3) Individual serving-size packages of foods containing less than ½ ounce or less than ½ fluid ounce for use in restaurants, institutions, and passenger carriers, and not intended for sale at retail, shall be exempt from the required declaration of net quantity of contents specified in this part.

(4) Individually wrapped pieces of "penny candy" and other confectionery of less than one-half ounce net weight per individual piece shall be exempt from the labeling requirements of this part when the container in which such confectionery is shipped is in conformance with the labeling requirements of this part. Similarly, when such confectionery items are sold in bags or boxes, such items shall be exempt from the labeling requirements of this part, including the required declaration of net quantity of contents specified in this part when the declaration on the bag or box meets the requirements of this part.

(5) (i) Soft drinks packaged in bottles shall be exempt from the placement requirements for the statement of identity prescribed by § 101.3 (a) and (d) of this chapter if such statement appears conspicuously on the bottle closure. When such soft drinks are marketed in a multiunit retail package, the multiunit retail package shall be exempt from the statement of identity declaration requirements prescribed by § 101.3 of this chapter if the statement of identity on the unit container is not obscured by the multiunit retail package.

(ii) A multiunit retail package for soft drinks shall be exempt from the declaration regarding name and place of business required by § 101.5 of this chapter if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on the unit containers complies with § 101.5 of this chapter. The declaration required by § 101.5 of this chapter may appear on the top or side of the closure of bottled soft drinks if the statement is conspicuous and easily legible.

(iii) Soft drinks packaged in bottles which display other required label information only on the closure shall be exempt from the placement requirements for the declaration of contents prescribed by § 101.105(f) of this chapter if the required content declaration is blown, formed, or molded into the surface of the bottle in close proximity to the closure.

(iv) Where a trademark on a soft drink package also serves as, or is, a statement of identity, the use of such trademark on the package in lines not parallel to the base on which the package rests shall be exempted from the requirement of § 101.3(d) of this chapter that the statement be in lines parallel to the base so long as there is also at least one statement of identity in lines generally parallel to the base.

(6) (i) Ice cream, french ice cream, ice milk, fruit sherbets, water ices, quiescently frozen confections (with or without dairy ingredients), special dietary frozen desserts, and products made in semblance of the foregoing, when measured by and packaged in ½-liquid pint and ½-gallon measure-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook

44," are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8-fluid ounces and 64-fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively.

(ii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in 1-liquid pint, 1-liquid quart, and ½-gallon measure-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook 44," are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter.

(iii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in ½-liquid pint, 1-liquid pint, 1-liquid quart, ½-gallon, and 1-gallon measured-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook 44," are exempt from the requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel.

(7) (i) Milk, cream, light cream, coffee or table cream, whipping cream, light whipping cream, heavy or heavy whipping cream, sour or cultured sour cream, half-and-half, sour or cultured half-and-half, reconstituted or recombined milk and milk products, concentrated milk and milk products, skim or skimmed milk, vitamin D milk and milk products, fortified milk and milk products, homogenized milk, flavored milk and milk products, buttermilk, cultured buttermilk, cultured milk or cultured whole buttermilk, low-fat milk (0.5 to 2.0 percent butterfat), and acidified milk and milk products, when packaged in containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively.

(ii) The products listed in paragraph (a)(6)(i) of this section, when packaged in glass or plastic containers of ½-pint, 1-pint, 1-quart, ½-gallon, and 1-gallon capacities are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel, provided that other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(iii) The products listed in paragraph (a)(6)(i) of this section, when packaged in containers of 1-pint, 1-quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter.

(8) Wheat flour products, as defined by §§ 137.105, 137.155, 137.160, 137.165, 137.170, 137.175, 137.180, 137.185, 137.200, and 137.205 of this chapter, packaged:

(i) In conventional 2-, 5-, 10-, 25-, 50-, and 100-pound packages are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label; and

(ii) In conventional 2-pound packages are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter provided the quantity of contents is expressed in pounds.

(9) (i) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs and designed to permit the division of such carton by the retail customer at the place of purchase into two portions of one-half dozen eggs each are exempt from the labeling requirements of this part with respect to each portion of such divided carton if the carton, when undivided, is in conformance with the labeling requirements of this part.

(ii) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs are exempt from the placement requirements for the declaration of contents prescribed by § 101.105 (f) of this chapter if the required content declaration is otherwise placed on the principal display panel of such carton and if, in the case of such cartons designed to permit division by retail customers into two portions of one-half dozen eggs each, the required content declaration is placed on the principal display panel in such a manner that the context of the content declaration is destroyed upon division of the carton.

(10) Butter as defined in 42 Stat. 1500 (excluding whipped butter):

(i) In 8-ounce and in 1-pound packages is exempt from the requirements of § 101.105(f) of this chapter that the net contents declaration be placed within the bottom 30 percent of the area of the principal display panel;

(ii) In 1-pound packages is exempt from the requirements of § 101.105(j)(1) of this chapter that such declaration be in terms of ounces and pounds, to permit declaration of "1 pound" or "one pound"; and

(iii) In 4-ounce, 8-ounce, and 1-pound packages with continuous label copy wrapping is exempt from the requirements of §§ 101.3 and 101.105(f) of this chapter that the statement of identity and net contents declaration appear in lines generally parallel to the base on which the package rests as it is designed to be displayed, provided that such statement and declaration are not so positioned on the label as to be misleading or difficult to read as the package is customarily displayed at retail.

(11) Margarine as defined in § 166.110 of this chapter and imitations thereof in 1-pound rectangular packages, except for packages containing whipped or soft margarine or packages that contain more than four sticks, are exempt from the requirement of § 101.105(f) of this chapter that the declaration of the net quantity of contents appear within the bottom 30 percent of the principal display panel and from the requirement of § 101.105(j)(1) of this chapter that such declaration be expressed both in ounces and in pounds to permit declaration of "1 pound" or "one pound," provided an accurate statement of net weight appears conspicuously on the principal display panel of the package.

(12) Corn flour and related products, as they are defined by §§ 137.211, 137.215, and 137.230 through 137.290 of this chapter, packaged in conventional 5-, 10-, 25-, 50-, and 100-pound bags are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label.

(13) (i) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass or plastic containers of ½-pint, 1-pint, 1-quart, ½-gallon, and 1-gallon capacities are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel: *Provided*, That other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(ii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 1-pint, 1-quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter.

(iii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint (or half pint) and ½ gallon (or half gallon), respectively.

(14) The unit containers in a multiunit or multicomponent retail food package shall be exempt from compliance with the requirements of section 403(g)(2), (i)(2), and (k) of the act with respect to the requirements for label declaration of ingredients when (i) the multiunit or multicomponent retail food package labeling meets all the requirements of this part; (ii) the unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and (iii) each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth inch in height, and each multiunit or multicomponent package principal display panel is labeled with the statement "Inner Units Not Labeled For Retail Sale" in type size not smaller than the minimum type size required for the declaration of net quantity of contents by § 101.105 of this chapter.

(b) *Drugs.* Liquid over-the-counter veterinary preparations intended for injection shall be exempt from the declaration of net quantity of contents in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof as required by § 201.62(b), (i), and (j) of this chapter, and from the dual declaration requirements of § 201.62(i) of this chapter, if such declaration of net quantity of contents is expressed in terms of the liter and milliliter, or cubic centimeter, with the volume expressed at 68° F (20° C).

(c) *Cosmetics.* Cosmetics in packages containing less than one-fourth ounce avoirdupois or one-eighth fluid ounce shall be exempt from compliance with the requirements of section 602(b)(2) of the Federal Food, Drug, and Cosmetic Act and section 4(a)(2) of the Fair Packaging and Labeling Act:

(1) When such cosmetics are affixed to a display card labeled in conformance with all labeling requirements of this part; or

(2) When such cosmetics are sold at retail as part of a cosmetic package consisting of an inner and outer container and the inner container is not for separate retail sale and the outer container is labeled in conformance with all labeling requirements of this part.

§ 1.31 Package size savings.

Any food, drug, cosmetic, or device that bears on the label or labeling a representation that the consumer commodity is being offered at a lower price per unit of weight, measure, or count because of economy resulting from the size of the container or quantity of its contents is subject to the following conditions:

(a) The container may bear a representation of economy by virtue of its size (for example, "economy size," "economy pack," "big value," "thrifty pack," "bargain size," "budget pack," etc.) only if:

(1) The sponsor of the economy size promotion at the same time offers the same brand of that commodity in at least one other packaged size or labeled form.

(2) Only one packaged or labeled form of that brand of commodity is labeled with an "economy size" representation.

(3) The sponsor of the economy size promotion and all subsequent levels of commerce sell the commodity labeled with an "economy size" representation at a price per unit of weight, volume, measure, or count which is substantially reduced (i.e., at least 5 percent) from the actual price of all other packaged or labeled units of the same brand of that commodity offered simultaneously.

(b) The sponsor of the economy size promotion and all subsequent levels of commerce such as wholesalers and jobbers shall maintain for at least 1 year invoices or other records showing that the wholesale price per unit of weight, measure, or count in the economy size package is such that the retailers can sell the economy size container at a significantly lower price per unit.

(Sec. 5, 80 Stat. 1298; 15 U.S.C. 1454.)

§ 1.35 "Cents-off," or other savings representations.

Any food, drug, cosmetic, or device that bears on the label or labeling a representation that the consumer commodity is being offered for retail at a reduction in retail price is subject to the following conditions: *Provided, however,* That such conditions do not apply to any such savings representations initiated by persons who do not manufacture, package, or import such commodities and who do not prescribe or specify by any means the manner in which such commodities are packaged or labeled by a manufacturer, packager, or importer:

(a) A "cents-off," or other savings representation that states or implies a reduction in the ordinary and customary retail price may be used by a manufacturer, packer, distributor, or retailer, hereinafter known as the sponsor, initiating such promotion only if:

(1) An ordinary and customary selling price of such consumer commodity has been established at the retail level,

(2) The sponsor's selling price and the selling price at all subsequent levels of commerce such as wholesalers and jobbers has been reduced by at least the savings differential represented on the package or labeling, and

(3) The sponsor and all subsequent levels of commerce keep and maintain invoices or other records for each promotion and for all successive promotions which occur within a 12-month period for at least 1 year subsequent to the end of the year (calendar, fiscal, or market) in which the promotion occurs in order to show that the invoice cost to the retailer has been reduced in an amount sufficient to enable the retailer to pass the savings on to the purchaser.

(b) (1) Each "cents-off" price reduction representation imprinted on the package or label shall be limited to a phrase which reflects that the price marked by the retailer represents the savings in the amount of the "cents-off" the retailer's regular price, e.g., "Price Marked Is ____ Cents Off the Regular Price," "Price Marked Is ____ Cents-Off the Regular Price of This Package:" *Provided,* The package or label may in addition bear in the usual pricing spot a form reflecting a space for the regular price, the represented "cents-off," and a space for the price to be paid by the consumer. The sponsor who sells the commodity at retail shall display the regular price, clearly and conspicuously designated as "regular price," on the package or label of the commodity or on a sign, placard, or shelf-marker placed in a position contiguous to the retail display of the "cents-off" marked commodity. The sponsor who does not sell at retail shall provide the retailer with a sign, placard, shelf-marker, or other device for the purpose of clearly and conspicuously displaying the retailer's regular price, designated as "regular price," in a position contiguous to the "cents-off" marked commodity.

(2) Other savings representations which appear on the label or labeling of a package, e.g., "bonus offer," "two-for-one sales," "one-cent sales," etc., are subject to the provisions of this section. Due to the infinite variety and scope of such promotions, the label format of such representations may differ from that set forth in paragraph (b)(1) of this section for "cents-off" promotions; however, such representations shall include all material facts relative to the offer and shall in no way be misleading.

(3) For the purposes of this section, the terms "ordinary and customary" and "regular" when used with the term "price" mean the price at which a consumer commodity has been openly and actively sold in the most recent and regular course of business in a particular retail outlet or a trade area for a reasonably substantial period of time (at least 30 days). For consumer commodities that fluctuate in price, the ordinary and customary price shall be the lowest price at which any substantial sales were made during said 30 days.

(c) Shipments of consumer commodities bearing "cents-off," or other savings representations to a given geographic trade area made by the sponsor initiating such promotion shall be in no greater volume than 50 percent of the total units of that identical consumer commodity distributed in the same geographic trade area during any period of 12 consecutive months comprising a calendar, fiscal, or market year.

(d) The "cents-off," or other savings promotion may not be employed by a sponsor on consumer commodities for distribution to a specific geographic trade area until after 1 month has elapsed since their last distribution of that identical consumer commodity bearing a savings representation to the same geographic trade area. The number of such promotions for that identical consumer commodity that may occur within a 12-month period comprising a calendar, fiscal, or market year shall not exceed a total of six with no more than three of any one type or kind (e.g., "cents-off," "bonus offer," "two-for-one sale," "1-cent sale," etc.), and the total period of time for all such promotions shall not exceed 6 months within that 12-month period.

(e) A newly developed consumer commodity, one which has been changed in a functionally significant respect, or one which is newly introduced into a given geographic trade area may be the subject of an "introductory offer" type promotion. Such offers are not considered subject to the provisions of paragraphs (a) through (d) of this section, provided:

(1) Each such labeled offer is clearly and conspicuously qualified with the phrase "Introductory Offer," and

(2) If the introductory offer promotion is in the form of a "cents-off" representation, each such labeled offer shall include clearly and conspicuously in immediate conjunction therewith the phrase "____ Cents Off the After-Introductory-Offer Price"; and

(3) Labeled representations do not exceed a period of 6 months duration.

Any subsequent price reduction promotion of the consumer commodity is sub-

ject to the provisions of paragraphs (a) through (d) of this section and shall be preceded by the 30-day period required for a determination of the ordinary and customary selling price in that retail establishment. At the time of making the introductory offer promotion, the sponsor must intend in good faith to offer the commodity alone, immediately following the introductory offer promotion, for a reasonably substantial period of time (at least 30 days) at the anticipated after-introductory-offer price. The sponsor of the introductory offer promotion and all subsequent levels of commerce shall sell the commodity at a reduction from their anticipated after-introductory-offer price which reduction shall be at least equal to the savings differential represented on the package or labeling. The sponsor and all subsequent levels of commerce shall maintain invoices and records for at least 1 year subsequent to the end of the year (calendar, fiscal, or market) in which such introductory offer occurs.

(Secs. 5, 6, 80 Stat. 1293–1300; 15 U.S.C. 1454–1455.)

Subparts C and D—[Reserved]

Subpart E—Imports and Exports

§ 1.83 Definitions.

For the purposes of regulations prescribed under section 801 (a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

(b) The term "district director" means the director of the district of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the district as he may designate to act in his behalf in administering and enforcing the provisions of section 801 (a), (b), and (c).

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the district director, the collector of customs having jurisdiction over the article shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the district director or the collector of customs of the results of examination of the sample.

§ 1.91 Payment for samples.

The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration district headquarters in whose territory the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance or rendered not a food, drug, device, or cosmetic as set forth in § 1.95.

§ 1.94 Hearing on refusal of admission.

(a) If it appears that the article may be subject to refusal of admission, the district director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request, giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the district director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

§ 1.95 Application for authorization to relabel and recondition.

Application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device or cosmetic may be filed only by the owner or consignee, and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

§ 1.96 Granting of authorization to relabel and recondition.

(a) When authorization contemplated by § 1.95 is granted, the district director shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or the Bureau of Customs, as the case may be;

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the district director may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the district director.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

§ 1.97 Bonds.

(a) The bonds required under section 801(b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the district director is in full agreement with the action.

§ 1.99 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

The cost of supervising the relabeling or other action in connection with an import of food, drugs, devices, or cosmetics which fails to comply with the Federal Food, Drug, and Cosmetic Act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 801(b) of the act, as amended. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law.

(c) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS–11/4 employee, except that such services performed by a customs

officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(d) The charge for the service of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS–12/4 employee. The rate per hour equal to 266 percent of the equivalent hourly rate of regular pay of the supervising officer (GS–11/4) and the analyst (GS–12/4) is computed as follows:

	Hours
Gross number of working hours in 52 40-hr weeks	2,080
Less:	
9 legal public holidays—New Years Day, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day	72
Annual leave—26 d	208
Sick leave—13 d	104
Total	384
Net number of working hours	1,696
Gross number of working hours in 52 40-hr weeks	2,080
Working hour equivalent of Government contributions for employee retirement, life insurance, and health benefits computed at 8½ pct of annual rate of pay of employee	176
Equivalent annual working hours	2,256
Support required to equal to 1 man-year	2,256
Equivalent gross annual working hours charged to Food and Drug appropriation	4,512

NOTE.—Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours $\frac{4,512}{1,696} = 266$ pct.

(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than ½ hour.

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

Subpart A—General Provisions

Sec.
2.5 Imminent hazard to the public health.
2.10 Examination and investigation samples.
2.19 Methods of analysis.

Subpart B—Human and Animal Foods

2.25 Grain seed treated with poisonous substances; color identification to prevent adulteration of human and animal food.
2.35 Use of secondhand containers for the shipment or storage of food and animal feed.

Subparts C–E—[Reserved]

Subpart F—Caustic Poisons

2.110 Definition of ammonia under Federal Caustic Poison Act.

AUTHORITY: Sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371), unless otherwise noted.

Subpart A—General Provisions

§ 2.5 Imminent hazard to the public health.

(a) Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The "imminent hazard" may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an "imminent hazard" of such occurrence exists.

(b) In exercising his judgment on whether an "imminent hazard" exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

(Secs. 505, 507, 512, 52 Stat. 1051–53, as amended, 59 Stat. 463, as amended, 82 Stat. 343–51, 21 U.S.C. 355, 357, 360b; secs. 2, 3, 10(a), 74 Stat. 372–75, as amended, 378, 15 U.S.C. 1261–62, 1269.)

§ 2.10 Examination and investigation samples.

(a) (1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated, in which case he shall collect as much as is available and reasonably accessible.

(2) The cost of twice the quantity so estimated exceeds $50.

(3) The sample cannot by diligent use of practicable preservation techniques available to the Food and Drug Administration be kept in a state in which it could be readily and meaningfully analyzed in the same manner and for the same purposes as the Food and Drug Administration's analysis.

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States.

(5) The sample is collected from a person named on the label of the article or his agent, and such person is also the owner of the article.

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon.

In addition to the quantity of sample set forth in this paragraph, the officer or employee shall, if practicable, collect such further amount as he estimates will be sufficient for use as trial exhibits.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample to which such person or owner is a party. The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of food, drug, or cosmetic is the basis of a notice given under section 305 of the act, or of a case under the act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(e) The Food and Drug Administration is authorized to destroy:

(1) Any official sample when it determines that no analysis of such sample will be made;

(2) Any official sample or part thereof when it determines that no notice under section 305 of the act, and no case under the act, is or will be based on such sample;

(3) Any official sample or part thereof when the sample was the basis of a notice under section 305 of the act, and when, after opportunity for presentation of views following such notice, it determines that no other such notice, and no case under the act, is or will be based on such sample;

(4) Any official sample or part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;

(5) Any official sample or part thereof if the article is perishable;

(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;

(7) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

(Secs. 701, 702, 52 Stat. 1055, as amended; 1056, as amended; 21 U.S.C. 371, 372.)

§ 2.19 Methods of analysis.

Where the method of analysis is not prescribed in a regulation, it is the policy of the Food and Drug Administration in its enforcement programs to utilize the methods of analysis of the Association of Official Analytical Chemists (AOAC) as published in the latest edition of their publication, "Official Methods of Analysis of the Association of Official Analytical Chemists," and the supplements thereto ("Changes in Methods" as published in the March issues of the "Journal of the Association of Official Analytical Chemists"), when available and applicable. Upon request, the Commissioner will furnish advice as to the availability and applicability of an AOAC method with respect to the enforcement of any specific regulation or statutory requirement. In the absence of an AOAC method, the Commissioner will furnish a copy of the particular method, or a reference to the published method, that the Food and Drug Administration will use in its enforcement program. Other methods may be used for quality control, specifications, contracts, surveys, and similar nonregulatory functions, but it is expected that they will be calibrated in terms of the method which the Food and Drug Administration uses in its enforcement program. Use of an AOAC method does not relieve the practioner of the responsibility to demonstrate that he can perform the method properly through the use of positive and negative controls and recovery and reproducibility studies.

(Sec. 707, 57 Stat. 500; 21 U.S.C. 377.)

Subpart B—Human and Animal Foods

§ 2.25 Grain seed treated with poisonous substances; color identification to prevent adulteration of human and animal food.

(a) In recent years there has developed increasing use of poisonous treatments on seed for fungicidal and other purposes. Such treated seed, if consumed, presents a hazard to humans and livestock. It is not unusual for stocks of such treated food seeds to remain on hand after the planting season has passed. Despite the cautions required by the Federal Seed Act (53 Stat. 1275, as amended 72 Stat. 476, 7 U.S.C. 1551 et seq.) in the labeling of the treated seed, the Food and Drug Administration has encountered many cases where such surplus stocks of treated wheat, corn, oats, rye, barley, and sorghum seed had been mixed with untreated seed and sent to market for food or feed use. This has resulted in livestock injury and in legal actions under the Federal Food, Drug, and Cosmetic Act against large quantities of food adulterated through such admixture of poisonous treated seeds with good food. Criminal cases were brought against some firms and individuals. Where the treated seeds are prominently colored, buyers and users or processors of agricultural food seed for food purposes are able to detect the admixture of the poisonous seed and thus reject the lots; but most such buyers, users, and processors do not have the facilities or scientific equipment to determine the presence of the poisonous chemical at the time crops are delivered, in cases where the treated seeds have not been so colored. A suitable color for this use is one that is in sufficient contrast to the natural color of the food seed as to make admixture of treated, denatured seeds with good food easily apparent, and is so applied that it is not readily removed.

(b) On and after December 31, 1964, the Food and Drug Administration will regard as adulterated any interstate shipment of the food seeds wheat, corn, oats, rye, barley, and sorghum bearing a poisonous treatment in excess of a recognized tolerance or treatment for which no tolerance or exemption from tolerance is recognized in regulations promulgated pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act, unless such seeds have been adequately denatured by a suitable color to prevent their subsequent inadvertent use as food for man or feed for animals.

(c) Attention is called to the labeling requirements of the Federal Hazardous Substances Act, where applicable to denatured seeds in packages suitable for household use.

(Secs. 402(a), 408, 52 Stat. 1046, as amended; 68 Stat. 511; 21 U.S.C. 342(a), 348; sec. 2(f)(1), 74 Stat. 372; 15 U.S.C. 1261.)

§ 2.35 Use of secondhand containers for the shipment or storage of food and animal feed.

(a) Investigations by the Food and Drug Administration, the National Communicable Disease Center of the U.S. Public Health Service, the Consumer and Marketing Service of the U.S. Department of Agriculture, and by various State public health agencies have revealed practices whereby food and animal feed stored or shipped in secondhand containers have been rendered dangerous to health. Such contamination has been the result of the original use of these containers for the storage and shipment of articles containing or bearing disease organisms or poisonous or deleterious substances.

(b) The Commissioner concludes that such dangerous or potentially dangerous practices include, but are not limited to, the following:

(1) Some vegetable growers and packers employ used poultry crates for shipment of fresh vegetables, including cabbage and celery. Salmonella organisms are commonly present on dressed poultry and in excreta, and fluid exudates from dressed birds. Thus wooden crates in which dressed poultry has been iced and packed are potential sources of Salmonella or other enteropathogenic microorganisms that may contaminate fresh vegetables which are frequently consumed without heat treatment.

(2) Some potato growers and producers of animal feeds use secondhand bags for shipment of these articles. Such bags may have originally been used for shipping or storing pesticide-treated seed or other articles bearing or containing poisonous substances. Thus these secondhand bags are potential sources of contamination of the food or animal feed stored or shipped therein.

(c) In a policy statement issued April 11, 1968, the Food and Drug Administration declared adulterated within the meaning of section 402(a) of the Federal Food, Drug, and Cosmetic Act shipments of vegetables or other edible food in used crates or containers that may render the contents injurious to health. This policy statement is extended so that the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of vegetables, other edible food, or animal feed in used crates, bags, or other containers that may render the contents injurious to health.

(Secs. 402(a), 52 Stat. 1046, as amended; 21 U.S.C. 342(a).)

Subparts C–E—[Reserved]

Subpart F—Caustic Poisons

§ 2.110 Definition of ammonia under Federal Caustic Poison Act.

For the purpose of determining whether an article containing ammonia is subject to the Federal Caustic Poison Act, the ammonia content is to be calculated as NH_3.

(Secs. 2, 9, 44 Stat. 1406, 1409; 15 U.S.C. 402, 409.)

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

Sec.

5.1 Delegations from the Secretary and Assistant Secretary.

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

Sec.
5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.
5.21 Emergency functions.
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5.36 Certification following inspections.
5.37 Issuance of reports of minor violations.
5.45 Imports.
5.46 Manufacturer's resident import agents.
5.61 Issuance of notices of filing of petitions and notices of proposed rule making pertaining to food standards, food additives, and color additives.
5.63 Detention of meat, poultry, eggs, and related products.
5.64 Certification of color additives.
5.66 Approval of schools providing food-processing instruction.
5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.
5.70 Issuance of notices implementing the provisions of the Drug Amendments of 1962.
5.71 Termination of exemptions for new drugs for investigational use in human beings or in animals.
5.73 Certification of insulin.
5.75 Designation of official master and working standards for antibiotic drugs.
5.76 Certification of antibiotic drugs.
5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use.
5.80 Approval of new drug applications and their supplements.
5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.
5.83 Approval of new animal drug applications and their supplements.
5.84 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new animal drug applications and their supplements.
5.86 Granting and withdrawing variances from performance standards for electronic products.
5.87 Exemptions from performance standards for electronic products.
5.88 Testing programs and methods of certification and identification for electronic products.
5.89 Notification of defects in, and repair or replacements of, electronic products.
5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.
5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.
5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.

Subpart C—Organization

5.100 Headquarters.
5.105 Assistant General Counsel for Food and Drugs, Office of General Counsel, Department of Health, Education, and Welfare.
5.110 FDA Public Records and Documents Center.
5.115 Field structure.

AUTHORITY: Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371).

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§ 5.1 Delegations from the Secretary and Assistant Secretary.

(a) The Assistant Secretary for Health has redelegated to the Commissioner of Food and Drugs with authority to redelegate (35 FR 606 as amended) all authority delegated to him by the Secretary of Health, Education, and Welfare as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Filled Milk Act (21 U.S.C. 61–63), the Federal Import Milk Act (21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406), and The Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), pursuant to section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigation); section 307 (International Cooperation); section 310 (Health Education and Information); section 311 (Federal-State Cooperation); and section 314(f) (Interchange of Personnel with States) of the Public Health Service Act (42 U.S.C. 241, 242l, 242o, 243, 246(f)) which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under sections 354 through 360F of the Public Health Service Act (42 U.S.C. 263b through 263n) which relate to electronic product radiation control.

(4) Functions vested in the Secretary under section 361 of the Public Health Service Act (42 U.S.C. 264) which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiological agents under 42 CFR 72.25); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, and electronic products, and other items or products regulated by the Food and Drug Administration.

(5) Functions vested in the Secretary under sections 351 and 352 of the Public Health Service Act (42 U.S.C. 262 and 263) which relate to biological products.

(6) Functions vested in the Secretary pertaining to section 302(a) of the Public Health Service Act (42 U.S.C. 242(a)) which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(7) Functions vested in the Secretary pertaining to section 303 of the Public Health Service Act (42 U.S.C. 242a) which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Public Law 91–513 for which a notice of claimed exemption for an investigational new drug is filed with the Food and Drug Administration and with respect to all drugs not scheduled under Public Law 91–513.

(8) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(9) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) which relate to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act, and the merits of the research protocol.

(10) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.) which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(11) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(12) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(13) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(14) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(15) Function of issuing all regulations of the Food and Drug Administration. The reservation of authority contained in Chapter 2–000 of the Department Organization Manual shall not apply.

(16) Functions vested in the Secretary under section 1103(4) of Executive Order 11490, as amended, and those portions of sections 1103(1), 1103(2), 1103(3), 3001(2), 3001(3), 3002(1), 3002(3), 3004, and 3009 of the Order, which relate to foods, drugs, and biologicals.

(17) Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.

(18) Function vested in the Secretary under the Federal Advisory Committee Act, Public Law 92–463, to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefor may be closed to the public for those committees under the administrative jurisdiction of the Commissioner of Food and Drugs. This authority may not be redelegated. This authority is to be exercised in accordance with the requirements of the Act and only with respect to the following:

(i) Meetings, to the extent that they directly involve review, discussion or consideration of records of the Department

which are exempt from disclosure under 5 U.S.C. 552(b) (4), (6), and (7), namely, (a) records containing trade secrets and commercial or financial information obtained from a person and privileged or confidential; (b) personnel, medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (c) investigatory files compiled for law enforcement purposes;

(ii) Meetings to the extent that they involve the review, discussion, and evaluation of specific drugs and devices regulated by FDA which are intended to result in recommendations for regulatory decisions under the Federal Food, Drug, and Cosmetic Act and which are concerned with matters listed in 5 U.S.C. 552(b) (4), (5), and (7);

(iii) Meetings held for the sole purpose of considering and formulating advice which the committee will give or any final report it will render, *Provided:*

(a) The meetings will involve solely the internal expression of views and judgments of the members and it is essential to close the meeting or portions thereof to protect the free exchange of such views and avoid undue interference with agency or committee operations, and such views if reduced to writing would be protected from mandatory disclosure under 5 U.S.C. 552(b);

(b) The meeting is closed for the shortest time necessary, summarizing the work of the committee during the closed session, and a report, prepared by the executive secretary will be made available promptly to the public.

(c) When feasible, the public is given a timely opportunity to present relevant information and views to the committee; and

(d) Concurrence for closing the meetings for such purpose is obtained from the Office of the General Counsel and the Office of Public Affairs.

(19) Functions vested in the Secretary under the second sentence of section 309 (Health Conferences) of the Public Health Service Act (42 U.S.C. 242n) to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration.

(20) Functions vested in the Secretary under section 501 (Gifts) of the Public Health Service Act (42 U.S.C. 219) to accept offers of unconditional gifts, of other than real property, provided such gifts are of $1,000 value or less and the total costs associated with acceptance of property will not exceed the cost of purchasing a similar item and the cost of normal care and maintenance.

(21) Functions vested in the Secretary under section 362 of the Public Health Service Act (42 U.S.C. 265) which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(22) Functions vested in the Secretary under section 1003(b)(3), Title X, of the Public Works and Economic Development Act of 1965 (42 U.S.C. 3246b(b)(3)) to waive any matching requirements for programs or projects of State and local governments funded under Title X of that act where it is determined that State or local governments concerned cannot reasonably obtain any non-Federal contributions.

(b) The Assistant General Counsel in charge of the Food and Drug Division has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act, section 4 of the Federal Import Milk Act, and section 9(b) of the Federal Caustic Poison Act.

(c) The Assistant Secretary for Health has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority delegated to him by the Assistant Secretary for Administration and Management: (1) To certify true copies of any books, records, papers, or other documents on file within the Department, or extracts from such; to certify that true copies are true copies of the entire file of the Department; to certify the complete original record or to certify the nonexistence of records on file within the Department; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(2) To establish volunteer service programs and accept volunteer services for use in the operation of a health care facility or the provision of health care under section 223 of the Public Health Service Act (42 U.S.C. 217b).

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs is redelegated as set forth in this subpart. Further redelegation of the authority vested herein is not authorized. Authority redelegated herein to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting" or unless not legally permissible.

(b) The Deputy Commissioner of Food and Drugs and the Associate Commissioner for Compliance are authorized to perform all the functions of the Commissioner of Food and Drugs.

§ 5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health, Education, and Welfare regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters.

§ 5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of or extracts from any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) Associate and Deputy Associate Commissioners.

(2) Assistant and Deputy Assistant Commissioners.

(3) Director of the Executive Secretariat.

(4) Director and Deputy Director of the Office of Legislative Services.

(5) The FDA Regulations Officer and the Federal Register Liaison Officer and their alternates, and Director, Public Records and Documents Center of the Office of Compliance.

(6) Directors and Deputy Directors of Bureaus and Executive Director and Deputy Executive Director of Regional Operations.

(7) Director of the Office of Planning and Evaluation, the Associate Director and Deputy Associate Director for Compliance, and the Directors of the Divisions of: Methadone Monitoring; Drug Product Quality; Drug Labeling Compliance; and Drug Manufacturing of the Bureau of Drugs.

(8) Associate Director for Management, the Associate Director and Deputy Associate Director for Compliance, and the Directors of the Divisions of: Regulatory Guidance; Food Technology; and Food Service of the Bureau of Foods.

(9) Associate Director and the Director of the Division of Compliance of the Bureau of Biologics.

(10) Director and Deputy Director of the Division of Compliance of the Bureau of Veterinary Medicine.

(11) Associate Director for Administration of the Bureau of Radiological Health, and the Director of the Division of Compliance of that Bureau.

(12) Assistant Director for Program Operations and the Director of the Division of Compliance of the Bureau of Medical Devices and Diagnostic Products.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents.

(1) Associate and Deputy Associate Commissioners.

(2) The Director of the Division of Personnel Management of the Office of Administration and the Chief of the Career Development and Training Branch of that Division and Office.

(c) The Federal Register Writer and his alternates of the Office of Compliance are authorized to certify true copies of FEDERAL REGISTER documents.

§ 5.23 Disclosure of official records.

(a) The following officials are authorized to make determinations to disclose official records and information in accordance with Part 20 of this chapter.

(1) The Director and Deputy Director of the Bureau of Drugs, and the Associate Director and Deputy Associate Director for Compliance and the Directors of the Divisions of: Methadone Monitoring; Drug Product Quality; Drug Labeling Compliance; and Drug Manufacturing of that Bureau.

(2) The Director and Deputy Director of the Bureau of Foods, and the Associate Director and Deputy Associate Director for Compliance and the Director of the Division of Regulatory Guidance of that Bureau.

(3) The Director and Deputy Director of the Bureau of Veterinary Medicine and the Director and Deputy Director of the Division of Compliance of that Bureau.

(4) The Director and Deputy Director, Bureau of Radiological Health, and the Director of the Division of Electronic Products and the Director of the Division of Compliance of that Bureau.

(5) The Director and Deputy Director of the Bureau of Biologics, and the Associate Director and the Director of the Division of Compliance of that Bureau.

(6) The Director and Deputy Director of the Bureau of Medical Devices and Diagnostic Products and the Director of the Division of Compliance of that Bureau.

(b) The Chief of the Drug Listing Branch of the Division of Drug Labeling Compliance of the Bureau of Drugs is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

(c) The Chief of the Records Section of the Administrative Services Branch, Division of Management Services, Office of Administration, is authorized to sign affidavits regarding the presence or absence of records in the files of that section.

§ 5.25 Grants.

(a) The Associate and Deputy Associate Commissioner for Science are authorized to approve or disapprove all applications for grants under secs. 301, 307, 311, and 356 of the Public Health Service Act, and to select officials to serve as program managers to exercise scientific oversight and to monitor grantee progress.

(b) The Associate and Deputy Associate Commissioner for Administration and the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Administration are authorized to execute grant awards upon approval by the Associate or Deputy Associate Commissioner for Science, and to notify grantees of officials who will serve as the Food and Drug Administration program manager for their grant.

§ 5.26 Service fellowships.

The Associate and Assistant Commissioners, the Directors of Bureaus, the Director, National Center for Toxicological Research, and the Executive Director of Regional Operations are authorized to designate persons to receive service fellowships in the Food and Drug Administration Staff Fellowship Program under sec. 207(g) of the Public Health Service Act.

§ 5.30 Hearings and review boards.

(a) The Directors and Deputy Directors of Bureaus, Regional Food and Drug Directors, and District Directors are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act, section 6 of the Fair Packaging and Labeling Act, section 9(b) of the Federal Caustic Poison Act, and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under or in enforcement of any law as cited in this section.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to appoint review boards as provided by § 601.41 of this chapter.

(c) The Director and Deputy Director of the Bureau of Radiological Health are authorized to hold hearing under section 360(a) of the Public Health Service Act, and to designate officials to hold informal hearings under section 360(a) of the act.

(d) The Directors and Deputy Directors of Bureaus, Regional Food and Drug Directors, and District Directors are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing pursuant to the provisions of Part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he satisfies the requirements of § 16.40(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part.

§ 5.35 Enforcement activities.

(a) Duly appointed and authorized inspectors, officers, and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FD-200a entitled "Identification Record" and Form FD-200b entitled "Specification of General Authority" are designated by the Commissioner of Food and Drugs:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records; and to supervise compliance operations, for the enforcement of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, and section 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the Act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Duly appointed and authorized inspectors, officers, and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FD-200a entitled "Identification Record" and Form FD-200c entitled "Specification of General and Special Authority" are designated by the Commissioner of Food and Drugs:

(1) To perform the duties enumerated in paragraph (a) (1) and (2) of this section.

(2) As officers and employees having the authority to request and the authority to have access to and copy and verify records and reports required by sections 505 (i) and (j), 507 (d) and (g), and 512 (l) and (m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (i) and (j), 357 (d) and (g), and 360b (l) and (m)).

(c) The Food and Drug Administration official credentials referred to in paragraphs (a) and (b) of this section are described as follows:

(1) Form FD-200a entitled "Identification Record" bears a color photograph, description, and signature of the bearer, an identification number, an expiration date, the Department of Health, Education, and Welfare seal with blue imprint centered to the left of the photograph and the Food and Drug Administration symbol centered to the right of the photograph.

(2) Form FD-200b entitled "Specification of General Authority" bears the holder's name, his general authority, an identification number, an expiration date, and the Commissioner's signature.

(3) Form FD-200c entitled "Specification of General and Special Authority" bears the holder's name, his general and

special authority, an identification number, an expiration date, and the Commissioner's signature and is superimposed in the lower right corner with a red, white, and blue stripe imprint.

(4) Both Form FD-200b and Form FD-200c bear the name of the Department of Health, Education, and Welfare, Public Health Service, and Food and Drug Administration and are superimposed with the Department seal with blue imprint.

(d) The Director and Deputy Director of the Bureau of Radiological Health are authorized to refuse admission of noncomplying electronic product imports and to notify the Secretary of the Treasury of such refusal under section 360(a) of the Public Health Service Act and are authorized to refuse or to grant permission and time extensions to bring such products into compliance, and are authorized to supervise or designate an official to supervise such operations under section 360(b) of the act.

(e) The Director and Deputy Director of the Bureau of Radiological Health and the Director of the Division of Compliance of that Bureau are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 360A(a) of the Public Health Service Act relating to electronic product safety and inspection of electronic product manufacturers' premises, and to perform all of the functions of the Commissioner of Food and Drugs under section 360A(b) of the act relating to the establishment, maintenance, and inspection of electronic product manufacturers' records.

(f) The Director and Deputy Director of the Bureau of Radiological Health are authorized to designate officials to make accident and investigation reports under section 360A(d) of the Public Health Service Act.

(g) The Director, Deputy Director, and Associate Director of the Bureau of Biologics and the Director of the Division of Compliance of that Bureau may authorize, pursuant to section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)), any officer, agent, or employee to enter and inspect any establishment which is subject to the provisions of section 351 of the act (42 U.S.C. 262).

§ 5.36 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under § 1240.20 of this chapter.

§ 5.37 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 306 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

(1) The Director and Deputy Director of the Bureau of Drugs and the Associate Director and Deputy Associate Director for Compliance of that Bureau.

(2) The Director and Deputy Director of the Bureau of Foods and the Associate Director and Deputy Associate Director for Compliance of that Bureau.

(3) The Director and Deputy Director of the Bureau of Veterinary Medicine and the Director and Deputy Director of the Division of Compliance of that Bureau.

(4) The Director and Deputy Director of the Bureau of Medical Devices and Diagnostic Products and the Director of the Division of Compliance of that Bureau.

(5) The Director and Deputy Director of the Bureau of Biologics, and the Associate Director and the Director of the Division of Compliance of that Bureau.

(b) The Director and Deputy Director of the Bureau of Radiological Health are authorized to perform all the functions of the Commissioner of Food and Drugs under section 360C(d) of the Public Health Service Act regarding the issuance of written notices or warnings.

§ 5.45 Imports.

(a) The Regional Food and Drug Directors and District Directors are authorized to designate officials who may request, under section 801(a) of the Federal Food, Drug, and Cosmetic Act, from the Secretary of the Treasury samples of foods, drugs, devices, or cosmetics imported, or offered for import, in order to determine whether such articles are in compliance with the act.

(b) The Director and Deputy Director of the Bureau of Radiological Health, and the Director of the Division of Compliance of that Bureau are authorized to request, under section 360(a) of the Public Health Service Act, from the Secretary of the Treasury samples of electronic products imported or offered for import in order to determine whether such articles are in compliance with the act.

(c) The Director and Deputy Director of the Bureau of Radiological Health, and the Director of the Division of Compliance of that Bureau may, under section 360B(b) of the Public Health Service Act, exempt persons from issuing a certification as required by section 358(h) of the act, for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function, will be destroyed or exported in accord with Bureau of Customs regulations.

(d) The Regional Food and Drug Directors and District Directors are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the Public Health Service Act (42 U.S.C. 265) that relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

§ 5.46 Manufacturer's resident import agents.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to reject manufacturers' designations of resident import agents pursuant to § 1005.25(b) of this chapter.

§ 5.61 Issuance of notices of filing of petitions and notices of proposed rule making pertaining to food standards, food additives, and color additives.

The Director of the Bureau of Foods is authorized to perform all the functions of the Commissioner of Food and Drugs under sections 401, 409, and 706 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of notices of filing of petitions and notices of proposed rule making pertaining to food standards, food additives, and color additives.

§ 5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 et seq.)

§ 5.64 Certification of color additives.

The Director and Deputy Director of the Bureau of Foods, the Associate Director and Deputy Associate Director for Technology, and the Director and Deputy Director of the Division of Color Technology of that Bureau are authorized to certify batches of color additives for use in foods, drugs, or cosmetics, under section 706 of the Federal Food, Drug, and Cosmetic Act.

§ 5.66 Approval of schools providing food-processing instruction.

The Director and Deputy Director of the Bureau of Foods are authorized to perform all of the functions of the Commissioner of Food and Drugs under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging systems operations, and container closure inspections.

§ 5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The Director and Deputy Director of the Bureau of Biologics and the Associate Director of that Bureau are author-

ized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request.

§ 5.70 Issuance of notices implementing the provisions of the Drug Amendments of 1962.

The Director and Deputy Director of the Bureau of Drugs are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and 357).

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings or in animals.

(a) The Director and Deputy Director of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of exemptions for new drugs for investigational use in human beings under § 312.1 and in animals under § 312.9 of this chapter, except those pertaining to biological products (unless the product is also a radioactive drug), urokinase products, and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components for which authority has been delegated in paragraph (b) of this section. The Associate Director and Deputy Associate Director for New Drug Evaluation and the Directors of the Divisions of: Anti-Infective Drug Products; Cardio-Renal Drug Products; Surgical-Dental Drug Products; Metabolism and Endocrine Drug Products; Neuropharmacological Drug Products; and Oncology and Radiopharmaceutical Drug Products of the Bureau of Drugs are authorized to notify sponsors and invite correction before termination action on such exemptions.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of exemptions for new drugs for investigational use in human beings under § 312.1 and in animals under § 312.9 of this chapter pertaining to nonradioactive biological products subject to the licensing provisions of section 351 of the Public Health Service Act (42 U.S.C. 262), nonradioactive urokinase products, and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components.

(c) The Director and Deputy Director of the Bureau of Veterinary Medicine are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of exemptions for new animal drugs for investigational use in animals under § 511.1 of this chapter.

§ 5.73 Certification of insulin.

The Director, Deputy Director, and the Associate Director and Deputy Associate Director for Compliance of the Bureau of Drugs, the Director and Deputy Director of the Division of Drug Product Quality of that Bureau, and the Chief and Assistant Chief of the Certification Services Branch of that Division and Bureau are authorized to certify or reject batches of drugs containing insulin, pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act.

§ 5.75 Designation of official master and working standards for antibiotic drugs.

The Director, Deputy Director, and Associate Director for Pharmaceutical Research and Testing of the Bureau of Drugs, and the Director of the National Center for Antibiotics Analysis of that Bureau are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter.

§ 5.76 Certification of antibiotic drugs.

The Director, Deputy Director, and the Associate Director and Deputy Associate Director for Compliance of the Bureau of Drugs, the Director and Deputy Director of the Division of Drug Product Quality of that Bureau, and the Chief and Assistant Chief of the Certification Services Branch of that Division and Bureau are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act.

§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use.

The Director and Deputy Director of the Bureau of Drugs and the Assistant Director for Regulatory Affairs are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use.

§ 5.80 Approval of new-drug applications and their supplements.

(a) The Director, Deputy Director, and Associate Director for New Drug Evaluation of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new-drug applications and supplements thereto which are for drugs for human use and have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section.

(1) The Directors of the Divisions of: Anti-Infective Drug Products; Cardio-Renal Drug Products; Surgical-Dental Drug Products; Metabolism and Endocrine Drug Products; Neuropharmacological Drug Products; and Oncology and Radiopharmaceutical Drug Products of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications which are for drugs for human use and have been submitted pursuant to §§ 314.1(c) and 314.8 of this chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section.

(2) The Associate and Deputy Associate Director for Drug Monographs and the Director of the Division of Generic Drug Monographs of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs regarding the approval of abbreviated new drug applications and supplements thereto which are for drugs for human use and have been submitted pursuant to §§ 314.1(f) and 314.8 of this chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new drug applications and supplements thereto which are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components and which have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

§ 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new-drug applications and their supplements.

(a) The Director and Deputy Director of the Bureau of Drugs are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto which are for drugs for human use and have been submitted pursuant to section 505 of the Federal Food, Drugs, and Cosmetic Act and §§ 314.1 and 314.8 of this chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section, and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to issue notices

of opportunity for hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto which are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components and which have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and §§ 314.1 and 314.8 of this chapter, and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

§ 5.83 Approval of new animal drug applications and their supplements.

The Director of the Bureau of Veterinary Medicine is authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act. The Director of the Division of Animal Feeds of the Bureau of Veterinary Medicine is authorized to perform the functions of the Commissioner with regard to the approval of applications for animal feeds containing new animal drugs.

§ 5.84 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new animal drug applications and their supplements.

The Director of the Bureau of Veterinary Medicine is authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications and new animal drug application supplements for drugs for animal use submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

§ 5.86 Granting and withdrawing variances from performance standards for electronic products.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to grant and withdraw variances from the provisions of performance standards for electronic products established in Subchapter J of this chapter.

§ 5.87 Exemptions from performance standards for electronic products.

The Director of the Bureau of Radiological Health is authorized to exempt from performance standards any electronic product intended solely or predominantly for departments or agencies of the United States under section 358 (a) (5) of the Public Health Service Act.

§ 5.88 Testing programs and methods of certification and identification for electronic products.

The Director and Deputy Director of the Bureau of Radiological Health and the Director of the Division of Compliance of that Bureau are authorized to review and evaluate industry testing programs under section 358(g) of the Public Health Service Act, and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 358(h) of the act.

§ 5.89 Notification of defects in, and repair or replacement of, electronic products.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to perform all the functions of the Commissioner of Food and Drugs relating to notification of defects in, and repair or replacement of, electronic products under section 359 of the Public Health Service Act and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter. The Director of the Division of Compliance of the Bureau of Radiological Health is authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the Public Health Service Act.

§ 5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

§ 5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.

The Director and Deputy Director of the Bureau of Radiological Health and the Director of the Division of Compliance of that Bureau are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 306A(f) of the Public Health Service Act.

§ 5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to accept assistance from State and local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

Subpart C—Organization

§ 5.100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER [1]

Commissioner of Food and Drugs.
Deputy Commissioner.
Administrative Law Judge.
Associate Commissioner for Compliance.
Hearing Clerk.
Associate Commissioner for Medical Affairs.
Associate Commissioner for Science.
Associate Commissioner for Administration.
Assistant Commissioner for Public Affairs.
Assistant Commissioner for Planning and Evaluation.
Assistant Commissioner for Professional and Consumer Programs.

BUREAU OF BIOLOGICS [2]

Office of the Director.
Division of Compliance.
Division of Virology.
Division of Blood and Blood Products.
Division of Control Activities.
Division of Pathology.
Division of Bacterial Products.

BUREAU OF DRUGS [2]

Office of the Director.
Office of Planning and Evaluation.
Associate Director for Drug Monographs.
Division of OTC Drug Evaluation.
Division of Biopharmaceutics.
Division of Generic Drug Monographs.
Associate Director for Biometrics and Epidemiology.
Division of Biometrics.
Division of Poison Control.
Division of Drug Experience.
Associate Director for Compliance.
Division of Methadone Monitoring.
Division of Drug Product Quality.
Division of Drug Labeling Compliance.
Division of Drug Manufacturing.
Associate Director for Pharmaceutical Research and Testing.
Division of Drug Biology.
Division of Drug Chemistry.
National Center for Antibiotics Analysis.
National Center for Drug Analysis.
Associate Director for New Drug Evaluation.
Division of Anti-Infective Drug Products.
Division of Cardio-Renal Drug Products.
Division of Surgical-Dental Drug Products.
Division of Metabolism and Endocrine Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology and Radiopharmaceutical Drug Products.
Division of Drug Advertising.
Associate Director for Information Systems.
Division of Drug Information Resources.
Division of Information Systems Design.
Medical Library.

BUREAU OF FOODS [2]

Office of the Director.
Associate Director for Compliance.
Division of Regulatory Guidance.
Division of Compliance Programs.
Division of Industry Programs.
Division of Food and Color Additives.
Associate Director for Sciences.
Division of Chemistry and Physics.
Division of Toxicology.
Division of Pathology.
Division of Microbiology.
Division of Mathematics.
Associate Director for Technology.
Division of Food Technology.
Division of Chemical Technology.

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[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.
[2] Mailing address: 8800 Rockville Pike, Bethesda, MD 20014.
[3] Mailing address: 200 C St. SW., Washington, D.C. 20204.

Division of Color Technology.
Division of Cosmetics Technology.
Associate Director for Nutrition and Consumer Sciences.
Division of Consumer Studies.
Division of Food Service.
Division of Nutrition.

BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS [1]

Office of the Director.
Division of Compliance.
Division of Diagnostic Product Standards and Research.
Division of Medical Device Standards and Research.
Division of Classification and Scientific Evaluation.

BUREAU OF RADIOLOGICAL HEALTH [1]

Office of the Director.
Division of Compliance.
Division of Biological Effects.
Division of Electronic Products.
Division of Radioactive Materials and Nuclear Medicine.
Division of Training and Medical Applications.

BUREAU OF VETERINARY MEDICINE [1]

Office of the Director.
Division of Veterinary Medical Research.
Division of Drugs for Avian Species.
Division of Drugs for Ruminant Species.
Division of Drugs for Swine and Minor Species.
Division of Drugs for Non-Food Animals.
Division of Compliance.
Division of Surveillance.
Division of Animal Feeds.

EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS [1]

Office of the Executive Director.
Division of Field Operations.
Division of Planning and Analysis.
Division of Federal-State Relations.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH [4]

Office of the Director.
Office of Program and Resource Planning.
Division of Animal Husbandry.
Division of Microbiology and Immunology.
Division of Diet Preparation.
Division of Facilities Engineering and Maintenance.
Division of Chemistry.
Division of Scientific Information Systems.
Division of Analytical Services.
Division of Carcinogenic Research.
Division of Teratogenic Research.
Division of Mutagenic Research.
Division of Molecular Biology.

§ 5.105 Assistant General Counsel for Food and Drugs, Office of General Counsel, Department of Health, Education, and Welfare.

Assistant General Counsel for Food and Drugs, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

§ 5.110 FDA Public Records and Documents Center.

The FDA Public Records and Documents Center, HFC-18, is located in Rm. 4-62, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-6310.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857

[4] Mailing address: Jefferson, AR 72079.

§ 5.115 Field structure.

REGION I

Regional Field Office: 585 Commercial Street, Boston, MA 02109.
District Office: 585 Commercial Street, Boston, MA 02109.
Winchester Engineering and Analytical Center: 109 Holton Street, Winchester, MA 01890.

REGION II

Regional Field Office: 850 Third Avenue, Brooklyn, NY 11232.
District Office: 850 Third Avenue, Brooklyn, NY 11232.
District Office: 599 Delaware Avenue, Buffalo, NY 14202.
District Office: 20 Evergreen Place, East Orange, NJ 07018.
District Office: Post Office Box S-4427, San Juan Station, San Juan, PR 00905.

REGION III

Regional Field Office: Room 1204, Second and Chestnut Streets, Philadelphia, PA 19106.
District Office: Room 1204, Second and Chestnut Streets, Philadelphia, PA 19106.
District Office: 900 Madison Avenue, Baltimore, MD 21201.

REGION IV

Regional Field Office: 880 West Peachtree Street, Atlanta, GA 30309.
District Office: 880 West Peachtree Street, Atlanta, GA 30309.
District Office: 297 Plus Park Boulevard, Nashville, TN 37217.
District Office: Post Office Box 118, Orlando, FL 32802.

REGION V

Regional Field Office: Room A-1945, 175 West Jackson Boulevard, Chicago, IL 60607.
District Office: Room 1222, 433 West Van Buren Street, Chicago, IL 60607.
District Office: 1141 Central Parkway, Cincinnati, OH 45202.
District Office: 1560 East Jefferson Avenue, Detroit, MI 48207.
District Office: 240 Hennepin Avenue, Minneapolis, MN 55401.
Minneapolis Center for Microbiological Investigations: 240 Hennepin Avenue, Minneapolis, MN 55401.

REGION VI

Regional Field Office: 5032 Bryan Street, Dallas, TX 75204.
District Office: 3032 Bryan Street, Dallas, TX 75204.
District Office: Room 222, 423 Canal Street, New Orleans, LA 70130.
Houston Section: Suite 250, 1440 North Loop, Houston, TX 77009.

REGION VII

Regional Field Office: 1009 Cherry Street, Kansas City, MO 64106.
District Office: 1009 Cherry Street, Kansas City, MO 64106.

REGION VIII

Regional Field Office: 721 19th Street, U.S. Customhouse, Denver, CO 80202.
District Office: 721 19th Street, U.S. Customhouse, Denver, CO 80202.

REGION IX

Regional Field Office: Room 518, 50 Fulton Street, San Francisco, CA 94102.
District Office: Room 518, 50 Fulton Street, San Francisco, CA 94102.
District Office: 1521 West Pico Boulevard, Los Angeles, CA 90015.

REGION X

Regional Field Office: Room 5003, 909 First Avenue, Seattle, WA 98104.
District Office: Room 5003, 909 First Avenue, Seattle, WA 98104.

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Sec.
7.1 Scope.
7.3 Definitions.
7.12 Guaranty.
7.13 Suggested forms of guaranty.

Subparts B-D—[Reserved]

Subpart E—Criminal Violations

7.84 Informal hearing before report of criminal violation.
7.85 Conduct of informal hearing before report of criminal violation.
7.87 Records relating to hearings conducted before report of criminal violation.

AUTHORITY: Secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 335, 371(a)), unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part is promulgated to clarify and explain the regulatory enforcement practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

§ 7.3 Definitions.

(a) "Agency" means the Food and Drug Administration.

(b) "Notice of Hearing" means the document (Form FD-466), also referred to as a "citation" or "cite," that provides notice to a person against whom criminal prosecution is contemplated of the opportunity to present his views to the agency regarding an alleged violation.

(c) "Other laws administered by the Food and Drug Administration" includes, but is not limited to, the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), the Federal Caustic Poison Act (15 U.S.C. 401-411), the Radiation Control for Health and Safety Act (42 U.S.C. 263b-263n), and provisions of the Public Health Service Act relating to biologics (section 351 (42 U.S.C. 262)), and interstate quarantine, including milk and food service and shellfish sanitation, (section 361 (42 U.S.C. 264)).

(d) "Responsible individual" includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) "Respondent" means a person named in a Notice of Hearing, who either in person, by designated representative, or in writing presents his views concerning an alleged violation.

§ 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

(Sec. 301, 52 Stat. 1042, as amended; 21 U.S.C. 331.)

§ 7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303 (c) (2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

(Sec. 303, 52 Stat. 1043; 21 U.S.C. 333.)

Subparts B Through D—[Reserved]

Subpart E—Criminal Violations

§ 7.81 Informal hearing before report of criminal violation.

(a) A person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is being contemplated by the Food and Drug Administration shall, except in compelling circumstances, be given appropriate notice and an opportunity for an informal hearing before the agency to present information and views to show cause why institution of criminal prosecution should not be recommended to a United States attorney.

(b) An opportunity for such a hearing shall be afforded all persons who, in the judgment of the Food and Drug Administration, appear to have had a responsible share in the furtherance of a transaction that violates the law.

(c) Opportunity for hearing shall be provided by a Notice of Hearing (Form FD-466) sent to each person who appears to share responsibility for a violation. A Notice of Hearing shall identify the products and/or shipments alleged to be in violation, and shall be sent by registered or certified mail, telegram, telex, personal delivery, or any other appropriate mode of written communication. The Notice of Hearing shall specify the time and place of the hearing and shall be accompanied by:

(1) A Charge Sheet (Form FD-1854) summarizing the apparent violations of the act and of other laws administered by the agency that constitute the basis of the contemplated prosecution.

(2) An Information Sheet (Form FD-466a) describing the purpose and procedure of the hearing.

(3) A Legal Status Sheet (Form FD-454) which the respondent is requested to fill out and return with the response to the Notice of Hearing.

(d) If more than one person is named in a Notice of Hearing, a separate hearing for any named person shall be scheduled on request. Otherwise, the time and place specified for a hearing may be changed only upon a showing of reasonable grounds. Requests for any change shall be addressed to the office in the Food and Drug Administration that issued the Notice of Hearing and shall be received in that office at least 3 working days before the date set in the Notice of Hearing.

(e) A person who has received a Notice of Hearing is under no legal obligation to appear or answer in any manner. If a person chooses to respond, he may appear personally, with or without a representative, or he may designate a representative to appear for him. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled for the hearing, the Food and Drug Administration will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the evidence available.

(f) When a respondent chooses to appear solely by designated representative, such representative shall present to the hearing officer a signed statement of authorization. When a representative appears for more than one respondent, he shall submit independent documentation of his authority to act for each. If a representative appears without written authorization, the hearing with respect to that respondent may proceed only if the hearing officer first verifies by telephone, or other appropriate means, the authenticity of the representative.

§ 7.85 Conduct of informal hearing before report of criminal violation.

(a) The hearing shall be conducted by a Food and Drug Administration employee who has been designated as a hearing officer. Other Food and Drug Administration employees may be present, and the purpose of their attendance will be stated for the record.

(b) The hearing shall be conducted in the following fashion:

(1) The hearing shall commence at the time and place designated in the Notice of Hearing, or as otherwise agreed to by the participants.

(2) The hearing shall not be open to the public. The hearing officer will permit participation of other persons only if they appear with the respondent or his designated representative and at the request of and on behalf of the respondent, provided they identify themselves and their relationship to the respondent and

state on the record that they are appearing for the respondent.

(3) The hearing shall be informal and shall be conducted in a manner that facilitates the presentation of information and views by the respondent. Rules of evidence shall not apply. At the outset, the hearing officer shall briefly review the basis on which criminal prosecution is contemplated. The Food and Drug Administration is under no obligation to present evidence or witnesses.

(4) A respondent may present any information bearing on why he should not be prosecuted. Such information may consist of statements of persons appearing on his behalf, letters, documents, laboratory analyses, if applicable, or any other data or arguments relevant to the allegations set forth in the Charge Sheet. Such information, including statements by the respondent, may be introduced at any subsequent trial.

(5) If the respondent holds a "guaranty or undertaking" (as described in section 303 of the act (21 U.S.C. 333(c))) that is applicable to any article on which the Notice of Hearing is based, such guaranty or undertaking, or verified copy thereof, may be presented by the respondent. Such document will be made a part of the record of the hearing.

(c) The respondent shall have the right to have the hearing transcribed at his expense, in which case a copy of such transcription shall be furnished to the Food and Drug Administration. Alternatively, the hearing officer may, at his discretion, order the hearing transcribed at the expense of the Food and Drug Administration, in which case a copy of such transcription shall be provided to each respondent.

(d) If the hearing is not transcribed, the hearing officer shall dictate a written summary of the hearing at its conclusion. The respondent shall be offered the opportunity to remain during the dictation to offer additional comments or corrections. A copy of the completed written summary shall be provided to each respondent whether or not he remains during dictation. Respondents may submit comments on the summary in accordance with paragraph (g) of this section.

(e) If a respondent obtains new information that was not reasonably available to him at the time of the hearing, a timely written request to reopen the hearing may be submitted to the office in the Food and Drug Administration where the hearing was held. Such a request shall specify the nature of the new information sought to be presented, the reason why it was not previously available to the respondent, and the reason it should not be submitted in documentary form. If the Commissioner concludes that presentation of the information may have a bearing on the decision to prosecute, he shall designate an employee of the Food and Drug Administration to conduct the reopened hearing. Any reopened hearing shall be governed by the procedures set forth in this subpart, and the written request and the summary or transcript of the reopened session shall become part of the record of the hearing.

(f) The record of the hearing shall consist of the following:

(1) The Notice of Hearing.

(2) The Charge Sheet.

(3) The Legal Status Sheet, if completed and returned by the respondent.

(4) All documentary information submitted by the respondent.

(5) The transcript or summary of the hearing and of any reopened session of such hearing.

(g) A respondent may supplement any response made on his behalf with additional written or documentary evidence and/or provide written comment on the summary of hearing or the transcript. To ensure that any submission will receive consideration before the agency decides whether or not to recommend prosecution, such submission shall be furnished to the office in the Food and Drug Administration where the hearing was held no later than 10 calendar days after either the date of a written response to a Notice of Hearing or the date the respondent receives the transcript or the summary of hearing. Any materials received after the 10-day supplemental response period has expired will be considered and added to the record of hearing if the final decision has not yet been made. Any such supplemental material shall be made a part of the record of the hearing.

(h) When consideration of criminal prosecution involving the same violations is closed by the agency with respect to all persons named in the Notice(s) of Hearing and no further criminal action is contemplated for the offenses charged, the agency will so notify each person in writing.

(i) When it is finally determined that a person named in a Notice of Hearing will not be included in the agency recommendation for prosecution, the agency will notify that person, if and when it concludes that notification will not prejudice the prosecution of any other person.

(j) When a United States attorney informs the agency that he will prosecute some but not all persons who had been provided an opportunity for a hearing and were subsequently named in an agency recommendation for prosecution, the Food and Drug Administration will notify those persons eliminated from further consideration after being advised by the United States attorney that such notification will not prejudice the prosecution of any other person. When a United States attorney informs the agency that no persons recommended by the agency will be prosecuted, the agency will so notify each person in writing.

§ 7.87 Records related to hearings conducted before report of criminal violation.

(a) Records relating to a section 305 hearing constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memoranda.

(1) Notwithstanding the rule established in § 20.21 of this chapter, no record relating to a section 305 hearing is available for public disclosure until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in § 20.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise his discretion to disclose records (pursuant to § 20.82 of this chapter) relating to a section 305 hearing before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed, such records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in Subpart D of Part 20 of this chapter are applicable. No statements of persons obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based upon a particular section 305 hearing shall be deemed to be closed within the meaning of this section and § 7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based upon charges set forth in the Notice of Hearing and considered at that hearing, or such recommendation has been finally refused by the United States attorney, or criminal prosecution has been instituted and the matter and all related appeals have been concluded, or the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual whose prosecution was considered but who was not recommended for prosecution or, if recommended for prosecution was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from section 305 hearing records before public disclosure only pursuant to § 20.32 of this chapter.

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

Subpart A—General

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10.3 Definitions.
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AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679 (b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f (b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-609 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures applicable to all petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws with respect to which authority has been delegated to the Commissioner of Food and Drugs pursuant to § 5.1 of this chapter, except to the extent that specific provisions in other sections of this chapter state different requirements with respect to a particular matter.

(b) Where a specific provision in another section of this chapter states a different requirement with respect to a particular matter (e.g., the use of a form different from the one specified in § 10.30 (b)), the sections in this part shall apply to the extent that they do not conflict with such other provisions (e.g., the requirements for inclusion of all data and information and for translations of foreign language in § 10.20(b) shall apply regardless of which form is used).

§ 10.3 Definitions.

(a) As used in this part and Parts 12, 13, 14, 15, 16, and 19 of this chapter, the following terms shall have the meanings specified:

(1) "Act" means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

(2) "Department" means the United States Department of Health, Education, and Welfare.

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

(4) "Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health, Education, and Welfare, or his designee.

(5) "Agency" means the Food and Drug Administration.

(6) "Person" includes an individual, partnership, corporation, association, or other legal entity.

(7) "Presiding officer" means the Commissioner or his designee or an Administrative Law Judge appointed as provided in 5 U.S.C. 3105.

(8) "Hearing Clerk" means the Hearing Clerk of the Food and Drug Administration, United States Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

(9) "Proceeding" and "administrative proceeding" mean any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

(10) "Party" means the bureau of the Food and Drug Administration responsible for the matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a formal evidentiary public hearing pursuant to Part 12 of this chapter or a regulatory hearing before the Commissioner pursuant to Part 16 of this chapter, or who has waived any such right in order to obtain the establishment of a Public Board of Inquiry pursuant to Part 13 of this chapter, and as a result of whose action a formal evidentiary hearing or a regulatory hearing before the Commissioner has been granted or a Public Board of Inquiry has been established.

(11) "Participant" means any person participating in any proceeding, including each party and any other interested person.

(12) "Interested person" or "any person who will be adversely affected" means any person who submits a petition or comment or objection or otherwise requests an opportunity to participate in any informal or formal administrative proceeding or court action.

(13) "Public Board of Inquiry" or "Board" means an administrative law tribunal constituted pursuant to the provisions of Part 13 of this chapter.

(14) "Public advisory committee" or "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, that is not composed wholly of full-time officers or employees of the Federal government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

(15) "Formal evidentiary public hearing" means any hearing conducted pursuant to the provisions of Part 12 of this chapter.

(16) "Public hearing before a Public Board of Inquiry" means any hearing conducted by a Board pursuant to the provisions of Part 13 of this chapter.

(17) "Public hearing before a public advisory committee" means any hearing conducted by an advisory committee pursuant to the provisions of Part 14 of this chapter.

(18) "Public hearing before the Commissioner" means any hearing conducted by the Commissioner or his designee pursuant to the provisions of Part 15 of this chapter.

(19) "Regulatory hearing before the Food and Drug Administration" means any hearing conducted by an authorized employee of the Food and Drug Administration pursuant to the provisions of Part 16 of this chapter.

(20) "The laws administered by the Commissioner" means all the statutory provisions with respect to which authority has been delegated to the Commissioner pursuant to § 5.1 of this chapter.

(21) "Petition" means any petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him.

(22) "Regulation" means any agency rule of general or particular applicability and future effect implementing or applying any law administered by the Commissioner or relating to administrative practices and procedures. Pursuant to § 10.90(a), all agency regulations shall be promulgated in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

(23) "Order" means any final agency disposition, other than the issuance of a regulation, in a proceeding concerning any matter and includes action on any new drug application, new animal drug application, or biological license.

(24) "Meeting" means any oral discussion, whether by telephone or in person.

(25) "Office of the Commissioner" includes the offices of the associate and assistant commissioners and excludes the bureaus, the office of the Executive Director for Regional Operations, and all regional and district offices.

(26) "Administrative action" includes every form and kind of act, including the refusal or failure to act, involved in the implementations of the laws administered by the Commissioner, except that it does not include the referral of apparent violations to United States attorneys for the institution of civil and criminal proceedings and acts preparatory or incidental thereto.

(27) "Administrative file" means the file maintained by the Food and Drug Administration, in which all documents pertaining to an administrative proceeding, including internal working memoranda and recommendations, are retained.

(28) "Food and Drug Administration employee" or "Food and Drug Administration representative" shall be deemed to include members of the Food and

Drug Division of the office of the General Council of the Department of Health, Education, and Welfare.

(29) "Ex parte communication" means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding.

(b) Any term which is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or Part 1 of this chapter shall have that definition.

(c) Words in the singular form shall be deemed to include the plural, words in the masculine form shall be deemed to include the feminine form, and vice versa, as the case may require.

(d) Whenever any reference is made in this part to any person in the Food and Drug Administration, e.g., the director of a bureau, such reference shall also be deemed to include all persons to whom that person has delegated the specific function involved.

§ 10.10 Summaries of administrative practices and procedures.

The Commissioner shall prepare for public distribution summaries of Food and Drug Administration administrative practices and procedures in terms that are readily understood in order to encourage and facilitate participation in all agency activities.

§ 10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or the presiding officer, with respect to matters pending before him, may on his own initiative or at the request of any participant waive, suspend, or modify any provision in Parts 12 through 16 of this chapter applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing, if he determines that no partcipant will be prejudiced, the ends of justice will thereby be served, and such action is in accordance with law.

Subpart B—General Administrative Procedures

§ 10.20 Submission of documents to Hearing Clerk; computation of time; availability for public disclosure.

(a) All submissions to the Hearing Clerk of petitions, comments, objections, notices, compilations of data and information, and any other documents pursuant to this part or other sections in this chapter shall be filed in four copies except as otherwise specifically provided in any relevant FEDERAL REGISTER notice or in other sections of this chapter. The Hearing Clerk shall be the agency custodian of such documents.

(b) All such submissions shall be signed by the person making the submission, or by an attorney or other authorized representative on his behalf. Submissions by trade associations shall also be subject to the requirements of § 10.105(b).

(c) All data and information referred to or in any way relied upon in any such submissions shall be included in full and may not be incorporated by reference, unless previously submitted as part of the administrative file in the same proceeding.

(1) A copy of any article or other reference or source cited shall be included, except where the reference or source is:

(i) A reported Federal court case,

(ii) A Federal law or regulation,

(iii) A Food and Drug Administration document that is routinely publicly available, or

(iv) A recognized medical or scientific textbook that is readily available to the agency.

(2) If any part of the material submitted is in a foreign language, it shall be accompanied by an English translation verified under oath to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. Translations of literature or other material in a foreign language shall be accompanied by copies of the original publication.

(3) Where relevant data or information are contained in a document also containing irrelevant matter, the irrelevant matter shall be deleted and only the relevant data or information shall be submitted.

(4) Pursuant to § 20.63 (a) and (b) of this chapter, the names and other information which would identify patients or research subjects shall be deleted from any record before it is submitted to the Hearing Clerk in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter shall be deleted from any record before it is submitted to the Hearing Clerk.

(6) The failure to comply with the requirements of this paragraph or any other requirement in this part shall result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion of the submission which fails to comply. If a submission fails to meet any requirement of this section and such deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall return the submission with a copy of the applicable regulations indicating those provisions not complied with in the submission. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Hearing Clerk is not equipped to make decisions regarding the confidentiality of submitted documents. Persons wishing to voluntarily submit information considered confidential shall do so in accordance with the presubmission review requirements of § 20.44 of this chapter.

(d) The filing of a submission shall mean only that the Hearing Clerk has not determined that it fails to meet the technical requirements for filing established in this section and in any other applicable sections in this chapter, e.g., § 10.30 relating to a citizen petition. The filing of a petition shall not mean or imply that it in fact meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Hearing Clerk shall be considered as submitted on the date on which they are postmarked or, if delivered in person during regular business hours, on the date on which they are so delivered, unless a provision in this part, an applicable FEDERAL REGISTER notice, or an order issued by an Administrative Law Judge specifically states that such documents must be received by a specified date, e.g., § 10.33(g) relating to a petition for reconsideration, in which case they shall be considered submitted on the date actually received.

(f) All such submissions shall be mailed or delivered in person to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, except that a submission which is required to be received by the Hearing Clerk by a specified date may be delivered in person to the Food and Drug Administration building in downtown Washington (Rm. 6819, 200 C St. SW., Washington, DC 20201) and shall be considered as received by the Hearing Clerk on the date on which it is logged in at Rm. 6819.

(g) The Food and Drug Administration ordinarily will not acknowledge or give receipt for such documents, except:

(1) Documents delivered in person or submitted by certified or registered mail with a return receipt requested.

(2) Petitions for which acknowledgment of receipt of filing is provided by regulations in this chapter or by customary practice, e.g., § 10.30(c) relating to a citizen petition.

(h) Saturdays, Sundays, and Federal legal holidays shall be included in computing the time allowed for the submission of any document, except that when such time expires on a Saturday, Sunday, or Federal legal holiday, such period shall be extended to include the next following business day.

(i) All submissions to the Hearing Clerk constitute a representation that, to the best of the knowledge, information, and belief of the person making the submission, all statements made in the submission are true and accurate. All such submissions are subject to the False Reports to the Government Act, 18 U.S.C. 1001, under which a willfully false statement is a criminal offense.

(j) The availability for public examination and copying of submissions to the Hearing Clerk shall be governed by the following rules:

(1) Except to the extent provided in paragraph (j) (2) and (3) of this section, the following submissions, including all supporting material, shall be on public display and shall be available for public examination between the hours of 9 a.m. to 4 p.m., Monday through Friday. Requests for copies of such submissions shall be filed and handled pursuant to the provisions of Subpart C of Part 20 of this chapter.

(i) Petitions.

(ii) Comments on petitions, on documents published in the FEDERAL REGISTER, and on similar public documents.

(iii) Objections and requests for hearings filed pursuant to Part 12 of this chapter.

(u) Material submitted at a formal evidentiary public hearing pursuant to Part 12 of this chapter, a public hearing before a Public Board of Inquiry pursuant to Part 13 of this chapter, a public hearing before the Commissioner pursuant to Part 15 of this chapter, or an alternative form of hearing before a public advisory committee pursuant to § 12.32(a)(2) of this chapter.

(v) Material placed on public display pursuant to regulations in this chapter, e.g., agency guidelines filed pursuant to § 10.90(b).

(2) (i) Material prohibited from public disclosure pursuant to § 20.63 of this chapter (clearly unwarranted invasion of personal privacy) as interpreted and applied in Part 20 of this chapter and the regulations referenced therein, and, except as provided in paragraph (j)(3) of this section, material submitted with objections and requests for hearings filed pursuant to Part 12 of this chapter, or at a formal evidentiary public hearing pursuant to Part 12 of this chapter, a public hearing before a Public Board of Inquiry pursuant to Part 13 of this chapter, or an alternative form of public hearing before a public advisory committee or a public hearing before the Commissioner pursuant to § 12.32(a)(2) or (3) of this chapter, of the following types shall not be on public display, shall not be available for public examination, and shall not be available for copying or any other form of verbatim transcription unless they are otherwise available for public disclosure pursuant to the provisions of Part 20 of this chapter and the regulations referenced therein:

(a) Safety and effectiveness data and information, which include all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

(b) A protocol for a test or study.

(c) Manufacturing methods or processes, including quality control procedures.

(d) Production, sales, distribution, and similar data and information, except any compilation of such data and information aggregated and prepared in a way that does not reveal confidential data and information.

(e) Quantitative or semiquantitative formulas.

(f) Data and information on design or construction of products.

(ii) Material submitted pursuant to the provisions of paragraph (j)(2) of this section shall be segregated from all other submitted material and clearly so marked. Any person who does not agree that such a submission is properly subject to the provisions of paragraph (j)(2) of this section may request a ruling thereon from the Assistant Commissioner for Public Affairs whose decision on the matter shall be final, subject to judicial review pursuant to § 20.46 of this chapter.

(3) Material listed in paragraph (j)(2)(i) (a) and (b) of this section may be disclosed pursuant to a protective order issued by the Administrative Law Judge or other presiding officer at any hearing referenced in paragraph (j)(2)(i). The order shall only permit disclosure of the data in camera and only to the extent necessary for the proper conduct of the hearing. The order shall state to whom the information is to be made available (e.g., to parties or participants, or only to counsel for parties or participants), and persons not specifically permitted access to the data shall be excluded from the in camera part of the proceeding. The Administrative Law Judge or other presiding officer may impose other conditions or safeguards with the requirements of this section. The limited availability of material pursuant to this paragraph shall be deemed not to constitute prior disclosure to the public as defined in § 20.81 of this chapter, and no such data and information shall be submitted to or received or considered by the Food and Drug Administration in support of a petition or other request from any other person.

§ 10.25 Initiation of administrative proceedings.

An administrative proceeding under the laws administered by the Commissioner may be initiated in any of the following three ways:

(a) Any interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him. Any such petition shall be either (1) in the form specified in other applicable sections in this chapter, e.g., the form for a food additive petition in § 171.100 of this chapter or for a new drug application in § 314.1 of this chapter or for a new animal drug application in § 514.1 of this chapter, or (2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may on his own initiative institute a proceeding to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him. The Food and Drug Administration has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any such issue which has not previously been determined by the agency or which, if it has previously been so determined, the agency concludes should be reconsidered and subject to a new administrative determination. The Commissioner may, in his discretion, utilize any of the procedures established in this part in reviewing and making a determination on any matter on his own initiative.

(c) The Commissioner shall institute a proceeding to determine whether he should issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action under the laws administered by him, whenever any court, without his initiative, holds in abeyance or refers any such matter to him for an administrative determination and he concludes that such an administrative determination is feasible in light of agency priorities and resources.

§ 10.30 Citizen petition.

(a) The provisions of this section shall apply to any petition submitted by any person, except to the extent that specific provisions in other sections of this chapter state different requirements with respect to a particular matter.

(b) Any petition (including any attachments) shall be submitted in accordance with § 10.20 and in the following form:

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

CITIZEN PETITION

The undersigned submits this petition pursuant to ---------- (relevant statutory sections, if known) of the ---------- (Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act and/or any other statutory provision with respect to which authority has been delegated to the Commissioner of Food and Drugs pursuant to 21 CFR 5.1) to request the Commissioner of Food and Drugs to ---------- (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. *Action Requested.*

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy or the exact wording of and citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies. Such grounds shall include all relevant data, information, and views on which the petitioner relies, as well as representative data and information known to the petitioner which are unfavorable to the petitioner's position, and shall be submitted in a well-organized format.)

C. *Environmental Impact.*

(An environmental impact analysis report in the form specified in 21 CFR 25.1(g), except for the types of actions specified in 21 CFR 25.1(e).)

D. *Economic Impact.*

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on (1) cost (and price) increases to industry, government, and consumers; (2) productivity of wage-earners, businesses, or government; (3) competition; (4) supplies

of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

The undersigned certifies, that, to the best of his knowledge and belief this petition includes all data, information, and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)

(c) Any petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 shall be filed by the Hearing Clerk, stamped with the date of filing, and assigned a docket number. The docket number shall be used to identify the administrative file established by the Hearing Clerk for all submissions relating to the petition, as provided in this part. All subsequent submissions relating to the matter shall refer to such docket number and shall be filed in such administrative file. Identical, similar, or related petitions may be filed together and given the same docket number. The Hearing Clerk shall promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) Any interested person may submit written comments to the Hearing Clerk on any filed petition, which shall become part of the administrative file. Such comments shall specify the docket number of the petition and may support or oppose the petition in whole or in part. Any request for alternative or different administrative action shall be in the form of a separate petition.

(e) (1) The Commissioner shall, in accordance with paragraph (e) (2) of this section, review and rule upon every petition filed pursuant to paragraph (c) of this section, taking into consideration (i) the agency resources available to handle the category of subject matter involved, (ii) the priority assigned to the petition in relation both to the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) A response shall be furnished to each petitioner under this section within 180 days of the receipt of the petition. Such response shall either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate agency action (e.g., the publication of a FEDERAL REGISTER notice) implementing the approval; or

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the merits of the petition, e.g., because of the existence of other agency priorities, a need for additional information, or other stated reason. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted by the petition. The petititioner shall be notified in writing of the Commissioner's decision on a petition. Such decision shall be placed in the public docket file in the office of the Hearing Clerk and may also be in the form of a notice published in the FEDERAL REGISTER.

(f) If a petition filed pursuant to paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, the provisions of §§ 10.40 or 10.50 shall also apply.

(g) A petitioner may supplement, amend, or withdraw his petition in writing without agency approval and without prejudice to its resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under Parts 12, 13, 14, or 15 of this chapter. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may in his discretion approve withdrawal, but with prejudice against resubmission of the petition.

(h) In reviewing any matter which is the subject of a petition filed pursuant to paragraph (c) of this section, the Commissioner may, in his discretion, utilize any of the following procedures.

(1) Conferences, meetings, discussions, and correspondence pursuant to § 10.65.

(2) A formal evidentiary public hearing pursuant to Part 12 of this chapter.

(3) A public hearing before a Public Board of Inquiry pursuant to Part 13 of this chapter.

(4) A public hearing before a public advisory committee pursuant to Part 14 of this chapter.

(5) A public hearing before the Commissioner pursuant to Part 15 of this chapter.

(6) A regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

(7) A notice published in the FEDERAL REGISTER requesting data, information, and views.

(8) A proposal to issue, amend, or revoke a regulation, in accordance with the provisions of § 10.40 or § 12.5 of this chapter.

(9) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by those provisions.

(i) The record of the administrative proceeding shall consist of the following:

(1) The petition, including all data and information on which it relies, filed by the Hearing Clerk.

(2) All comments received on the petition, including all data or information submitted as a part of such comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents, resulting from any of the optional procedures specified in paragraph (g) of this section, except that it shall not include the transcript of any closed portion of any public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(6) All documents filed with the Hearing Clerk pursuant to § 10.65(h).

(7) If any petition for reconsideration or for a stay of action is filed pursuant to paragraph (j) of this section, the administrative record specified in § 10.33 (k) or § 10.35(h) respectively.

(j) The administrative record specified in paragraph (i) of this section shall constitute the exclusive record for the Commissioner's decision. The record of the administrative proceeding shall be closed as of the date of the Commissioner's decision unless some other date for the closing of the record is specified by the Commissioner. Thereafter any interested person may submit a petition for reconsideration pursuant to § 10.33 and a petition for stay of action pursuant to § 10.35. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the decision pursuant to this section.

(k) The provisions of this section shall not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by the Food and Drug Administration. Such correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action with respect to such routine correspondence does not constitute final administrative action which is subject to judicial review pursuant to § 10.45.

(l) The Hearing Clerk shall maintain a chronological list of all petitions filed pursuant to this section and § 10.85, but excluding petitions submitted elsewhere in the agency pursuant to § 10.25(a)(1), showing:

(1) The docket number.

(2) The date the petition was filed by the Hearing Clerk.

(3) The name of the petitioner.

(4) The subject matter involved.

(5) The disposition of the petition.

§ 10.33 Administrative reconsideration of action.

(a) The Commissioner may at any time conclude to reconsider any matter, on his own initiative or on the petition of any interested person.

(b) Any interested person may request reconsideration of any part or all of a decision of the Commissioner on any petition submitted pursuant to § 10.25 (a). Any such request shall be submitted

in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. In the case of a decision published in the FEDERAL REGISTER, the day of publication shall be the day of decision.

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

PETITION FOR RECONSIDERATION

Docket No. ------

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. ------.

A. *Decision Involved.*

(A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.)

B. *Action Requested.*

(The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.)

C. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies. Such grounds shall demonstrate that relevant data, information, and views contained in the administrative record were not previously or not adequately considered by the Commissioner. No new data, information, or views may be included in a petition for reconsideration.)

Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telehpone number)

(c) A petition for reconsideration relating to a petition submitted pursuant to § 10.25(a)(2) shall be subject to the requirements of § 10.30 (c) and (d), except that it shall be filed in the same docket file as the petition to which it relates.

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant such a petition in any proceeding when he determines that it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if he determines that all of the following apply: (1) the petition demonstrates that relevant data, information, or views contained in the administrative record were not previously or not adequately considered by the Commissioner, (2) the petitioner's position is not frivolous and is being pursued in good faith, (3) the petitioner has demonstrated sound public policy grounds supporting reconsideration, and (4) reconsideration is not outweighed by public health considerations or other public interests.

(e) A petition for reconsideration shall be based only on data, information, and views contained in the administrative record on which the Commissioner made his decision. Any interested person who wishes to rely upon data, information, or views not included in such administrative record shall submit it to the Commissioner with a new petition to modify the decision pursuant to § 10.25(a).

(f) The Commissioner's decision on a petition for reconsideration shall be in writing and shall be placed on public display as part of the administrative file on the matter in the office of the Hearing Clerk. A determination to grant reconsideration shall be published in the FEDERAL REGISTER if the Commissioner's original decision was published in the FEDERAL REGISTER. Any other determination to grant or to deny reconsideration may also be published in the FEDERAL REGISTER.

(g) The Commission will consider a petition for reconsideration only if it is submitted within 30 days of the date of the decision involved and before such petitioner brings legal action in the courts to review such action, except that such a petition shall also be considered if the Commissioner has denied a petition for stay of action and such petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of such review. A petition for reconsideration submitted later than 30 days after the date of the decision involved shall be denied as untimely. A petition for reconsideration shall be considered as submitted on the day it is received by the Hearing Clerk.

(h) The Commissioner may on his own initiative decide to reconsider all or part of any matter at any time after it has been decided or action has been taken. If review of such matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding shall include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, whether on the petition of an interested person or on his own initiative, the Commissioner shall review and rule on the merits of the matter pursuant to § 10.30(e). The Commissioner may reaffirm, modify, or overrule his prior decision, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted.

(j) The Commissioner's reconsideration of any matter relating to a petition submitted pursuant to § 10.25(a)(2) shall be subject to the provisions of § 10.30 (f) through (h), (j), and (k).

(k) The record of the administrative proceeding shall consist of the following:

(1) The record of the original petition specified in § 10.30(i).

(2) The petition for reconsideration, including all data and information on which it relies, filed by the Hearing Clerk.

(3) All comments received on such petition, including all data or information submitted as a part of such comments.

(4) The Commissioner's decision on such petition pursuant to paragraph (f) of this section, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from such petition.

(6) All documents filed with the Hearing Clerk pursuant to § 10.65(h).

(7) If the Commissioner reconsiders the matter, the administrative record relating to such reconsideration specified in § 10.30(i).

§ 10.35 Administrative stay of action.

(a) The Commissioner may at any time stay (including extend) the effective date of any relevant action pending or following his decision on any matter, on his own initiative or on the petition of any interested person.

(b) Any interested person may request the Commissioner to stay the effective date of any administrative action. Such a stay may be requested for a specific time period or for an indefinite time period. Any such request shall be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. In the case of a decision published in the FEDERAL REGISTER, the day of publication shall be the day of decision.

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857

PETITION FOR STAY OF ACTION

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of his action with respect to the following matter.

A. *Decision Involved.*

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

B. *Action Requested.*

(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)

C. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies for the stay.)

Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)

(c) A petition for stay of action relating to a petition submitted pursuant to § 10.25(a)(2) shall be subject to the requirements of paragraphs (c) and (d) of § 10.30, except that it shall be filed in the same docket file as the petition to which it relates.

(d) Neither the filing of a petition for a stay of action pursuant to this section nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition pursuant to § 10.30 or a petition for reconsideration

pursuant to § 10.33 or a request for an advisory opinion pursuant to § 10.80, shall operate to stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner, in his discretion, determines that a stay or delay is in the public interest and stays the action.

(2) A statutory provision requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted by the petition. The Commissioner may grant a stay in any proceeding if he determines that it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if he determines that all of the following apply: (1) The petitioner will otherwise suffer irreparable injury, (2) the petitioner's case is not frivolous and is being pursued in good faith, (3) the petitioner has demonstrated sound public policy grounds supporting the stay, and (4) the delay resulting from the stay is not outweighed by public health considerations or other public interests.

(f) The Commissioner's decision on a petition for stay of action shall be in writing and shall be placed on public display as part of the file on the matter in the office of the Hearing Clerk. A determination to grant a stay shall be published in the FEDERAL REGISTER if the Commissioner's original decision was published in the FEDERAL REGISTER. Any other determination to grant or to deny a stay may also be published in the FEDERAL REGISTER.

(g) A petition for a stay of action submitted later than 30 days after the date of the decision involved shall be denied as untimely. A petition for a stay of action shall be considered as submitted on the day it is received by the Hearing Clerk.

(h) The record of the administrative proceeding shall consist of the following:

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all data and information on which it relies, filed by the Hearing Clerk.

(3) All comments received on such petition, including all data or information submitted as a part of such comments.

(4) The Commissioner's decision on such petition pursuant to paragraph (e) of this section, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from such petition.

(6) All documents filed with the Hearing Clerk pursuant to § 10.65(h).

§ 10.40 Promulgation of regulations for the efficient enforcement of the law.

(a) The Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by him whenever he concludes that it is necessary or appropriate to do so. The issuance, amendment, or revocation of any such regulation may be initiated in any of the ways specified in § 10.25.

(1) This section shall apply to any regulation (i) not subject to § 10.50 and Part 12 of this chapter or (ii) if it is subject to § 10.50 and Part 12 of this chapter, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted pursuant to § 10.25(a) shall be published by the Commissioner in the FEDERAL REGISTER as a proposal if he determines that:

(i) The petition contains facts demonstrating reasonable grounds for the proposal.

(ii) The petition contains a substantial showing that the proposal is in the public interest and will promote the objectives of the act and the agency.

(iii) The requested proposal is lawful.

(3) The Commissioner may publish two or more alternative proposed regulations on the same subject in order to obtain comment on the different alternatives.

(4) The Commissioner may publish a regulation proposed by an interested person in a petition submitted pursuant to § 10.25(a) together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except as provided in paragraphs (d) and (e) of this section, any such regulation shall be the subject of a notice of proposed rule making published in the FEDERAL REGISTER.

(1) Such notice shall contain (i) a general statement in the first or second paragraph describing the substance of the document in easily understandable terms, (ii) a preamble which summarizes the proposal and the facts and policy underlying it, (iii) references to all data and information on which the Commissioner relies for the proposal (copies or a full list of which shall be a part of the administrative file on the matter in the office of the Hearing Clerk), (iv) the authority under which the regulation is proposed, (v) either the terms or substance of the proposed regulation or a description of the subjects and issues involved, (vi) a proposed effective date, (vii) a reference to the existence or lack of need for an environmental impact statement pursuant to § 25.25(a)(3)(ii) or (iii) of this chapter, (viii) the time, place, and method for interested persons to submit written comments on the proposal, and a statement that comments shall be submitted in accordance with the requirements of this part and (ix) the docket number of the matter, which shall be used to identify the administrative file established by the Hearing Clerk for all submissions relating to the matter, as provided in this part.

(2) Such proposal shall ordinarily provide 60 days for comment, although the Commissioner may reduce or extend this time period for good cause. In no event shall the time for comment be less than 10 days.

(3) After publication of the notice of proposed rule making, any interested person may request the Commissioner to extend the comment period for an additional specified period of time by submitting a written request to the Hearing Clerk stating the grounds therefor. Such requests shall be pursuant to § 10.35, except that the heading shall be "REQUEST FOR EXTENSION OF COMMENT PERIOD."

(i) Any such request shall demonstrate why comments could not reasonably be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment. The Commissioner may grant or deny such request or may grant an extension for a time period different than that requested. Extensions of time to comment will not ordinarily be granted. An extension of time to comment may be limited to specific persons who have made and justified such a request, but shall ordinarily apply to all interested persons.

(ii) Any extension of time to comment of 30 days or longer shall be the subject of a notice published in the FEDERAL REGISTER and shall be applicable to all interested persons. Any extension of time to comment of less than 30 days shall be the subject either of a letter or memorandum filed with the Hearing Clerk or of a notice published in the FEDERAL REGISTER.

(4) Four copies of all comments shall be submitted to the Hearing Clerk, except that individuals may submit single copies of comments. Comments will be stamped with the date of receipt and will be numbered chronologically.

(5) Persons submitting comments critical of a proposed regulation are encouraged to include alternative wording that they believe would be preferable.

(c) After the time for comment on a proposed regulation has expired, the Commissioner shall review the entire administrative record on the matter, including all comments, and shall terminate the proceeding, issue a new proposal, or promulgate a final regulation, by notice published in the FEDERAL REGISTER.

(1) The quality and persuasiveness of the comments shall determine the Commissioner's decision with respect to such comments. The number or length of comments shall not ordinarily be a significant factor in such decision. However, the number of comments may be material where the degree of public interest is a legitimate factor for consideration.

(2) The decision of the Commissioner with respect to the matter shall be based solely upon the administrative record.

(3) The preamble to a final regulation published in the FEDERAL REGISTER shall contain in the first and second paragraphs reference to prior notices relating

to the same matter and a general statement describing the substance of the document in easily understandable terms, and shall summarize each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each such type of comment. The preamble shall contain a thorough and comprehensible articulation of the reasons for the Commissioner's decision on each issue.

(4) The notice promulgating a final regulation published in the FEDERAL REGISTER shall specify the effective date. Such effective date shall be not less than 30 days after the date of publication in the FEDERAL REGISTER, except for:

(i) A regulation that grants an exemption or relieves a restriction.

(ii) Any other regulation where the Commissioner finds, and states in the notice, good cause for an earlier effective date.

(d) The provisions for notice and comment in paragraphs (b) and (c) of this section shall apply to interpretive rules and to rules of agency practice and procedure except as provided in paragraph (e) of this section. The provisions of paragraphs (b) and (c) of this section shall not apply to general statements of policy in the form of informational notices published in the FEDERAL REGISTER or to matters involving agency organization.

(e) The requirements of notice and public procedure in paragraph (b) of this section shall not apply in any of the following situations:

(1) When the Commissioner determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In such cases, the notice promulgating the regulation shall state the reasons for such determination, and shall provide an opportunity for the submission of comments to determine whether the regulation should subsequently be modified or revoked. A subsequent notice based on those comments may, but need not, provide additional opportunity for public comment.

(2) To food additive and color additive petitions, which are subject to the provisions of § 12.5(b)(2) of this chapter.

(3) To new animal drug regulations, which shall be promulgated by notice pursuant to section 512(i) of the act.

(f) In addition to the notice and public procedure required pursuant to paragraph (b) of this section, the Commissioner may, in his discretion, also subject any proposed or final regulation, before or after publication in the FEDERAL REGISTER, to any of the following additional procedures, where they are reasonably applicable to the matter involved:

(1) Conferences, meetings, discussions, and correspondence pursuant to § 10.65.

(2) A formal evidentiary public hearing pursuant to Part 12 of this chapter.

(3) A public hearing before a public Board of Inquiry pursuant to Part 13 of this chapter.

(4) A public hearing before a public advisory committee pursuant to Part 14 of this chapter.

(5) A public hearing before the Commissioner pursuant to Part 15 of this chapter.

(6) A notice published in the FEDERAL REGISTER requesting data, information, and views before the Commissioner determines whether to propose a regulation.

(7) A draft of a proposed regulation placed on public display in the office of the Hearing Clerk. If this procedure is used, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the draft of the proposed regulation.

(8) A revised proposal published in the FEDERAL REGISTER, which shall be subject to all the provisions in this section relating to proposed regulations.

(9) A tentative final regulation or tentative revised final regulation placed on public display at the office of the Hearing Clerk and, if deemed desirable by the Commissioner, published in the FEDERAL REGISTER. If the tentative regulation is placed on display only, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the tentative final regulation and shall mail a copy of the tentative final regulation and the FEDERAL REGISTER notice to each person who submitted comments on the proposed regulation if one has been published.

(10) A final regulation published in the FEDERAL REGISTER which provides an opportunity for the submission of further comments, in accordance with paragraph (e)(1) of this section, to determine whether the regulation should subsequently be modified or revoked.

(11) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by the terms of those provisions.

(g) The record of the administrative proceeding shall consist of all of the following:

(1) If the regulation was initiated by a petition, the administrative record specified in § 10.30(i).

(2) If any petition for reconsideration or for a stay of action is filed, the administrative record specified in § 10.33(k) and § 10.35(h), respectively.

(3) The notice of proposed rule making published in the FEDERAL REGISTER, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the administrative record supporting the proposal.

(4) All comments received on the proposal, including all data or information submitted as a part of such comments.

(5) The notice promulgating the final regulation, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the administrative record supporting the final regulation.

(6) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from any of the optional procedures specified in paragraph (f) of this section, except that it shall not include any transcript of any closed portion of any public advisory committee meeting.

(7) All documents submitted to the Hearing Clerk pursuant to § 10.65(h).

(h) The record of the administrative proceeding shall be closed as of the date of the Commissioner's decision unless some other date for the closing of the record is specified by the Commissioner. Thereafter any interested person may submit a petition for reconsideration pursuant to § 10.33 and a petition for stay of action pursuant to § 10.35. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation.

(i) The Hearing Clerk shall maintain a chronological list of all regulations proposed and promulgated pursuant to this section and § 10.50, but excluding regulations resulting from petitions filed and assigned a docket number pursuant to § 10.30, showing:

(1) The docket number, which in the case of a petition submitted directly to a bureau shall be the number or other designation assigned by the bureau, e.g., the number assigned to a food additive petition.

(2) The name of the petitioner, if any.

(3) The subject matter involved.

(4) The disposition of the petition.

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

(a) The provisions of this section shall apply to court review of any final administrative action taken by the Commissioner, including action taken pursuant to §§ 10.25 through 10.40 and § 16.1(b) of this chapter except action subject to the provisions of § 10.50 and Part 12 of this chapter.

(b) Any request that the Commissioner take or refrain from taking any form of administrative action shall first be the subject of a final administrative decision based upon a petition submitted to the Commissioner pursuant to § 10.25(a) or, where applicable, a hearing pursuant to § 16.1(b) of this chapter before any legal action is filed in a court complaining of the Commissioner's action or failure to act. If any court action is filed complaining of the Commissioner's action or failure to act prior to the submission of and decision on a petition pursuant to § 10.25(a) or, where applicable, a hearing pursuant to § 16.1(b) of this chapter, the Commissioner will request dismissal of such court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust the administrative remedies provided in this part, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

(c) Any request that any form of administrative action be stayed shall first be the subject of an administrative deci-

sion based upon a petition for stay of action submitted to the Commissioner pursuant to § 10.35 before any request is made that a court stay such action. If any court action is filed requesting a stay of any administrative action taken by the Commissioner prior to the Commissioner's decision on a petition submitted in a timely manner pursuant to § 10.35, the Commissioner will request dismissal of such court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust the administrative remedies provided in this part, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201. If any court action is filed requesting a stay of any administrative action taken by the Commissioner after a petition for a stay of action is denied because it was submitted after expiration of the 30-day time period specified in § 10.35, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of such court action on the ground of a failure to exhaust the administrative remedies set out in this part.

(d) The Commissioner's final decision on a petition submitted pursuant to § 10.25(a), on a petition for reconsideration submitted pursuant to § 10.33, on a petition for stay of action submitted pursuant to § 10.35, on any advisory opinion issued pursuant to § 10.85, on any guideline issued pursuant to § 10.90, on any matter involving administrative action which is the subject of an opportunity for a hearing pursuant to § 16.1(b) of this chapter, or the issuance of any final regulation published in accordance with § 10.40, each constitutes final agency action reviewable in the courts pursuant to 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201.

(1) It is the position of the Food and Drug Administration except as otherwise provided in paragraph (d)(2) of this section that:

(i) Any such final agency action exhausts all administrative remedies and is ripe for preenforcement judicial review as of the date of such final decision, unless applicable law explicitly requires that the petitioner take further action before judicial review is available.

(ii) Any interested person is affected by, and thus has standing to obtain judicial review of, such final agency action.

(iii) It is not appropriate to move to dismiss a suit for preenforcement judicial review of such final agency action on the ground that indispensable parties are not joined or that it is an unconsented suit against the United States if such defect could be cured by amending the complaint.

(2) The Commissioner will object to judicial review of any matter if:

(i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act.

(ii) Review is not sought in a proper court.

(e) Any interested person may request judicial review of any final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section such person shall request a stay by the Commissioner pursuant to § 10.35 before he may request a stay by the court.

(f) The Commissioner will take the position in any action for judicial review under 5 U.S.C. 701 et seq., whether or not it includes a request for a declaratory judgment under 28 U.S.C. 2201, or in any other case in which the validity of administrative action is properly challenged, that the validity of the action shall be determined solely on the basis of the administrative record specified in §§ 10.30(i), 10.33(k), 10.35(h), 10.40(g), and 16.80(c) of this chapter, or the administrative record applicable with respect to any decision or action under the regulations referenced in § 16.1(b) of this chapter, and that additional data, information, or views may not be considered. Any interested person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the action pursuant to § 10.25(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single United States district court. If such petitions are filed in more than one jurisdiction, the Commissioner shall take appropriate action to prevent a multiplicity of suits in various jurisdictions, such as:

(1) A request for transfer of one or more suits to consolidate separate actions, pursuant to 28 U.S.C. 1404(a) or 28 U.S.C. 2112(a).

(2) A request that actions in all but one jurisdiction be stayed pending the conclusion of one proceeding.

(3) A request that all but one action be dismissed pending the conclusion of one proceeding, with the suggestion that the other plaintiffs intervene in that one suit.

(4) A request that one of the suits be maintained as a class action in behalf of all affected persons.

(h) Upon judicial review of administrative action pursuant to this section:

(1) If a court determines that the administrative record is inadequate to support the action, the Commissioner shall determine whether he wishes to proceed with such action.

(i) If the Commissioner concludes that such action should be pursued, he shall either request that the court remand the matter to the agency to reopen the administrative proceeding and record, or on his own initiative reopen the administrative proceeding and record upon receipt of the court determination. Any such reopened administrative proceeding shall be conducted pursuant to the provisions of this part and in accordance with any directions of the court.

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further administrative proceedings, he shall request that the court not stay the matter in the interim and shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action requires further elucidation:

(i) The Commissioner shall request either that such further explanation be provided in writing directly to the court without further administrative proceedings, or that the administrative proceeding be reopened pursuant to paragraph (h)(1)(i) of this section.

(ii) If he concludes that the public interest requires that the action remain in effect pending further court or administrative proceedings, he shall request that the court not stay the matter in the interim and shall expedite such further proceedings.

§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing, in accordance with the procedures established in Part 12 of this chapter, whenever all of the following apply:

(1) The subject matter of the regulation or order involved is subject by statute to an opportunity for a formal evidentiary public hearing.

(2) The person requesting such a hearing has a right to an opportunity for a hearing and submits adequate justification for such a hearing as required by §§ 12.5 through 12.22 of this chapter and other applicable provisions in this chapter, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(b) The Commissioner may order a formal evidentiary public hearing on any matter whenever he determines, in his discretion, that it would be in the public interest to do so.

(c) The statutory provisions which permit a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing are as follows (the foregoing list imparts no right to a hearing where no opportunity for a hearing is provided by the statutory sections listed):

(1) Section 401 of the act relating to definitions and standards for food.

(2) Section 403(j) of the act relating to regulations for labeling of foods for special dietary uses.

(3) Section 404(a) of the act relating to regulations providing for emergency permit control.

(4) Section 406 of the act relating to tolerances for poisonous substances in food.

(5) Section 409 (c), (d), and (h) of the act relating to food additive regulations.

(6) Section 501(b) of the act relating to tests or methods of assay for drugs described in official compendia.

(7) Section 502(d) of the act relating to regulations designating habit-forming drugs.

(8) Section 502(h) of the act relating to regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) of the act relating to prescription drug advertising regulations.

(10) Section 506(c) of the act relating to insulin regulations.

(11) Section 507(f) of the act relating to regulations for antibiotic drug certification.

(12) Section 512(n)(5) of the act relating to regulations for animal antibiotic drugs and certification requirements.

(13) Section 706 (b) and (c) of the act relating to regulations for color additives listing and certification.

(14) Section 4(a) of the Fair Packaging and Labeling Act relating to food, drug, device, and cosmetic labeling.

(15) Section 5(c) of the Fair Packaging and Labeling Act relating to additional economic regulations for food, drugs, devices, and cosmetics.

(16) Section 505 (d) and (e) of the act relating to new drug applications.

(17) Section 512 (d), (e), (m) (3) and (4) of the act relating to new animal drug applications.

(18) Section 515(g) of the act relating to device premarket approval applications.

(19) Section 351(a) of the Public Health Service Act relating to plant and product licenses for a biologic.

§ 10.55 Separation of functions; ex parte communications.

(a) The provisions of this section shall apply with respect to any matter which is subject by statute to an opportunity for a formal evidentiary public hearing, as listed in § 10.50(c), and any matter subject to a public hearing before a Public Board of Inquiry pursuant to Part 13 of this chapter.

(b) In the case of any matter listed in § 10.50(c) (1) through (10) and (12) through (15):

(1) Any interested person may meet or correspond with any representative of the Food and Drug Administration with respect to any such matter prior to publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry on the matter. The provisions of § 10.65 shall apply to such meetings and correspondence.

(2) Upon publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry, the following separation of functions shall apply:

(i) The bureau responsible for the matter involved in the hearing shall, as a party to the hearing, be responsible for all investigative functions and for presentation of the position of the bureau at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the bureau shall not participate or advise in any decision except as witness or counsel in public proceedings. There shall be no other communication between representatives of the bureau and representatives of the office of the Commissioner with respect to the matter involved in the hearing prior to the decision of the Commissioner. The Commissioner may, however, when he determines it necessary to ensure the best use of agency resources in deciding a particular matter, designate representatives of a bureau to advise him, or representatives of his office to advise a bureau. The designation shall be in writing and shall be filed with the Hearing Clerk no later than the time specified in paragraph (b)(2) of this section for the application of separation of functions. All members of the Food and Drug Administration other than representatives of the involved bureau (except those specifically designated otherwise) shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(ii) The Chief Counsel for the Food and Drug Administration shall designate members of his office who shall advise and participate with the bureau in its functions in the hearing and members who shall advise the Commissioner in his functions related to the hearing and his final decision. The members of the office of General Counsel designated to advise and participate with the bureau shall not participate or advise in any decision of the Commissioner except as counsel in public proceedings. Such designation shall be in the form of a memorandum filed with the Hearing Clerk and made a part of the administrative record in the proceeding. There shall be no other communication between those members of the office of General Counsel designated to advise the Commissioner and any other persons in the office of General Counsel or in the involved bureau with respect to the matter involved in the hearing prior to the decision of the Commissioner. The Chief Counsel may in his discretion assign new attorneys to advise either the bureau or the Commissioner at any stage of the proceedings. The Chief Counsel shall ordinarily advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(iii) The office of the Commissioner shall be responsible for the agency review of and final decision on the matter, with the advice and participation of anyone in the Food and Drug Administration other than representatives of the involved bureau and those members of the office of General Counsel who have been designated to assist in the bureau's functions relating to the hearing.

(c) In the case of any matter listed in § 10.50(c) (11) and (16) through (18), the specific provisions relating to separation of functions set forth in §§ 314.200 (f), 430.20(b)(9), 514.200, and 601.7(a) of this chapter shall be applicable prior to publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry. Upon publication of any such notice the rules in paragraph (b)(2) of this section shall apply.

(d) Except as provided in paragraph (e) of this section, between the date that separation of functions applies pursuant to paragraph (b) or (c) of this section and the date of the Commissioner's decision on the matter, communication with respect to the matter involved in the hearing shall be restricted as follows:

(1) No person outside the agency shall have any ex parte communication with the presiding officer or any person representing the office of the Commissioner with respect to the matter involved in the hearing. Neither the presiding officer nor any person representing the office of the Commissioner shall have any ex parte communication with any person outside the agency with respect to the matter involved in the hearing. All such communications shall be public communications, as witness or counsel, in accordance with the applicable provisions of this part.

(2) Any participant in the hearing may submit a written communication to the office of the Commissioner with respect to a proposal for settlement. Such written communications shall be in the form of pleadings and shall be served on all other participants and filed with the Hearing Clerk in the same manner as any other pleading.

(3) Any written communication contrary to this section shall immediately be served on all other participants and filed with the Hearing Clerk, and any oral communication contrary to this section shall immediately be recorded in a written memorandum served on all other participants, and filed with the Hearing Clerk to become a part of the administrative record of the proceeding. Any person, including any representative of any participant in the hearing, who is involved in any such oral communication shall, if possible, be made available for cross-examination during the hearing wtih respect to the substance of that conversation. Rebuttal testimony pertinent to any such written or oral communication shall be permitted. Any cross-examination and rebuttal testimony shall be transcribed and filed in the administrative record of the proceeding.

(e) The prohibitions specified in paragraph (d) of this section shall apply to any person having knowledge of a notice of hearing in advance of publication from the time such knowledge is acquired.

(f) The making of any communication contrary to this section may, consistent with the interests of justice and the policy of the underlying statute, result in a decision adverse to the person knowingly making or causing the making of such a communication.

§ 10.60 Referral by court.

(a) The provisions of this section shall apply whenever any Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an

initial administrative determination pursuant to § 10.25(c) or § 10.45(b).

(b) The Commissioner shall promptly agree or decline to accept such referral. Whenever feasible in light of agency priorities and resources, the Commissioner shall agree to accept any such referral and shall institute a proceeding to determine the matter so referred.

(c) In reviewing such a matter, the Commissioner may, in his discretion, utilize any of the following procedures:

(1) Conferences, meetings, discussions, and correspondence pursuant to § 10.65.

(2) A formal evidentiary public hearing pursuant to Part 12 of this chapter.

(3) A hearing before a Public Board of Inquiry pursuant to Part 13 of this chapter.

(4) A public hearing before a public advisory committee pursuant to Part 14 of this chapter.

(5) A public hearing before the Commissioner pursuant to Part 15 of this chapter.

(6) A regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

(7) A notice published in the FEDERAL REGISTER requesting data, information, and views before the Commissioner makes his decision on it.

(8) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by those provisions.

(d) If the Commissioner's review of the matter results in the proposal of a regulation, the provisions of § 10.40 or § 10.50 shall also apply.

§ 10.65 Meetings and correspondence.

(a) In addition to the public hearings and proceedings established by the provisions of this part and in other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of the Food and Drug Administration and any interested person outside the Food and Drug Administration with respect to any matter within the jurisdiction of the laws administered by the Commissioner. Action with respect to such meetings and correspondence does not constitute final administrative action which is subject to judicial review pursuant to § 10.45.

(b) The Commissioner may conclude, in his discretion, that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before the Food and Drug Administration, at which any interested person may participate.

(1) The Commissioner shall give public notice through the public calendar described in § 10.100(a) of the time and place of the meeting and of the matters to be discussed, and may also publish such notice in the FEDERAL REGISTER.

(2) The meeting shall be conducted informally, i.e., any interested person may attend and participate fully in the discussion without giving prior notice to the agency or requesting time to make a presentation.

(3) No transcript or recording of any such meeting shall be required. A written memorandum summarizing the substance of the meeting shall be prepared by a representative of the Food and Drug Administration.

(c) Any meeting with any person outside the Department, including any person in the executive or legislative branch of the Federal government, relating to a pending court case, administrative hearing, or other regulatory action or decision, which involves more than a brief description of the matter shall be summarized in a written memorandum which shall be filed in the administrative file on the matter.

(d) Every person outside the Federal government has a right to request and obtain a private meeting with a representative of the Food and Drug Administration in agency offices to discuss any matter in which he is interested.

(1) The person requesting such a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom he has a commercial arrangement within the meaning of § 20.81(a) of this chapter. Neither the Food and Drug Administration nor any other person may require the attendance of any person who is not an employee of the Executive Branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and the Food and Drug Administration.

(2) The Food and Drug Administration shall determine which representatives of the Food and Drug Administration shall attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of any specific Food and Drug Administration employee.

(3) Whenever appropriate (e.g., the meeting involved a matter covered by paragraph (c) of this section or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be required as part of an administrative record), a written memorandum summarizing the substance of the meeting shall be prepared by a representative of the Food and Drug Administration.

(4) Any person who wishes to attend a specific private meeting, but who is not permitted to attend because the person requesting the meeting or the Food and Drug Administration does not grant permission for such attendance, or because it is conducted by telephone, may request and obtain a separate meeting with the Food and Drug Administration to discuss the same matter or any additional matter.

(e) Food and Drug Administration employees have a responsibility to meet with all segments of the public in order to promote the objectives of the laws administered by the Food and Drug Administration and the agency. In pursuing this responsibility the following general policy shall apply where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the agency.

(1) A person outside the Executive Branch of the Federal Government may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate in any such meeting, but may do so where he concludes that it is in the public interest and will promote the objectives of the act and the agency.

(2) An agency representative may request that any such meeting be an open meeting when he concludes that this would be in the public interest. The agency representative may agree to decline to participate in any such meeting which is held as a private meeting, depending upon which action he concludes will best serve the public interest.

(3) An agency representative shall not knowingly participate in any meeting which is closed on the basis of sex, race, or religion.

(4) Any such meeting, whether open or closed, shall be subject to the requirements of paragraph (d)(3) of this section with respect to memoranda summarizing the substance of the meeting.

(f) Representatives of the Food and Drug Administration may initiate a meeting or correspondence with any person outside the Federal Government with respect to any matter relating to the laws administered by the Commissioner.

(1) Any meeting initiated by the Food and Drug Administration which involves a small number of interested persons, e.g., a meeting with a petitioner or with two manufacturers of a particular product which requires additional testing or with a trade association employee to discuss an industry labeling problem, may be a private meeting. Any meeting initiated by the Food and Drug Administration which involves a large number of interested persons, e.g., 10 manufacturers of an ingredient to discuss appropriate testing or labeling, shall be held as an open conference or meeting pursuant to paragraph (b) of this section.

(2) Whenever appropriate (e.g., the meeting involved a matter covered by paragraph (c) of this section or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be required as part of the administrative record), a written memorandum summarizing the substance of any meeting shall be prepared by a representative of the Food and Drug Administration.

(g) Any person who participates in any meeting described in paragraphs (b) through (f) of this section may prepare and submit to the Food and Drug Administration for inclusion in the administrative file a written memorandum summarizing the substance of the meeting.

(h) All memoranda of such meetings prepared by a representative of the Food and Drug Administration or by any other person and all correspondence

which relate to any matter pending before the agency shall prompty be filed in the relevant administrative file of the proceeding.

(i) Any meeting with a representative of Congress relating to a pending or potential investigation, inquiry, or hearing by a congressional committee or a member of Congress shall be summarized in a written memorandum which shall be forwarded to the Food and Drug Administration, Office of Legislative Services. This provision shall not restrict the right of any agency employee to participate in any such meeting.

(j) Any meeting of an advisory committee shall be subject to the requirements of Part 14 of this chapter.

(k) Pursuant to 42 U.S.C. 2631(a) (8), a log or summary shall be made of all meetings held between representatives of the Food and Drug Administration and representatives of industry and other interested parties with respect to implementation of the Radiation Control for Health and Safety Act of 1968.

§ 10.70 Documentation of significant decisions in administrative file.

(a) The provisions of this section shall apply to every significant Food and Drug Administration decision on any matter under the laws administered by the Commissioner, whether it is raised formally, e.g., by a petition, or informally, e.g., by correspondence.

(b) The Food and Drug Administration employees responsible for handling any matter shall be responsible for assuring the completeness of the administrative file relating to it. Such file:

(1) Shall contain appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinion of consultants, minutes of meetings, and all other written documents pertinent to the matter.

(2) Shall contain the recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter.

(i) Such recommendations and decisions shall reveal any significant controversies or differences of opinion and their resolution.

(ii) Any agency employee working on a matter and, consistent with the prompt completion of his other assignments, any agency employee who has worked on a matter shall have the opportunity to record his views on that matter in a written memorandum, which shall be included in the file.

(c) Each written document placed in such an administrative file:

(1) Shall relate to the factual, scientific, legal, or related issues under consideration.

(2) Shall be dated and signed by the author.

(3) Shall be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and shall show all persons to whom copies were sent.

(4) Shall avoid defamatory language, intemperate remarks, undocumented charges, or irrelevant matters (e.g., personnel complaints).

(5) Shall, if it records the views, analyses, recommendations, or decisions of any agency employee in addition to the author, be given to such other employees.

(6) Shall, once completed (i.e., typed in final form, dated, and signed), not be altered, added to, or removed. Subsequent additions to, or revisions of, any such document shall be accomplished by the preparation of a new document.

(d) Memoranda or other documents prepared by agency employees not contained in the administrative file shall have no status or effect.

(e) All Food and Drug Administration employees working on a matter shall have access to the administrative file on that matter, as appropriate for the conduct of their work. All Food and Drug Administration employees who have worked on a matter shall have access to the administrative file on that matter so long as their attention to their assignments is not impeded. Reasonable restrictions may be placed upon such access to assure the proper cataloging and storage of documents, the availability of the file to others, and the completeness of the file for review.

§ 10.75 Internal agency review of decisions.

(a) Any decision of a Food and Drug Administration employee, other than the Commissioner, on any matter, e.g., an informal opinion on the need for further animal toxicology tests to support a food additive regulation or new drug application, is subject to review by the employee's supervisor under any of the following circumstances:

(1) At the request of the employee.

(2) On the initiative of the supervisor.

(3) At the request of any interested person outside the agency.

(4) As required by duly promulgated delegations of authority.

(b) Such review shall be accomplished by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. Such review shall ordinarily follow the established agency channels of supervision or review for that matter.

(c) Any interested person outside the agency may request internal agency review of any such decision through the established agency channels of supervision or review for that matter. Personal review of such matters by bureau directors or the office of the Commissioner shall take place for any of the following purposes:

(1) To resolve an issue which cannot be resolved at lower levels within the agency:

(i) Between two parts of a bureau or other component of the agency, or

(ii) Between two bureaus or other components of the agency, or

(iii) Between the agency and an interested person outside the agency.

(2) To review policy matters requiring the attention of bureau or agency management.

(3) In unusual situations requiring an immediate review in the public interest.

(4) As required by duly promulgated delegations of authority.

(d) Internal agency review of any such decision shall be based upon the data and information available in the administrative file. In the event that any interested person presents new data or information not contained in such file, the matter shall be returned to the appropriate lower level within the agency for a reevaluation based upon such new information.

§ 10.80 Dissemination of draft FEDERAL REGISTER notices and regulations.

(a) Any representative of the Food and Drug Administration may discuss orally or in writing with any interested person ideas and recommendations for FEDERAL REGISTER notices or regulations. The Food and Drug Administration welcomes assistance in developing ideas for, and in gathering the data and information to support, notices and regulations.

(b) (1) Once it is determined that a proposed notice or regulation will be prepared, the general concepts may be discussed by a representative of the Food and Drug Administration with any interested person. Details of a draft of a proposed notice or regulation may be discussed with any person outside the Executive Branch of the Federal Government only with the specific permission of the Commissioner.

(2) A draft of a proposed notice or regulation or its preamble, or any portion thereof, may be furnished to an interested person outside the Executive Branch of the Federal Government only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER. A draft of a proposed notice or regulation so made available may, without the prior permission of the Commissioner, be discussed with any interested person to clarify and resolve questions raised and concerns expressed about the proposal.

(c) After publication of a proposed regulation in the FEDERAL REGISTER, and before preparation of a draft of the final regulation, a representative of the Food and Drug Administration may discuss the proposal with any interested person as provided in paragraph (b) (2) of this section.

(d) (1) Details of a draft of a final notice or regulation may be discussed with any interested person outside the Executive Branch of the Federal Government only with the specific permission of the Commissioner.

(2) A draft of a final notice or regulation or its preamble, or any portion thereof, may be furnished to an interested person outside the Executive Branch of the Federal Government only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER, except as otherwise provided in paragraphs (g) and (j) of this section. A draft of a final notice or regulation so made available to any interested person may, without the prior per-

mission of the Commissioner, be discussed with any interested person as provided in paragraph (b)(2) of this section.

(i) The final notice or regulation and its preamble shall be prepared solely on the basis of the administrative record.

(ii) If any additional technical information from a person outside the Executive Branch of the Federal government is necessary to draft the final notice or regulation or its preamble, it shall be requested by the Food and Drug Administration in general terms and furnished directly to the Hearing Clerk to be included as part of the administrative record.

(iii) If direct discussion by the Food and Drug Administration of a draft of a final notice or regulation or its preamble is required with a person outside the Executive Branch of the Federal Government, appropriate protective procedures will be undertaken to make certain that a full and impartial administrative record is established. Such procedures may include:

(*a*) The scheduling of an open public meeting conducted pursuant to § 10.65 (b) at which any interested person may participate in review of and comment on the draft document.

(*b*) The preparation of a tentative final regulation or tentative revised final regulation pursuant to § 10.40(f)(9), on which all interested persons will be given an additional period of time for oral and written comment.

(e) After a final regulation is published in the FEDERAL REGISTER, a representative of the Food and Drug Administration may discuss any aspect of it with any interested person.

(f) In addition to the requirements of this section, the provisions of § 10.55 shall apply to the promulgation of any regulation subject to the provisions of § 10.50 and Part 12 of this chapter.

(g) A draft of a final food additive, color additive, or new animal drug regulation or a proposed or final antibiotic regulation may be furnished to the petitioner for comment on the technical accuracy of such regulation. Every meeting with a petitioner relating to such a draft shall be recorded in a written memorandum, and all such memoranda and correspondence shall be filed with the Hearing Clerk as part of the administrative record of the regulation, pursuant to the provisions of § 10.65.

(h) Pursuant to 42 U.S.C. 263f, the Commissioner is required to consult with interested persons in the development of, and with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) before prescribing, any performance standard for an electronic product. Accordingly, the Commissioner shall publish in the FEDERAL REGISTER an announcement when a proposed or final performance standard, including any amendment thereof, is being considered for an electronic product, and thereafter any draft of any such document shall be furnished to any interested person upon request and may be discussed in detail with any interested person at any time.

(i) The provisions of § 10.65 shall apply to meetings and correspondence relating to draft FEDERAL REGISTER notices and regulations.

(j) The provisions of this section restricting discussion and disclosure of draft FEDERAL REGISTER notices and regulations shall not apply to those situations covered by §§ 20.83 through 20.89 of this chapter.

§ 10.85 Advisory opinions.

(a) Any person may request an advisory opinion from the Commissioner with respect to any matter of general applicability in which he is interested.

(1) Such request shall be granted whenever feasible.

(2) Such request may be denied if any of the following apply:

(i) The request contains incomplete information on which to base an informed advisory opinion.

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved.

(iii) The matter is adequately covered by a prior advisory opinion or a regulation.

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability.

(v) The Commissioner otherwise concludes, in his discretion, that an advisory opinion would not be in the public interest.

(b) A request for an advisory opinion shall be submitted in accordance with § 10.20, shall be subject to the provisions of § 10.30 (c) through (l), and shall be in the following form:

_____
(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857

REQUEST FOR ADVISORY OPINION

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to _____ (the general nature of the matter involved).

A. *Issues Involved.*

(A concise statement of the issues and questions on which an opinion is requested.)

B. *Statement of Facts and Law.*

(A full statement of all facts and legal points relevant to the request.)

The undersigned certifies that, to the best of his knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

Very truly yours,

_____
(Signature)

_____
(Person making request)

_____
(Mailing address)

_____
(Telephone number)

(c) The Commissioner may, in his discretion, handle any oral or written request to the agency as a request for an advisory opinion, in which case the request shall be filed with the Hearing Clerk and shall be subject to the provisions of this section.

(d) Any statement of policy or interpretation made in any of the following documents, unless subsequently repudiated by the agency or overruled by a court, shall constitute an advisory opinion:

(1) Any portion of a FEDERAL REGISTER notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

(2) Trade Correspondence (T.C. Nos. 1-431 and 1A-8A issued by the Food and Drug Administration between 1938 and 1946.

(3) Compliance Policy Guides issued by the Food and Drug Administration beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance standard for diagnostic x-ray systems, issued prior to July 1, 1975, and filed in a permanent public file for such prior advisory opinions maintained in the Public Records and Documents Center.

(5) Guidelines issued by the Food and Drug Administration pursuant to § 10.90 (b).

(e) An advisory opinion represents the formal position of the Food and Drug Administration on the matter involved, and except as provided in paragraph (f) of this section obligates the agency to follow it until it is amended or revoked. The Commissioner shall not recommend legal action against any person or product with respect to any action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion issued pursuant to this section prior to amending or revoking such advisory opinion as provided in paragraph (g) of this section. Such action shall be taken only with the approval of the Commissioner, which may not be delegated. Appropriate amendment or revocation of the advisory opinion involved shall be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of such amendment or revocation shall be given in the same manner in which notice was originally given of the advisory opinion or in the FEDERAL REGISTER, and in any event shall be placed on public display as part of the file on the matter in the office of the Hearing Clerk. The Hearing Clerk shall maintain a separate chronological index of all advisory opinions filed. The index shall specify the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

(h) Action undertaken or completed in conformity with an advisory opinion issued pursuant to this paragraph which has subsequently been amended or revoked shall remain acceptable to the Food and Drug Administration unless

the Commissioner determines that substantial public interest considerations preclude such continued acceptance. Whenever possible, an amended or revoked advisory opinion shall state when it has been determined that action previously undertaken or completed in conformity with a prior advisory opinion does not remain acceptable, and any transition period that may be applicable.

(i) Any interested person may submit written comments on an advisory opinion or modified advisory opinion. Three copies of any comments shall be sent to the Hearing Clerk for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Such comments shall be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an employee of the Food and Drug Administration shall constitute an advisory opinion only if it is issued in writing pursuant to this section. A statement or advice given by a Food and Drug Administration employee orally, or given in writing but not pursuant to this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of the Food and Drug Administration, and thus does not bind or otherwise obligate or commit the agency to the views expressed.

§ 10.90 Food and Drug Administration regulations, guidelines, recommendations, and agreements.

(a) *Regulations.* All Food and Drug Administration regulations having general applicability and legal effect shall be promulgated in the FEDERAL REGISTER pursuant to § 10.40 or § 10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions which will be enforced as legal requirements, or which are intended only as guidelines and recommendations, or both. The dissemination of draft notices and regulations shall be subject to the provisions of § 10.80.

(b) *Guidelines.* All Food and Drug Administration guidelines having general applicability shall be included in the public file of guidelines established by the Hearing Clerk, pursuant to this paragraph, unless they have been published in the FEDERAL REGISTER as regulations pursuant to paragraph (a) of this section.

(1) Guidelines establish principles or practices of general applicability and do not include decisions or advice limited to particular situations. Guidelines relate to such matters as performance characteristics, preclinical and clinical test procedures, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. Guidelines state procedures or standards of general applicability that are not legal requirements but that are acceptable to the Food and Drug Administration for a subject matter which falls within the laws administered by the Commissioner, e.g., a protocol for a particular type of animal toxicity test or human clinical trial.

(i) A person may rely upon a guideline with assurance that it is acceptable to the Food and Drug Administration, or may follow different procedures or standards. Where a person chooses to use different procedures or standards, he may, but is in no instance required to, discuss the matter in advance with the Food and Drug Administration to prevent the expenditure of money and effort on activity that may later be determined to be unacceptable.

(ii) Use of testing guidelines established by the Food and Drug Administration assures acceptance of a test as scientifically valid, if properly conducted, but does not assure approval of any ingredient or product so tested. The results of any such test or other available information may require disapproval or that additional testing be undertaken.

(2) A guideline represents the formal position of the Food and Drug Administration on the matter involved, and except as provided in paragraph (b)(3) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner shall not recommend legal action against any person or product with respect to any action taken in conformity with a guideline issued pursuant to this section that has not been amended or revoked.

(3) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to a guideline issued pursuant to paragraph (b) of this section prior to amending or revoking such guideline as provided in paragraph (b)(5) of this section. Such action shall be taken only with the approval of the Commissioner, which may not be delegated. Appropriate amendment or revocation of the guideline involved shall be expedited.

(4) A guideline shall be included in the public file upon approval of the guideline by the relevant bureau director and publication by the Commissioner in the FEDERAL REGISTER of a notice of its availability. The notice shall state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline.

(5) A guideline may be amended or revoked upon approval of the amended guideline or revocation of the guideline by the relevant bureau director and publication by the Commissioner in the FEDERAL REGISTER of a notice of such amendment or revocation. The notice shall state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline. All original guidelines and subsequent amendments shall be retained in the public file on a permanent basis so that a complete record of the development of each guideline remains available.

(6) Action undertaken or completed in conformity with a guideline issued pursuant to paragraph (b) of this section which has subsequently been amended or revoked shall remain acceptable to the Food and Drug Administration unless the Commissioner determines that substantial public interest considerations preclude such continued acceptance. Such determination may be made at the time of or subsequent to amendment or revocation of the guideline. Whenever possible, the notice of an amended or revoked guideline published pursuant to paragraph (b)(3) of this section shall state when it has been determined that action previously undertaken or completed in conformity with a prior guideline does not remain acceptable, and any transition period that may be applicable.

(7) The notice of a guideline or amended or revoked guideline published pursuant to paragraph (b)(2) or (3) of this section shall state that any interested person may submit written comments on the guideline or amended guideline. Two copies of any comments shall be sent to the Public Records and Documents Center for inclusion in the public file on the guideline and two copies shall be sent to the office or individual designated in the notice as responsible for maintaining the guideline. Such comments shall be considered in determining whether further amendments to or reinstitution of a guideline are warranted.

(8) A guideline may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as establishing a legal requirement.

(9) A statement relating to acceptable procedures or standards given by a Food and Drug Administration employee orally, or in writing but not pursuant to § 10.85 or this section, is an informal communication that represents the best judgment of that employee at that time but does not constitute a guideline, does not necessarily represent the formal position of the Food and Drug Administration, and thus does not bind or otherwise obligate the agency to the views expressed.

(10) Because of the large number of analytical methods involved in Food and Drug Administration activities, their length and complexity, and the volume and frequency of amendment, the provisions of paragraph (b)(4) of this section shall not apply to such material except to the extent that the Commissioner concludes, in his discretion, that particular analytical methods should be included in the public file for a particular purpose. Food and Drug Administration analytical methods are available for public disclosure pursuant to the provisions of Part 20 of this chapter.

(11) The dissemination of draft guidelines shall be subject to the same provisions as the dissemination of draft notices and regulations pursuant to § 10.80.

(c) *Recommendations.* In addition to the guidelines subject to paragraph (b) of this section, the Food and Drug Ad-

ministration often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model state and local ordinances, or personnel practices for reducing radiation exposure, issued pursuant to 42 U.S.C. 243 and 263d(b). Such recommendations may, in the discretion of the Commissioner, be handled pursuant to the procedures established in paragraph (b) of this section, except that such recommendations shall be included in a separate public file of recommendations established by the Public Records and Documents Center and shall be separated from the guidelines in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations pursuant to paragraph (a) of this section.

(d) *Agreements.* All formal agreements, memoranda of understanding, or other similar written documents executed by the Food and Drug Administration and another person shall be included in the public file on agreements established by the Public Records and Documents Center pursuant to § 20.108 of this chapter. Any such document not included in the public file shall be deemed to be rescinded and shall have no force or effect whatever.

§ 10.95 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by Food and Drug Administration employees in any standard-setting activities outside the Food and Drug Administration. Standard-setting activities include such matters as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. The Food and Drug Administration encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal government agencies.* (1) Any Food and Drug Administration employee may participate in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763 "Request for approval of appointment as liaison representative."

(2) The Form PHS–3763 and all pertinent background information describing such activities shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) If any members of the public are invited by the Food and Drug Administration to present views to, or to accompany, the Food and Drug Administration employee at any meeting, such invitations shall be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) Any Food and Drug Administration employee may participate in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763.

(2) The Form PHS–3763 and all pertinent background information describing such activities shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) The availability for public disclosure of records relating to such activities shall be governed by the regulations in Part 20 of this chapter.

(4) If any members of the public are invited by the Food and Drug Administration to present views to, or to accompany, the Food and Drug Administration employee at any meeting, such invitations shall be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(d) *Standard-setting activities by private groups and organizations.* (1) Any Food and Drug Administration employee may engage in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763. A request for such official participation shall be made by the group or organization in writing, shall describe the scope of the activity involved, and shall demonstrate that the minimum standards set out in paragraph (d)(5) of this section are met by the activity involved. Except as provided in paragraph (d)(7) of this section, any such request that is granted shall be the subject of a letter from the Commissioner or the bureau director to the organization stating:

(i) Whether participation by the individual will be as a voting or nonvoting liaison representative.

(ii) That participation by the individual shall not connote Food and Drug Administration agreement with, or endorsement of, any decisions reached.

(iii) That participation by the individual disqualifies him from serving as the deciding official on the standard involved if it should later come before the Food and Drug Administration. The "deciding official" is the person who signs a document ruling upon such standard.

(2) The letter requesting official Food and Drug Administration participation, the Form PHS–3763, and the Commissioner's or bureau director's letter, together with all pertinent background information describing the activities involved, shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) The availability for public disclosure of records relating to such activities shall be governed by the regulations in Part 20 of this chapter.

(4) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(5) The following minimum standards shall apply to all outside private standard-setting activities in which Food and Drug Administration employees participate.

(i) The activities shall be based upon consideration of sound scientific and technological information, shall permit revision on the basis of new information, and shall be designed to protect the public against unsafe, ineffective, or deceptive products or practices.

(ii) The activities and resulting standards shall not be designed for the economic benefit of any company, group, or organization, shall not be used as devices for such antitrust violations as fixing prices or hindering competition, and shall not involve establishment of certification or specific approval of individual products or services.

(iii) The group or organization responsible for the standard-setting activities shall have a procedure through which any interested person shall have an opportunity to provide information and views on the activities and standards involved, without the payment of fees, and such information and views shall be considered. The manner in which this is accomplished, including whether such presentation shall be in person or in writing, shall be decided by the group or organization responsible for the activities.

(6) Membership of a Food and Drug Administration employee in an organization that also conducts standard-setting activities does not invoke the provisions of this paragraph unless the employee participates in such standard-setting activities. Participation in any standard-setting activity shall be subject to the provisions of this paragraph.

(7) The Commissioner may determine in writing that, because direct involvement by the Food and Drug Administration in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, such participation shall be exempt from the requirements set forth in paragraph (d)(1)(ii) and/or (iii) of this section. Any such determination shall be included in this public file on standard-setting activities established by the Public Records and Documents Center and in any relevant administrative file. Such activities may include the

establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between the Food and Drug Administration and the associations of State and local government officials listed below, and the large number of agency employees who are members of or work with these associations, such participation in the activities of these associations shall be exempt from the provisions of paragraph (d) (1) through (7) of this section, except that a list of all committees and other groups of these associations shall be included in the public file on standard-setting activities established in the Public Records and Documents Center:

(i) Association of Food and Drug Officials.

(ii) International Association of Milk, Food and Environmental Sanitarians, Inc.

(iii) Conference of Radiation Control Program Directors.

(iv) Association of American Feed Control Officials, Inc.

(v) National Environmental Health Association.

(vi) National Conference on Weights and Measures.

(vii) American Public Health Association.

(viii) Conference of State Sanitary Engineers.

(ix) National Conference on Interstate Milk Shipments.

(x) National Shellfish Sanitation Program.

(xi) Interstate Seafood Seminar.

(xii) Association of Official Analytical Chemists.

§ 10.100 Public calendars.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar shall be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks all public meetings, public conferences, public hearings, public advisory committee meetings, public seminars, and other public proceedings of the Food and Drug Administration, and other significant public events involving the Food and Drug Administration, e.g., congressional hearings and trial or argument of court cases.

(2) A copy of this public calendar shall be placed on public display in the following places:

(i) Office of the Hearing Clerk.

(ii) Office of the Assistant Commissioner for Public Affairs.

(iii) A central place in each bureau.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

(b) *Retrospective public calendar of meetings.* (1) A public calendar shall be prepared and made publicly available each week showing for the previous week all meetings with persons outside the Executive Branch of the Federal Government and other significant events involving the representatives of the Food and Drug Administration designated under paragraph (b)(3) of this section, except that telephone conversations shall be included on an optional basis and meetings with the working press, except for "house organs" (i.e., publications of firms that manufacture or distribute regulated products, or industry associations), and with on-site contractors shall not be included. Meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees shall be included when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision and involves more than a brief description of the matter.

(2) Such calendar shall include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar shall specify the date, the person involved, and the subject matter involved. Where more than one Food and Drug Administration representative is in attendance, only the presiding or head representative shall report the meeting on the public calendar. If a large number of persons are involved, the name of each need not be specified. Meetings the existence of which would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in the Food and Drug Administration) shall not be reported.

(3) The following Food and Drug Administration representatives and their deputies shall be subject to the requirements of paragraphs (b) (1) and (2) of this section:

(i) Commissioner of Food and Drugs.

(ii) Deputy Commissioner.

(iii) Associate Commissioners.

(iv) Assistant Commissioners.

(v) Executive Director for Regional Operations.

(vi) Director, Office of Legislative Services.

(vii) Director, National Center for Toxicological Research.

(viii) Bureau Directors.

(ix) Chief Counsel for the Food and Drug Administration, or any representative of his office attending in his behalf.

(4) A copy of this public calendar shall be placed on public display in the following places:

(i) Office of the Hearing Clerk.

(ii) Office of the Assistant Commissioner for Public Affairs.

(iii) A central place in each bureau.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

§ 10.105 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in any administrative proceeding subject to this part.

(b) Any such petitions, comments, objections, or other representations by an organization shall not abridge the right of any member to take any action of a similar type in its own name.

(c) It is requested that each organization participating in Food and Drug Administration administrative proceedings file annually a current list of all of the members of such organization with the Hearing Clerk for permanent filing.

(d) The filing by an organization of an objection or request for hearing pursuant to §§ 12.5 through 12.22 shall not provide to any member any legal right with respect to such objection or request for hearing that the member may exercise in its own name. Any member of an organization wishing to so file an objection or request for a hearing to obtain legal rights thereunder shall do so in its own name.

(e) In any court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name for the reason that the organization does not represent their views. Regardless whether the case is brought or considered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and any member of the organization that such issues are precluded from further litigation by such member pursuant to the doctrines of collateral estoppel or res judicata.

§ 10.110 Settlement proposals.

At any time in the course of any proceeding subject to this part, any person may propose settlement of any of the issues involved. All participants in any proceeding shall have an opportunity to consider any proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, shall not be admissible in evidence in any administrative proceeding of the Food and Drug Administration. The Food and Drug Administration will oppose the admission in evidence of any such information in any court proceeding or in any other administrative proceeding.

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

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AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24 (b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-609 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 12.1 Scope.

This part governs the procedures applicable whenever any of the following applies:

(a) A person has a right to an opportunity for a hearing under the provisions of the laws administered by the Commissioner specified in § 10.50 of this chapter.

(b) The Commissioner concludes, in his discretion, that it would be in the public interest to hold a formal evidentiary public hearing on any matter, or class of matters, of importance pending before the Food and Drug Administration.

Subpart B—Initiation of Proceedings

§ 12.20 Initiation of a formal evidentiary public hearing involving the issuance, amendment, or revocation of a regulation.

(a) An administrative proceeding in which there is an opportunity for a formal evidentiary public hearing pursuant to section 409(f), 502(n), 507(f), 512(n)(5), 701(e), or 706(d) of the act or section 4 or 5 of the Fair Packaging and Labeling Act involving the issuance, amendment, or revocation of a regulation shall be initiated:

(1) By the Commissioner on his own initiative, e.g., as provided in § 170.15 of this chapter for food additives, or

(2) By a petition from an interested person:

(i) In the form specified in other applicable sections in this chapter, e.g., the form for a color additive petition in § 71.1 of this chapter or the form for an antibiotic petition in § 431.50 of this chapter, or

(ii) If no form is specified in other applicable sections of this chapter, in the form specified in § 10.30 of this chapter.

(b) Upon receiving a petition submitted pursuant to paragraph (a)(2) of this section, the Commissioner shall:

(1) If it involves any matter subject to section 701(e) of the act or section 4 or 5 of the Fair Packaging and Labeling Act, and meets the requirements for filing, follow the provisions of § 10.40 (b) through (f) of this chapter.

(2) If it relates to a color additive or food additive, and the petition meets the requirements for filing in §§ 71.1, 71.2, 171.1, 171.6, 171.7, and 171.100 of this chapter, publish a notice of filing of the petition in the FEDERAL REGISTER within 30 days after the petition is filed in lieu of a notice of proposed rule making.

(c) The Commissioner may issue, amend, or revoke an antibiotic regulation without the requirements of notice and public procedure in § 10.40(b) or delayed effective date in § 10.40(c)(4) of this chapter on his own initiative or as a result of a petition containing the required evidence of safety and effectiveness in the circumstances set forth in § 10.40(e)(1) of this chapter.

(d) The notice published in the FEDERAL REGISTER promulgating the regulation shall state the time, place, and method for adversely affected persons to submit objections and requests for hearing, and that objections and requests for hearing shall be submitted in accordance with the requirements of this part.

(e) On or before the 30th day after the date of the publication in the FEDERAL REGISTER of a final regulation, or of a notice withdrawing a proposal initiated by a petition pursuant to § 10.25(a) of this chapter, subject to this section, any person who would be adversely affected if such regulation were placed in effect may submit written objections thereto to the Commissioner and may make a written request for a formal evidentiary public hearing on the stated objections. This 30-day period shall not be extended by the Commissioner, except that additional information supporting any such objection may be received after 30 days upon a showing of inadvertent omission and hardship, and if review of the objection and request for hearing will not thereby be impeded. In the case of any petition or proposal to issue, amend, or repeal a color additive regulation after publication of the final regulation, if referral of such petition or proposal is made to an advisory committee in accordance with section 706(b)(5)(C) of the act, written objections and requests for a hearing may be submitted on or before the 30th day after the date on which the Commissioner publishes his order confirming or modifying his previous order.

§ 12.21 Initiation of a formal evidentiary public hearing involving the issuance, amendment, or revocation of an order.

(a) An administrative proceeding in which there is an opportunity for a formal evidentiary public hearing pursuant to sections 505 (d) or (e), 512 (d), (e), (m)(3), or (m)(4) of the act, or section 351(a) of the Public Health Service Act, involving the issuance, amendment, or revocation of an order shall be initiated:

(1) By the Commissioner on his own initiative, or

(2) By a petition submitted in the form specified in other applicable sections in this chapter, e.g., § 314.1(c) for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products, or

(3) By a petition from an interested person in the form specified in § 10.30 of this chapter.

(b) A notice of opportunity for hearing on any proposal to deny or revoke approval of an order or any part thereof shall be published in the FEDERAL REGISTER together with an explanation of the grounds for the proposed action. The notice of opportunity for hearing shall state the time, place, and method for adversely affected persons to submit requests for hearing, and that requests for hearing shall be submitted in accordance with the requirements of this part. The applicant for or holder of the approval or license that is the subject of the order in question and all other persons subject to the notice shall have 30 days after issuance of the notice within which to request a hearing on the proposed action pursuant to the provisions of §§ 314.200, 514.200, and 601.7(a) of this chapter.

This 30-day period shall not be extended by the Commissioner.

(c) In considering the issuance, amendment, or revocation of an order, the Commissioner may use any applicable optional procedure specified in § 10.30 (g) of this chapter.

§ 12.22 Filing objections and requests for a hearing on a regulation or order.

(a) Objections to agency action and requests for a hearing submitted pursuant to § 12.5(d) shall be submitted to the Hearing Clerk and shall be accepted for filing if they comply with all of the following conditions:

(1) Objections and requests for a hearing shall be submitted on or before the day specified in § 12.5(d).

(2) Each objection to a specific provision of the Commissioner's regulation or proposed order shall be separately numbered.

(3) Each numbered objection shall specify with particularity the provision of the regulation or proposed order to which objection is made.

(4) Each numbered objection on which a hearing is requested shall specifically so state. The failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection.

(5) Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. The failure to include such description and analysis for any particular objection shall constitute a waiver of the right to a hearing on that objection, but such description and analysis shall be used only for the purpose of determining whether a hearing has been justified pursuant to § 12.24 and shall not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon shall be submitted.

(ii) A summary of the nondocumentary testimony to be presented by any witnesses relied upon shall be submitted.

(b) Requests for hearing submitted pursuant to § 12.5(b) shall be submitted to the Hearing Clerk and shall be accepted for filing if they comply with all of the following conditions:

(1) Requests for hearing shall be submitted on or before the 30th day after the date of publication of the notice of opportunity for hearing in the FEDERAL REGISTER.

(2) Requests for hearing shall comply with the requirements specified in §§ 314.200, 514.200, and 601.7(a) of this chapter.

(c) Any objection or request for a public hearing which meets the requirements of this section shall be filed by the Hearing Clerk in the relevant docket file. If an objection or request for a public hearing fails to meet the requirements of this section and the deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in § 12.5(d) or § 12.20(b).

(d) If an objection to a regulation issued pursuant to a petition submitted pursuant to § 12.5(a)(2) is submitted by a person other than the petitioner and is filed by the Hearing Clerk, the petitioner may submit a written reply thereto to the Hearing Clerk.

§ 12.24 Ruling on objections and requests for hearing.

(a) As promptly as is feasible the Commissioner shall review all objections and requests for hearing filed pursuant to § 12.22 and shall determine:

(1) Whether any of the objections or requests for hearing filed justify modification or revocation of the regulation or order involved pursuant to § 12.26.

(2) If a formal evidentiary public hearing has been requested, whether it has been justified as required by this section.

(3) If a public hearing has been requested before a Public Board of Inquiry pursuant to Part 13 of this chapter, or before a public advisory committee pursuant to Part 14 of this chapter, or before the Commissioner pursuant to Part 15 of this chapter, whether it has been justified.

(b) A request for a formal evidentiary public hearing shall be granted on a matter involving the issuance, amendment, or revocation of a regulation or order if, based upon the data, information, and views contained in his objection and request for hearing, a person has shown that all of the following are true:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue is capable of being resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information identified in the objection and request for hearing, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that, even assuming the truth and accuracy of all of the data and information submitted in support of the objection and request for hearing, they are insufficient to justify the factual determination urged.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative or controlling with respect to the action requested, e.g., when the Commissioner concludes that his action would be the same even if the factual issue were resolved in the way sought, or in the case of a request that a final regulation include a provision not reasonably encompassed within the proposal. A hearing will be granted upon proper objection and request for hearing when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient, but not when such standard or regulation does not have such an effect.

(5) The action requested is not on its face inconsistent with or in violation of any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in such circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) All of the conditions and requirements specified in other applicable provisions of this chapter, e.g., §§ 10.20, 12.20, 12.22, 314.200, 430.20(b), 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are fully met.

(c) In making his determination pursuant to paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in § 10.30 (g) and in other applicable provisions of this chapter, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(d) Where a person files an objection and request for hearing pursuant to §§ 12.5 through 12.22 relating to a regulation or order, it is uncertain whether a hearing has been justified pursuant to the principles established in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, he may serve upon such person by registered mail a proposed order denying a hearing. Such person shall have 30 days after receipt of such proposed order to demonstrate that the submission justifies a hearing.

§ 12.26 Modification or revocation of regulation or order.

If the Commissioner determines upon review of an objection or request for hearing filed pursuant to §§ 12.5 through 12.22 that the regulation or order involved in the proceeding should properly be modified or revoked, he shall promptly issue a notice of such modification or revocation in the FEDERAL REGISTER. Further objections or requests for hearing may be submitted to such modification or revocation, but not to any other provisions in the regulation or order, pursuant to §§ 12.5 through 12.22. Objections and requests for hearing that are not affected by the modification or revocation shall remain on file and be acted upon in accordance with other applicable provisions of this part.

§ 12.28 Denial of formal evidentiary public hearing in whole or in part.

If the Commissioner determines upon review of the objections or requests for hearing filed pursuant to §§ 12.5 through 12.26 that a formal evidentiary public hearing is not justified, in whole or in part, he shall publish a notice of such determination in the FEDERAL REGISTER.

(a) The notice shall state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice

shall be combined with the notice of hearing required by § 12.35, and shall specify the objections and requests for hearing which have been granted and denied.

(1) Any determination denying a hearing in whole or in part shall specify in detail the reasons therefor. If such determination rests upon an analysis of the data and information submitted to justify a hearing, the inadequacy of such data and information submitted shall be explained.

(2) The notice shall confirm or modify or stay the effective date of the regulation or order involved.

(b) The record of the administrative proceeding relating to denial of a public hearing in whole or in part on any objection, and request for hearing shall consist of all of the following:

(1) If the proceeding involves the issuance, amendment, or revocation of a regulation:

(i) All of the documents specified in § 10.40(g) of this chapter.

(ii) All objections and requests for hearing filed by the Hearing Clerk with respect to such regulation pursuant to §§ 12.5 and 12.22.

(iii) If it involves a color additive regulation which was referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, the complete administrative record of the advisory committee proceedings and its report on the matter.

(iv) The notice denying a formal evidentiary public hearing published in the FEDERAL REGISTER.

(2) If the proceeding involves the issuance, amendment, or revocation of an order:

(i) The notice of opportunity for hearing.

(ii) All requests for hearing filed by the Hearing Clerk with respect to such order pursuant to §§ 12.20 and 12.22.

(iii) The record, consisting of the transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents, resulting from any of the optional procedures specified in § 12.24(c), except that it shall not include the transcript of any closed portion of any public advisory committee meeting.

(iv) The notice denying a formal evidentiary public hearing published in the FEDERAL REGISTER.

(c) The administrative record specified in paragraph (b) of this section shall constitute the exclusive record for the Commissioner's decision on denial of a formal evidentiary public hearing in whole or in part. The record of the administrative proceeding shall be closed as of the date of the Commissioner's decision unless some other date for the closing of the record is specified by the Commissioner. Thereafter any person who requested and was denied a hearing may submit a petition for reconsideration pursuant to § 10.33 and a petition for stay of action pursuant to § 10.35 of this chapter. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation or order pursuant to § 10.25(a) of this chapter.

(d) Any determination denying a request for a formal evidentiary public hearing in whole or in part by any person who has an opportunity for such a hearing under the provisions of the laws administered by the Commissioner specified in § 10.50(c) of this chapter constitutes final agency action reviewable in the courts, pursuant to the specific statutory provisions governing the matter involved, as of the date of publication in the FEDERAL REGISTER of the denial of the public hearing in whole or in part.

(1) Before requesting an order from a court for a stay of action pending review, any person seeking judicial review shall first submit a petition for a stay of action pursuant to § 10.35 of this chapter.

(2) The Food and Drug Administration will request consolidation in a single court of all petitions for judicial review related to a particular matter pursuant to 28 U.S.C. 2112(a).

(3) The time for filing a petition for judicial review of a determination by the Commissioner denying a public hearing on a particular objection or issue shall begin as of the date of publication in the FEDERAL REGISTER of the Commissioner's determination: (i) in the case of an objection or issue relating to a proposal to issue, amend, or revoke a regulation, when the determination denies a public hearing on all objections and issues relating to a part of the proposal the effectiveness of which the Commissioner has determined should not be deferred pending the outcome of any hearing granted with respect to other parts of the proposal; or (ii) in the case of an issue relating to a proposal to issue, amend, or revoke an order, when the determination denies a public hearing on all issues relating to a particular new drug application, new animal drug application, or biologics license. The failure to file such a petition within the period established in the specific statutory provisions governing the matter involved shall constitute a waiver of the right to judicial review of that objection or issue at any later time, regardless whether a hearing has been granted on other objections and issues.

§ 12.30 Judicial review after waiver of hearing on a regulation.

(a) Any person who has a right to submit objections and a request for hearing pursuant to § 12.5(d) may instead submit objections and waive the right to request a hearing. Such waiver may consist either of an explicit statement waiving such right, or of a failure to request a hearing as provided in § 12.22(a)(4).

(b) Where any person submits an objection and waives the right to request a hearing, the Commissioner shall rule upon such objection pursuant to §§ 12.24 through 12.28. The Commissioner may, in his discretion, order a hearing on the matter pursuant to any of the provisions of this part regardless whether a hearing is requested.

(c) If, after the notice published by the Commissioner in the FEDERAL REGISTER ruling upon any such objection, no hearing is granted with respect to the matters covered by such objection, and the Commissioner rules adversely on such objection, the person may petition for judicial review of the Commissioner's ruling on such objection in a United States Court of Appeals pursuant to the applicable provisions in the act.

(1) The record for judicial review shall be the record designated in § 12.28(b)(1).

(2) The time for filing such a petition for judicial review shall begin as of the date of publication in the FEDERAL REGISTER of the Commissioner's ruling on such objection.

§ 12.32 Request for alternative form of public hearing.

(a) A person who has a right to an opportunity for a hearing under this part may waive that opportunity and in lieu thereof request one of the following alternative forms of public hearing:

(1) A public hearing before a Public Board of Inquiry pursuant to Part 13 of this chapter.

(2) A public hearing before a public advisory committee pursuant to Part 14 of this chapter.

(3) A public hearing before the Commissioner pursuant to Part 15 of this chapter.

(b) Any such request:

(1) May be on his own initiative or at the suggestion of the Commissioner.

(2) Shall be submitted in writing to the Hearing Clerk pursuant to § 10.30 of this chapter.

(3) Shall be submitted at any time prior to publication of a notice of hearing pursuant to § 12.35 or a denial of hearing pursuant to § 12.28.

(4) Shall be:

(i) In lieu of a request for a hearing under this part, or

(ii) If submitted after or with a request for a hearing under this part, in the form of a waiver of the right to an opportunity for such a hearing conditioned upon an alternative form of public hearing. Upon acceptance by the Commissioner, such a waiver becomes binding and can thereafter be withdrawn only by waiving any right to any form of a hearing unless the Commissioner for good cause determines otherwise.

(c) Where more than one person has requested and justified a hearing under this part, an alternative form of hearing will be used only if all such persons concur and waive their right to an opportunity for a hearing under this part.

(d) The Commissioner will determine whether an alternative form of public hearing should be used, and if so which alternative will be acceptable to him, after considering the requests submitted and the appropriateness of the alternative forms of public hearing for the issues raised in the objections. Upon acceptance by the Commissioner, such acceptance becomes binding upon him unless the Commissioner for good cause determines otherwise.

(e) The Commissioner shall publish in the FEDERAL REGISTER a notice of hearing announcing an alternative form of public hearing pursuant to this section, setting forth the following information:

(1) A statement of the provisions of the regulation or order which is the subject of the public hearing.

(2) A statement specifying any part of the regulation or order which has been stayed.

(i) Any part of a regulation or order which is subject to an oportunity for a hearing under this part pursuant to statutory provisions under which the filing of proper objections and a request for hearing automatically stays the regulation or order, and for which a public hearing has been granted, shall be stayed.

(ii) The Commissioner may, in his discretion, stay in whole or in part any regulation or order which is not required by statute to be stayed.

(3) The time, date, and place of the hearing, or a statement that such information shall be contained in a subsequent notice published in the FEDERAL REGISTER.

(4) The names of the parties to the public hearing.

(5) A statement of the issues to be considered at the public hearing. The statement of the issues determines the scope of the public hearing.

(6) If the public hearing will be conducted by a Public Board of Inquiry:

(i) The time within which the parties may submit nominees for the Board pursuant to § 13.10(b) of this chapter.

(ii) The time within which a notice of participation shall be filed by any person who wishes to participate in the proceeding. A notice of participation shall be filed in the form and pursuant to the requirements specified in § 12.45.

(iii) The time within which participants shall submit written data and information pursuant to § 13.25 of this chapter. The notice shall list the contents of the portions of the administrative record of the proceeding as of that time relevant to the issues to be considered at the public hearing before the Board, and shall state that such portions have been placed on public display in the office of the Hearing Clerk and that additional copies of any material already submitted pursuant to § 13.25 of this chapter need not be included with any later submissions by participants in the proceeding.

(7) If the public hearing will be conducted by a Public Board of Inquiry or a public advisory committee, a statement whether the findings and conclusions resulting from such public hearing shall have the legal status and be handled as a recommended decision or as an initial decision pursuant to § 12.120. If the notice of hearing is silent on this matter, the findings and conclusions shall be an initial decision.

(f) The findings and conclusions resulting from a public hearing before a Public Board of Inquiry or a public advisory committee pursuant to this section shall have the same legal status and be handled as a recommended decision or an initial decision of a presiding officer issued pursuant to § 12.120, as determined by the notice of hearing published pursuant to paragraph (e) of this section. The findings and conclusions resulting from a public hearing before the Commissioner pursuant to this section shall have the same legal status and be handled as a tentative order issued pursuant to § 12.125. Thereafter, the participants in the proceeding may pursue the administrative and court remedies that are available as specified in §§ 12.120 through 12.159.

(g) If a public hearing before a public advisory committee pursuant to Part 14 of this chapter or a public hearing before the Commissioner pursuant to Part 15 of this chapter is used as an alternative form of hearing pursuant to this section, all submissions relating to the hearing which constitute the administrative record of the hearing shall be made to the Hearing Clerk and the provisions of § 10.20(j) of this chapter shall govern the availability of such submissions for public examination and copying.

§ 12.35 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing filed pursuant to §§ 12.5 through 12.26 that a formal evidentiary public hearing has been justified on any issue, he shall publish a notice of such determination in the FEDERAL REGISTER, setting forth the following information:

(1) A statement of the provisions of the regulation or order which is the subject of the formal evidentiary public hearing.

(2) A statement specifying any part of the regulation or order that has been stayed.

(i) Any part of a regulation or order which is subject to an opportunity for a hearing under this part pursuant to statutory provisions under which the filing of proper objections and a request for hearing automatically stays the regulation or order, and for which a hearing has been requested and justified, shall be stayed.

(ii) The Commissioner may, in his discretion, stay in whole or in part any regulation or order which is not required by statute to be stayed.

(3) The names of the parties to the formal evidentiary public hearing.

(4) A statement of the issues of fact raised by the objections and request for hearing as to which a hearing has been justified.

(5) A statement of any objections or requests for hearing as to which a hearing has not been justified, which shall be subject to the provisions of § 12.28.

(6) The designation of the presiding officer to conduct the hearing or a statement that the presiding officer will be designated in a subsequent notice.

(7) The time within which notices of appearance shall be filed pursuant to § 12.45.

(8) The date, time, and place when the prehearing conference will commence or a statement that such date, time, and place will be announced in a subsequent notice. The prehearing conference shall not commence until after the expiration of the time for filing the notice of participation required by § 12.45(a).

(9) The time within which participants shall submit written data, information, and views pursuant to § 12.85. The notice shall list the contents of the portions of the administrative record of the proceeding as of that time relevant to the issues to be considered at the public hearing and shall state that such portions have been placed on public display in the office of the Hearing Clerk and that additional copies of any material already submitted pursuant to § 12.85 need not be included with any later submissions by participants in the proceeding.

(b) The statement of the issues of fact raised by the objections or request for hearing as to which a hearing has been justified determines the scope of the formal evidentiary public hearing and the matters as to which the development of evidence will be permitted. The statement of the issues of fact may be revised by order of the presiding officer. Any participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer to revise the statement of the issues of fact to include an issue as to which the Commissioner has not granted a hearing or to eliminate an issue as to which the Commissioner has granted a hearing.

(c) A formal evidentiary public hearing shall be deemed to commence as of the date of publication of the notice of hearing in the FEDERAL REGISTER.

§ 12.37 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation pursuant to § 12.5(e), the regulation shall be effective on the date specified in the notice promulgating it.

(b) The Commissioner shall publish a notice in the FEDERAL REGISTER stating that fact. Such notice may extend the time for compliance with the regulation.

§ 12.38 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing published in the FEDERAL REGISTER pursuant to § 12.20(b) does not request a hearing, the Commissioner:

(1) Shall issue a final order published in the FEDERAL REGISTER withdrawing approval of an NDA, NADA, or biologics license, in whole or in part, and establishing the effective date of such final order.

(2) If the final order involves an NADA, shall forthwith revoke, in whole or in part, the applicable regulation pursuant to section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing published in the FEDERAL REGISTER pursuant to § 12.20(b) requests a hearing and others do not, the Commissioner may issue a final order covering all such drug products at once or may issue more than one final order covering different drug products at different times.

Subpart C—Appearance and Participation

§ 12.40 Appearance.

(a) Any person who has filed a written notice of participation pursuant to § 12.45 may appear in person or by or with counsel or other representative in any formal evidentiary public hearing and, subject to § 12.89, may be heard with respect to all matters relevant to the issues under consideration.

(b) Any person appearing in a representative capacity in any such hearing shall submit a signed statement of authorization or other documentation verifying his authority to do so.

(c) If there is a change in the person appearing in a representative capacity, such person shall submit the statement or other documentation required by paragraph (b) of this section.

(d) The presiding officer may strike the appearance of any person for violation of the rules of conduct established in § 12.90.

§ 12.45 Written notice of participation.

(a) Any person desiring to participate in any formal evidentiary public hearing shall, within 30 days after publication of the notice of hearing in the FEDERAL REGISTER pursuant to § 12.35, file with the Hearing Clerk in accordance with § 10.20 of this chapter a written notice of participation in the form specified in paragraph (b) of this section.

(b) The form of the written notice of participation shall be as follows:

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

NOTICE OF PARTICIPATION

Docket No. ------

Pursuant to the provisions of 21 CFR Part 12, governing the procedure in this matter, please enter the participation of:

(Name)

(Street address)

(City and State)

(Telephone number)

Service on behalf of the above will be accepted by:

(Name)

(Street address)

(City and State)

(Telephone number)

The following statements are made as part of this notice of participation.

A. *Specific Interest.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to Participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed)

(c) All notices, pleadings, documents, and other submissions to be served upon a person in the course of the hearing pursuant to § 12.82 shall be mailed to the address shown in the notice of participation or delivered in person to the person specified in the notice of participation.

(d) A written notice of participation may be amended by filing an amendment with the Hearing Clerk and serving it upon all participants in the hearing.

(e) No person may participate in any aspect or at any stage of a formal evidentiary public hearing if he has not filed a written notice of participation or if his notice of participation has been stricken pursuant to paragraph (g) of this section.

(f) The presiding officer may, upon motion, permit a person to file a written notice of participation in the hearing after the 30-day time period for filing such notices has expired, but only upon a showing of good cause as to why such a notice was not filed within such time period.

(g) The presiding officer may strike the participation of any person, after giving him an opportunity to show cause why his participation should not be stricken, for nonparticipation in the hearing or for failure to comply with any requirement of this subpart, e.g., disclosure of information as required by § 12.85 or the prehearing order issued pursuant to § 12.92. Any person whose participation has been stricken may petition the Commissioner for interlocutory review of such action.

§ 12.50 Advice on public participation in formal evidentiary public hearings.

(a) *Designated agency contact.* All inquiries from the public about scheduling, location, and general procedures should be addressed to the Associate Commissioner for Compliance. The staff of the Associate Commissioner for Compliance will attempt to respond promptly to all inquiries from members of the public, as well as to simple requests for information from participants in formal evidentiary public hearings. Such inquiries or requests should be addressed to the Office of the Associate Commissioner for Compliance (HFC–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, or telephone (301) 443–3480.

(b) *Hearing schedule changes.* Requests by hearing participants for changes in the schedule of a hearing or in the dates for filing documents, briefs, or other pleadings related to the hearing should be made in writing directly to the Administrative Law Judge. All such correspondence should be addressed to the Administrative Law Judge (HF–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) *Legal advice to individuals.* The Food and Drug Administration does not have the resources to provide individual legal advice to members of the public concerning participation in such proceedings. Furthermore, to do so would compromise the independence of the Commissioner's office and invite charges of improper interference in the hearing process. Accordingly, the Associate Commissioner for Compliance will decline to entertain inquiries about the strengths or weaknesses of any party's position at a hearing, litigation strategy, or other similar matters.

(d) *Role of the Office of the Chief Counsel.* Under no circumstances will the Office of the Chief Counsel, Food and Drug Administration, directly provide advice on the subject of any formal evidentiary public hearing to any person who is participating or may participate in the hearing. In every such hearing, certain attorneys in the office are designated to represent the bureau or bureaus whose action is the subject of the hearing. Other members of the office, including ordinarily the Chief Counsel, are designated to advise the Commissioner on any final decision in the matter. It is not compatible with these functions, nor would it be professionally responsible, for the attorneys in the Office of the Chief Counsel also to advise other participants in a hearing, or for any attorney who may be called on to advise the Commissioner to respond to inquiries from other participants in the hearing, for such participants may be urging views contrary to those of the bureau involved or to what may ultimately be the final conclusions of the Commissioner. Accordingly, members of the staff of the Office of the Chief Counsel, other than those attorneys responsible for representing the bureau or bureaus whose action is the subject of the hearing, will decline to respond to inquiries from any participating or potential participant relating to the content or conduct of any formal evidentiary public hearing.

(e) *Communication between participants and attorneys.* Participants in a hearing may communicate with the attorneys who are responsible for representing the bureau or bureaus whose action is the subject of the hearing, in the same way that they may communicate with counsel for any other party in interest about the presentation of matters at the hearing. It would be inappropriate to bar discussion of such matters as stipulations of fact, joint presentation of witnesses, or possible settlement of hearing issues. Members of the public, including participants at hearings, are advised, however, that all such communications, including those by telephone, will be recorded in memoranda that can be filed with the Hearing Clerk, Food and Drug Administration.

Subpart D—Presiding Officer

§ 12.60 Presiding officer.

A presiding officer shall preside over every formal evidentiary public hearing held pursuant to this subpart. The presiding officer shall be the Commissioner, a member of the office of the Commissioner to whom the Commissioner has delegated the responsibility for the matter involved, or an Administrative Law Judge qualified under 5 U.S.C. 3105 and

designated by the Commissioner to conduct the hearing in the notice of hearing or in a later notice published pursuant to § 12.35(a)(6).

§ 12.62 Commencement of functions.

The functions of the presiding officer shall commence upon his designation and terminate upon the forwarding of the recommended decision or the filing of the initial decision pursuant to § 12.120.

§ 12.70 Authority of presiding officer.

The presiding officer shall have the authority and duty to conduct a fair and expeditious hearing and to maintain order. He shall have all powers necessary to these ends, including, but not limited to, the power to:

(a) Arrange and issue notice of the date, time, and place of oral hearings and conferences and, upon proper notice, to change the date, time, and place of oral hearings and conferences previously set.

(b) Establish the methods of procedures to be used in the development of evidentiary facts, including the procedures specified in § 12.92(b) and to rule upon the need for oral testimony and cross-examination pursuant to § 12.87(b).

(c) Prepare, after considering the views of the participants, written statements of areas of factual disagreement among the participants.

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may facilitate the expeditious disposition of the hearing.

(e) Administer oaths and affirmations.

(f) Regulate the course of the hearing and govern the conduct of participants therein.

(g) Examine witnesses and inform witnesses that they must fully respond to all questions or have all of their testimony stricken.

(h) Rule on, admit, exclude, or limit evidence.

(i) Establish the time for filing motions, petitions, briefs, findings, or other submissions.

(j) Rule on motions and other procedural matters pending before him.

(k) Rule on motions for summary decision in accordance with § 12.93.

(l) Order that the hearing be conducted in stages in cases where the number of parties is large or the issues are numerous and complex.

(m) Waive, suspend, or modify any rule in this subpart pursuant to § 10.19 of this chapter if he determines that no party will be prejudiced, the ends of justice will be thereby served, and such action is in accordance with law.

(n) Strike the participation of any person pursuant to § 12.45(g) or exclude any person from the hearing pursuant to § 12.90 or otherwise take reasonable disciplinary action.

(o) Take any action permitted to the presiding officer as authorized by this part or in conformance with law for the maintenance of order at the hearing and for the expeditious, fair, and impartial conduct of the proceeding.

§ 12.75 Disqualification of presiding officer.

(a) Any participant in the proceeding may, by motion made to the presiding officer, request that the presiding officer disqualify himself and withdraw from the proceeding. The presiding officer shall rule upon any such motion and shall promptly certify the motion and his ruling thereon to the Commissioner for interlocutory review.

(b) A presiding officer shall withdraw from any proceeding in which he deems himself disqualified for any reason.

§ 12.78 Unavailability of presiding officer.

(a) In the event that the presiding officer is unable to act for any reason whatever, the powers and duties to be performed by him in connection with any proceeding shall be assigned by the Commissioner to another presiding officer. Such substitution shall have no effect on any aspect of the hearing, except as the new presiding officer may order pursuant to the provisions of this subpart.

(b) Any motion predicated upon such substitution shall be made within 10 days thereafter.

Subpart E—Hearing Procedures

§ 12.80 Filing and service of submissions.

(a) All submissions, including pleadings, relating to a formal evidentiary public hearing shall be filed with the Hearing Clerk pursuant to § 10.20 of this chapter.

(b) A copy of each such submission shall be served by the person making the submission upon each other participant in the proceeding, except that submissions of documentary data and information may but are not required to be served upon each participant. Any transmittal letter, pleading, summary, statement of position, certification pursuant to paragraph (d) of this section, or other similar document accompanying a submission of documentary data and information shall be served upon each participant pursuant to this paragraph.

(c) Service pursuant to this section shall be accomplished by mailing it to the address shown in the notice of participation or by personal delivery.

(d) All submissions pursuant to this section shall be accompanied by a signed certification stating the extent to which the submission has been served on each participant, or is exempt from such service, pursuant to paragraph (b) of this section.

(e) No written submission or other portion of the administrative record shall be held in confidence, except as provided in § 12.105.

§ 12.82 Petition to participate in forma pauperis.

(a) Any participant who believes that compliance with the filing and service requirements of this section constitutes an unreasonable financial burden shall submit to the Commissioner a petition to participate in forma pauperis.

(b) Such petition shall be pursuant to § 10.30 of this chapter, except that the heading shall be "REQUEST TO PARTICIPATE IN FORMA PAUPERIS, DOCKET NO. _____." Pursuant to the guidelines established in § 20.43 (b) and (c) of this chapter, such petition shall demonstrate that either (i) the person is indigent and his participation has a strong public interest justification, or (ii) such participation is in the public interest because it can be considered primarily as benefiting the general public. Filing and service requirements for such a petition shall be those provided for the filing and service of submissions in paragraph (c) of this section, whether or not the petition is subsequently granted.

(c) The Commissioner may, in his discretion, grant or deny such petition. If such petition is granted, the participant may file only one copy of each submission with the Hearing Clerk, and it shall be the responsibility of the Hearing Clerk, at agency expense, to make sufficient additional copies for the administrative record and to serve a copy upon each other participant.

§ 12.83 Advisory opinions.

Prior to or during the pendency of any formal evidentiary public hearing any person may request the Commissioner for an advisory opinion as to the applicability to a specific situation of any regulation or order under consideration in an administrative proceeding. Requests for such opinions shall be made pursuant to § 10.85 of this chapter.

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 12.35, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding up to that time. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be placed on public display and shall not be part of the administrative record of that proceeding.

(2) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(3) All other documentary data and information on which he relies.

(4) A narrative statement of his position on the factual issues stated in the notice of hearing and the type of evidence he intends to introduce in the hearing in support of his position.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within 60 days after the notice of hearing is published in the FEDERAL REGISTER pursuant to § 12.35, or, where no participant will be prejudiced, within such shorter or longer period of time as the presiding officer orders, each par-

ticipant shall submit to the Hearing Clerk all data and information specified in paragraph (a) (2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a) (1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen at that time.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall also constitute a waiver of the right to a hearing.

(e) Any documentary data and information submitted by one participant may be referenced by another. Participants are encouraged to exchange and consolidate lists of documentary evidence prior to reproducing it for submission to the Hearing Clerk in order to reduce duplicative submissions. If a particular document is bulky or is in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, a participant may request the presiding officer for permission to submit a reduced number of copies to the Hearing Clerk.

(f) The presiding officer shall rule on questions relating to this section.

§ 12.87 Purpose; oral and written testimony; burden of proof.

(a) A formal evidentiary public hearing is held for the purpose of receiving evidence relating to an issue of fact determining the validity of a regulation or order subject to such a hearing. The objective of such a hearing is the fair determination of facts in a manner consistent with the right of all interested persons to participate and the public interest in expeditiously concluding controversies over matters affecting the public health and welfare.

(b) To achieve this objective, the evidence at a formal evidentiary public hearing shall be developed to the maximum feasible extent through written submissions, including written direct testimony which may be in narrative or in question-and-answer form, written cross-examination, and such other methods for the testing and proper evaluation of factual propositions as the presiding officers determines are necessary for a full and true disclosure of relevant evidentiary facts.

(1) In a formal evidentiary public hearing, the issues may have general applicability and depend upon general facts that do not concern any particular action of a specific party, e.g., the safety or effectiveness of a class of drug products, the safety of a food or color additive, or a definition and standard of identity for a food, or the issues may have specific applicability to past action and depend upon particular facts concerning only that party, e.g., the applicability of a grandfather clause to a particular brand of a drug or the failure of a particular manufacturer to meet required manufacturing and processing specifications or other general standards.

(i) Where the proceeding involves general issues, all direct testimony shall be submitted in writing, except upon a showing that written direct testimony is insufficient to adduce testimony for a full and true disclosure of relevant evidentiary facts and that the participant will be prejudiced by denial of a request to present oral direct testimony. Where the proceeding involves particular issues, each party shall determine whether, and the extent to which, he wishes to present his direct testimony orally or in writing.

(ii) Oral cross-examination of witnesses shall be permitted only upon a showing that the cross-examination requested is necessary because alternative means of developing relevant evidentiary facts are insufficient to adduce testimony required for a full and true disclosure of relevant evidentiary facts, and that the party requesting opportunity for oral cross-examination will be prejudiced by denial of the request.

(2) All oral and written testimony of witnesses shall be under oath.

(c) In considering whether a request for cross-examination of a particular witness has been justified, the presiding officer shall take into account the following factors:

(1) The extent to which a full and true disclosure with respect to any disputed issue of fact can be achieved through the presentation of additional direct evidence.

(2) The extent to which there are circumstantial guarantees of the trustworthiness of the direct evidence sought to be made the subject of cross-examination.

(3) Whether the particular person's testimony sought to be made the subject of cross-examination is required for the resolution of any disputed issue of fact.

(4) Whether a dispute concerns facts in contrast to the inferences and conclusions to be drawn from the facts.

(5) Whether the direct evidence sought to be made the subject of cross-examination is relevant and material to the issues of fact as to which the hearing has been justified.

(6) Whether the direct evidence of the witness sought to be cross-examined was introduced by oral direct testimony, and granting the request would expedite the hearing.

(d) Except as provided in paragraph (e) of this section, in any formal evidentiary public hearing involving the issuance, amendment, or revocation of a regulation or order, the originator of the proposal or petition or of any significant modification thereof shall be, within the meaning of 5 U.S.C. 556(d), the proponent of the regulation or order, and accordingly shall have the burden of proof. Any participant who proposes the substitution of a new provision for a provision objected to shall have the burden of proof in relation to the new provision so proposed.

(e) At any formal evidentiary public hearing involving the issuance, amendment, or revocation of a regulation or order relating to the safety or effectiveness of a drug, food additive, or color additive, the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval shall have the burden of proof in establishing safety or effectiveness or both and thus the right to approval. The burden of proof remains on such participant in an amendment or revocation proceeding.

§ 12.89 Participation of nonparties.

(a) A nonparty participant shall have the right:

(1) To attend all conferences (including the prehearing conference), oral proceedings, and arguments held in connection with or as part of a formal evidentiary public hearing.

(2) To submit written testimony and documentary evidence for inclusion in the record.

(3) To file written objections, briefs, and other pleadings.

(4) To present oral argument.

(b) A nonparty participant shall not have the right:

(1) To submit written interrogatories.

(2) To conduct cross-examination.

(c) Any person whose petition is the subject of the hearing shall have the same rights as a party.

(d) The presiding officer shall permit a nonparty participant additional rights when he concludes that the participant's interests would not be adequately protected otherwise or that broader participation is required for a full and true disclosure of relevant evidentiary facts, but the rights of a nonparty participant shall in no event exceed the rights of a party.

§ 12.90 Conduct at oral hearings or conferences.

All participants in a formal evidentiary public hearing shall conduct themselves with dignity and observe judicial standards of practice and ethics. They shall not indulge in personal attacks, unseemly wrangling, or intemperate accusations or characterizations. A representative of any party shall use his best efforts to restrain his client from improprieties in connection with any proceeding. Disrespectful, disorderly, or contumacious language or contemptuous conduct, refusal to comply with directions, continued use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any such hearing, shall constitute grounds for immediate exclusion from the proceeding at the direction of the presiding officer.

§ 12.91 Time and place of prehearing conference.

A prehearing conference shall commence at the date, time, and place announced in the notice of hearing, or in a

later notice, published in the FEDERAL REGISTER pursuant to § 12.35(a)(8), or as specified by the presiding officer in a notice published in the FEDERAL REGISTER modifying a prior notice. At that conference the presiding officer shall establish the methods and procedures to be used in developing the evidence, determine reasonable time periods for the conduct of the hearing, and designate the times and places for the production of witnesses for direct and cross-examination if leave to conduct oral examination is granted on any issue, insofar as is practicable at that time.

§ 12.92 Prehearing conference procedure.

(a) All participants in a formal evidentiary hearing shall appear at the prehearing conference fully prepared to discuss in detail and resolve all matters specified in paragraph (b) of this section as may be issued by the Commissioner or the presiding officer.

(1) All participants shall cooperate fully at all stages of the proceeding to achieve the objective of a fair and expeditious hearing, through advance preparation for the prehearing conference, including communications between the participants, requests for information at the earliest possible time, and the commencement of preparation of testimony. The failure of any participant to appear at the prehearing conference or to raise any matters that could reasonably be anticipated and resolved at the prehearing conference shall not be permitted to delay the progress of the hearing and shall consitute a waiver of the rights of the participant with regard thereto, including all objections to the agreements reached, actions taken, or rulings issued by the presiding officer with regard thereto, and may be grounds for striking his participation pursuant to § 12.45.

(2) Each participant shall bring to the prehearing conference (to the first session or, if that is impracticable, to a subsequent session scheduled by the presiding officer) the following specific information, which shall be filed with the Hearing Clerk pursuant to § 12.82.

(i) Any additional data or information to supplement the submission filed pursuant to § 12.85, which may be filed if approved pursuant to § 12.85(c).

(ii) A list of all witnesses whose testimony will be offered, orally or in writing, at the hearing, together with a full curriculum vitae for each such witness. Additional witnesses may later be identified, with the approval of the presiding officer, upon a showing that the witness was not reasonably available at the time of the prehearing conference or that the relevance of his views could not reasonably have been foreseen at that time.

(iii) All prior written statements, which shall include articles and any written statement signed or adopted, or a recording or transcription of an oral statement made, by the persons who have been identified as witnesses if all of the following conditions apply:

(a) The statement is available without making request of the witness or any other person.

(b) The statement relates to the subject matter of the witness's testimony.

(c) The statement either was made before the time the person agreed to become a witness or has been made publicly available by the person.

(b) The presiding officer shall conduct a prehearing conference for the following purposes:

(1) To determine the areas of factual disagreement which are to be considered at the formal evidentiary hearing. The presiding officer may:

(i) Require each participant to prepare and file written statements of position on the areas of disagreement described in the notice of hearing.

(ii) Require each participant to summarize the testimony which he proposes to present in support of his position, and to describe and justify any additional documentary evidence not included with the submission pursuant to § 12.93 and expected to be introduced.

(iii) Consider oral or written argument with respect to the areas of disagreement described in the notice of hearing or with respect to objections thereto.

(iv) Hold conferences off the record in an effort to reach agreement as to factual questions on which disagreement exists, except that all statements as to areas of disagreement shall be reduced to writing or be the subject of a verbatim transcript approved by the participants.

(2) To identify the most appropriate techniques for the development of the evidence on issues in controversy in addition to the submissions pursuant to § 12.85, and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, the oral examination. The methods and procedures which the presiding officer may consider for use in developing the evidence include but are not limited to:

(i) Submission of narrative statements of position on each factual issue in controversy.

(ii) Submission of evidence or identification of previously submitted evidence in support of such statements, such as affidavits, verified statements of fact, data, studies, reports, and any other type of written material.

(iii) Identification of all witnesses and submission of testimony of such witnesses.

(iv) Exchange of written interrogatories directed to particular witnesses for the purpose of developing the evidence on particular disputed facts.

(v) Written requests to any party for the production of additional documentation, data, or other information relevant and material to the facts in issue.

(vi) Submission of written questions to be orally propounded by the presiding officer to a specific witness.

(vii) Isolation of disputed facts as to which oral examination and/or cross-examination is appropriate pursuant to § 12.87(b).

(3) To group participants with substantially like interests for purposes of eliminating duplicative or repetitive development of the evidence, making and arguing motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and determine objections to the admission into evidence of data and information submitted pursuant to § 12.85.

(5) To investigate the possibility of obtaining stipulations and admissions of facts.

(6) To consider such other matters and take such other action as may aid in the expeditious disposition of the proceeding.

(c) The presiding officer shall prepare a written prehearing order reciting the actions taken at the prehearing conference and setting forth the schedule for the hearing. Such order shall include a written statement of the areas of factual agreement and disagreement and of the methods and procedures to be used in developing the evidence and the respective duties of the parties in connection therewith. Such order shall control the subsequent course of the hearing unless modified by the presiding officer for good cause shown.

§ 12.93 Summary decisions.

(a) Any participant in a formal evidentiary public hearing may, after commencement of the hearing, submit to the Hearing Clerk pursuant to § 12.80 a motion with or without supporting affidavits for a summary decision in his favor with respect to any issue under consideration. Any other participant may, within 10 days after service of the motion, which time may be extended for an additional 10 days by the presiding officer for good cause shown, serve opposing affidavits or countermove for summary decision. The presiding officer may, in his discretion, set the matter for argument and call for the submission of briefs.

(b) The presiding officer shall grant such motion if the objections, requests for hearing, other pleadings, affidavits, and any material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits shall set forth such facts as would be admissible in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated therein. When a motion for summary decision is made and supported as provided in this section, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions. His response, by affidavits or as otherwise provided in this section, must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that he cannot, for sound reasons stated, present by affidavit facts essential

to justify his opposition, the presiding officer may deny the motion for summary decision or may order a continuance to permit affidavits or additional evidence to be obtained or may make such order as is just.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked, and development of evidentiary facts is found necessary, the presiding officer shall make an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified shall be deemed established.

(f) Any participant may obtain interlocutory review by the Commissioner of a summary decision of the presiding officer.

§ 12.94 Receipt of evidence.

(a) A formal evidentiary public hearing consists of the development of evidence and the resolution of factual issues in the manner set forth in the procedures established in this subpart and in the order issued by the presiding officer after the prehearing conference.

(b) All orders issued by the presiding officer, transcripts of oral hearings or arguments, written statements of position, written direct testimony, written interrogatories and the responses thereto, and any other data, studies, reports, documentation, information, and other written material of any kind submitted in the proceeding shall be a part of the administrative record of the hearing, and shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office, except as provided in § 12.105.

(c) A written submission to the record shall be admissible as evidence unless a participant objects and the presiding officer excludes it as inadmissible.

(1) The presiding officer shall exclude written evidence as inadmissible only on the following grounds:

(i) The evidence is a document that is not authentic, or

(ii) Exclusion of part or all of the written evidence of a participant is necessary or appropriate to enforce the requirements of this subpart.

(2) The presiding officer shall not exclude any written evidence as inadmissible on the ground that it is irrelevant, immaterial, or repetitive. All such written evidence shall be admitted even if it is of no probative value. Irrelevant or immaterial written evidence shall be regarded as such and shall not be given weight or probative value because of its admission.

(3) Any written evidence excluded by the presiding officer as inadmissible shall remain a part of the administrative record, as an offer of proof, for purposes of judicial review.

(d) Oral testimony, whether on direct or on cross-examination, shall be admissible as evidence unless a participant objects and the presiding officer excludes it as inadmissible.

(1) The presiding officer shall exclude oral evidence as inadmissible only on the following grounds:

(i) The oral evidence is irrelevant, immaterial, or repetitive, or

(ii) Exclusion of part or all of the oral evidence of a participant is necessary or appropriate to enforce the requirements of this part.

(2) Whenever oral evidence is excluded by the presiding officer as inadmissible, the participant may take written exception to such ruling in his brief to the Commissioner, without formally taking oral exception at the hearing. Upon review, the Commissioner may reopen the hearing to permit such evidence to be admitted if he determines that its exclusion was erroneous and prejudicial.

(e) All participants shall be responsible for apprising themselves of the contents of the administrative record in timely fashion for purposes of formulating objections to the admissibility of any item into evidence and evaluating the need for the submission of additional evidence.

(f) The presiding officer shall, on his own initiative as the circumstances warrant, or upon the motion of any participant for good cause shown, schedule conferences to monitor the progress of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(g) The presiding officer shall conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted to him by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall screen written questions submitted to him to be asked orally of witnesses in order to exclude irrelevant or repetitious questions. The presiding officer shall limit oral cross-examination to prevent irrelevant or repetitious examination.

(h) The presiding officer shall order that the proceedings be closed for the taking of oral testimony relating to matters specified in § 10.20(j)(3) of this chapter. Participation in such closed proceedings shall be limited to the witness, his counsel, and Federal Government Executive Branch employees and special government employees. Such closed proceedings shall be permitted only for such oral testimony as directly relates to matters specified in § 10.20 (j)(3) of this chapter and shall not include other matters.

(i) Any party may at any time move for an order that the taking of evidence be concluded. Such motion shall be granted unless within 10 days of service thereof a participant files an opposition to such motion, supported by an affidavit stating that he wishes to submit, or by specified means adduce, additional evidence on facts relevant to the issues at the hearing, describing the nature of such evidence, and estimating the time necessary to submit or adduce it. In the event that such an opposition is filed, the presiding officer may (1) grant the motion if it appears that the evidence described in the affidavit filed in support of the opposition does not relate to relevant facts or is duplicative or cumulative of evidence already on record at the hearing, (2) deny the motion, (3) grant the motion but postpone its effect to a specified date in order that the participant opposing it may submit or adduce the evidence described in the affidavit, or (4) take such other action as is appropriate under the circumstances. Upon the denial of a motion made under this paragraph, or the granting of a motion with a postponed effective date, no participant may submit additional evidence unless he has filed an opposition to the motion, and any participant who has filed an opposition shall confine the submission of additional evidence to the matters set forth in the affidavit in support of the opposition.

§ 12.95 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of the Food and Drug Administration as an expert agency.

(b) Where official notice is taken of a material fact not appearing in the evidence of record, any participant, on timely request, shall be afforded an opportunity to show the contrary.

§ 12.96 Briefs and argument.

(a) As soon as possible after the completion of the taking of evidence, the presiding officer shall announce a schedule for the filing of briefs. Briefs shall include a statement of position on each issue as supported by the evidence of record, with specific and complete citations to the evidence, together with citations of points of law relied upon. Briefs shall contain proposed findings of fact and conclusions of law.

(b) The presiding officer may permit the presentation of oral argument at his discretion and in such manner as he believes is both practical and fair.

(c) Briefs and oral argument shall attempt to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(3) of this chapter, but any reference essential to resolution of the issues involved shall be permitted.

§ 12.97 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 12.35(b), 12.45(g), 12.75(a), 12.93(f), and 12.99(c), where an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner prior to his consideration of the entire administrative record of the hearing.

(b) Any ruling of the presiding officer shall be the subject of an interlocutory

appeal to the Commissioner where the presiding officer certifies on the record or in writing that such an interlocutory appeal is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) Where an interlocutory appeal is made to the Commissioner, any participant may file a brief with the Commissioner within such period as the Commissioner directs. Oral argument will be heard only at the discretion of the Commissioner.

§ 12.98 Official transcript.

(a) Any oral testimony given at a formal evidentiary public hearing shall be reported verbatim. The presiding officer will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as he requires for his own purpose.

(b) One copy of such transcript shall be placed on public display in the office of the Hearing Clerk upon receipt, where it may be reviewed by any interested person.

(c) Any person desiring a copy of the transcript of the testimony taken at the hearing or of any part thereof shall be entitled to the same, except as provided in § 12.105, upon application to the official reporter and payment of the costs thereof or pursuant to the provisions of Part 20 of this chapter.

§ 12.99 Motions.

(a) Any participant may make a motion, including any request, to the presiding officer with respect to any matter relating to the proceeding. All motions shall be filed pursuant to § 12.80, except those made in the course of an oral hearing before the presiding officer.

(b) Within 10 days after service of any such motion, which may be shortened to 3 days or extended for an additional 10 days by the presiding officer for good cause shown, any participant in the proceeding may file a response to the motion.

(c) The presiding officer shall rule upon such motion and may certify such motion, together with his ruling, to the Commissioner for interlocutory review.

Subpart F—Administrative Record

§ 12.100 Administrative record of a formal evidentiary public hearing.

(a) The record of the administrative proceeding shall consist of the following:

(1) The order or regulation which gave rise to the hearing.

(2) All objections and requests for hearing filed by the Hearing Clerk pursuant to §§ 12.5 through 12.22.

(3) The notice of hearing published pursuant to § 12.35.

(4) All notices of participation filed pursuant to § 12.45.

(5) All FEDERAL REGISTER notices pertinent to the proceeding.

(6) All submissions filed pursuant to § 12.82, e.g., the submissions required by § 12.85, all other documentary evidence and written testimony, pleadings, statements of position, briefs, and other similar documents.

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared pursuant to § 12.92.

(8) All documents relating to any motion for summary decision pursuant to § 12.93.

(9) All documents of which official notice is taken pursuant to § 12.95.

(10) All pleadings filed pursuant to § 12.96.

(11) All documents relating to any interlocutory appeal pursuant to § 12.97.

(12) All transcripts prepared pursuant to § 12.98.

(13) Any other documents relating to the hearing and filed with the Hearing Clerk by the presiding officer or any participant.

(b) The record of the administrative proceeding shall be closed:

(1) With respect to the taking of evidence, at the time specified in § 12.94(g).

(2) With respect to pleadings, at the time specified in § 12.96(a) for the filing of briefs.

(c) The presiding officer may, in his discretion, reopen the record to receive further evidence at any time prior to the filing of a recommended or initial decision.

§ 12.105 Examination of administrative record.

The availability for public examination and copying of each document which is a part of the administrative record of the hearing shall be governed by the provisions of § 10.20(j) of this chapter. Each document which is available for public examination or copying shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

§ 12.110 Correction of administrative record.

After the close of the taking of evidence, the presiding officer shall afford witnesses, participants, and their counsel time, not longer than 30 days except in unusual cases, in which to submit written proposed corrections of the transcript of any oral testimony taken at the hearing, pointing out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony.

§ 12.115 Record for administrative decision.

The administative record of the hearing specified in § 12.100 shall constitute the exclusive record for decision.

Subpart G—Initial and Final Decisions

§ 12.120 Initial decision.

(a) Within 90 days after the filing of briefs and any oral argument pursuant to § 12.96, the presiding officer shall prepare and file an initial decision based solely upon the administrative record of the hearing. The time for filing an initial decision may be extended by the Commissioner upon request of the presiding officer stating reasons therefor.

(b) The initial decision shall contain:

(1) Findings of fact based upon relevant, material, and reliable evidence of record.

(2) Conclusions of law.

(3) A full articulation of the reasons for the findings and conclusions, including a discussion of the significant factual and legal contentions made by any participant.

(4) Full citations to the administrative record supporting the findings and conclusions.

(5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law.

(6) An effective date for the regulation or order.

(c) The initial decision shall attempt to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(3) of this chapter, but any references essential to resolution of the issues involved shall be permitted.

(d) The initial decision shall be filed with the Hearing Clerk and served upon all participants.

(e) The initial decision shall become the final decision of the Commissioner by operation of law unless a participant in the proceeding files timely exceptions with the Hearing Clerk pursuant to § 12.125(a) or the Commissioner, on his own initiative, files with the Hearing Clerk a notice of review pursuant to § 12.125(f).

(f) Notice that an initial decision has become the decision of the Commissioner without appeal to or review by the Commissioner shall be published in the FEDERAL REGISTER, or the Commissioner may publish the entire decision if he determines that it is of widespread public interest.

§ 12.125 Appeal from or review of initial decision.

(a) Any participant in a proceeding may appeal an initial decision to the Commissioner by filing exceptions to the initial decision with the Hearing Clerk, and serving such exceptions on the other participants. Exceptions will be filed and served within the period specified in the initial decision. Such period shall not exceed 30 days, unless extended by the Commissioner pursuant to paragraph (d) of this section.

(b) Exceptions to the initial decision shall contain specific statements of alleged error in the findings of fact or conclusions of law in the initial decision, with specific reference to those parts of the record upon which the exceptions are based. If oral argument before the Commissioner is desired, it shall be specifically requested in the exceptions.

(c) Any participant may file with the Hearing Clerk, and serve on the other participants, a reply to the exceptions of a participant. A reply shall be filed

and served within the period specified in the initial decision. Such period shall not exceed 30 days after the period (including any extensions) for filing exceptions, unless extended by the Commissioner pursuant to paragraph (d) of this section.

(d) The Commissioner may extend the time for filing exceptions or replies to exceptions for good cause shown.

(e) After the filing of exceptions and replies, the Commissioner shall determine whether he wishes to hear oral argument on the matter. If the Commissioner concludes that he should hear oral argument on the matter, the participants shall be informed of the date, time, and place for such oral argument, the amount of time that will be allotted to each participant for such oral argument, and the issues to be addressed.

(f) Prior to 10 days following the expiration of the time for filing exceptions (including any extensions), the Commissioner may file with the Hearing Clerk, and serve on the participants, a notice stating that he will review the initial decision on his own initiative. The Commissioner may invite the participants to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument shall be specified in the notice of review or in a later notice.

§ 12.130 Decision by Commissioner on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Commissioner shall have all the powers he would have in making the initial decision. The Commissioner may, on his own initiative or on the motion of any participant, remand the proceeding to the presiding officer with specific directions, e.g., to receive further evidence relating to a particular issue, where he concludes that such action is necessary for a proper decision in the matter.

(b) The scope of the issues on appeal shall be the same as the scope of the issues at the public hearing unless the Commissioner specifies otherwise.

(c) As soon as practicable after the filing of briefs and any oral argument, the Commissioner shall issue in the FEDERAL REGISTER his final decision in the proceeding based solely upon the administrative record of the hearing. Such final decision shall meet the requirements established in § 12.120 (b) and (c).

(d) The Commissioner may adopt the initial decision as the final decision, in whole or in part, if he concludes, after reviewing the administrative record, that it meets all the requirements specified in § 12.120 (b) and (c) and represents a sound, reasonable, and fair decision based upon all relevant factual, legal, and policy considerations.

(e) Notice of the Commissioner's decision shall be published in the FEDERAL REGISTER, or the Commissioner may publish the entire decision if he determines that it is of widespread public interest.

§ 12.139 Reconsideration and stay of action.

Following notice or publication of the final decision, any participant may petition the Commissioner for reconsideration of any part or all of such decision pursuant to § 10.33 of this chapter or may petition for a stay of such decision pursuant to § 10.35 of this chapter.

Subpart H—Judicial Review

§ 12.140 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which any participant may petition for judicial review pursuant to the statutory provisions governing the matter involved. Before requesting an order from a court for a stay of action pending review, any participant seeking court review shall first submit a petition for a stay of action pursuant to § 10.35 of this chapter.

(b) The Food and Drug Administration will request consolidation in a single court of all petitions for judicial review related to a particular matter pursuant to 28 U.S.C. 2112(a).

§ 12.159 Copies of petitions for judicial review.

The Chief Counsel for the Food and Drug Administration has been designated by the Secretary as the officer upon whom copies of petitions for judicial review shall be served. Such officer shall be responsible for filing in the court the record of the proceedings on which the final decision is based. The record of the proceeding shall be certified by the Commissioner.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

Subpart A—General Provisions

Sec.

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Subpart B—Public Board of Inquiry Hearing Procedures

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Subpart C—Records of a Public Hearing Before a Public Board of Inquiry

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AUTHORITY: Sec. 201 et seq., 52 Stat. 1040; 21 U.S.C. 321 et seq.; sec. 1 et seq., 68 Stat. 682, as amended; 42 U.S.C. 201 et seq.; sec. 4, 84 Stat. 1241; 42 U.S.C. 257a; sec. 301 et seq., 84 Stat. 1253; 21 U.S.C. 821 et seq.; sec. 409 (b), 81 Stat. 600; 21 U.S.C. 679(b); sec. 24 (b), 82 Stat. 807; 21 U.S.C. 467f(b); sec. 2 et seq., 84 Stat. 1620; 21 U.S.C. 1031 et seq.; secs. 1 through 9, 44 Stat. 1101; 21 U.S.C. 141 et seq.; secs. 1 through 10, Chapter 358, 29 Stat. 604; 21 U.S.C. 41 et seq.; sec. 2, et seq., 44 Stat. 1406; 15 U.S.C. 401–411 notes; sec. 1, et seq., 80 Stat. 1296; 15 U.S.C. 1451 et seq., and all other statutory authority delegated to the Commissioner (21 CFR 5.1).

Subpart A—General Provisions

§ 13.1 Scope.

This part governs the practices and procedures applicable whenever:

(a) The Commissioner concludes, in his discretion, that it is in the public interest to hold a public hearing before a Public Board of Inquiry, hereinafter referred to as a "Board," with respect to any matter, or class of matters, of importance pending before the Food and Drug Administration.

(b) Pursuant to specific provisions in other sections of this chapter, a matter pending before the Food and Drug Administration is subject to a public hearing before a Board.

(c) A person who has a right to an opportunity for a formal evidentiary public hearing under Part 12 of this chapter waives that opportunity and in lieu thereof requests pursuant to § 12.32 of this chapter the establishment of a Board to act as an administrative law tribunal with respect to the matters involved, and the Commissioner, in his discretion, accepts this request.

§ 13.5 Notice of a public hearing before a Public Board of Inquiry.

If the Commissioner determines that a Board should be established to conduct a public hearing on any matter, he shall publish in the FEDERAL REGISTER a notice of hearing setting forth the following information:

(a) If the hearing is pursuant to § 13.1 (a) or (b), all applicable information described in § 12.32(e) of this chapter.

(1) If any written document is to be the subject matter of the hearing, it shall be published as part of the notice, or reference shall be made to it if it has already been published in the FEDERAL REGISTER, or the notice shall state that the document is available from the Hearing Clerk or an agency employee designated in the notice.

(2) For purposes of any hearing pursuant to § 13.1 (a) or (b), all participants who file a notice of appearance pursuant to § 12.32(e)(6)(ii) of this chapter shall be deemed to be parties and shall be entitled to participate in selection of the Board pursuant to § 13.15(b).

(b) If the hearing is in lieu of a formal evidentiary hearing as provided in § 13.1 (c), all of the information described in § 12.32(e) of this chapter.

§ 13.10 Members of a Public Board of Inquiry.

(a) All members of a Board shall have medical, technical, scientific, or other qualifications relevant to the issues to be considered at the hearing, shall be subject to the conflict of interest rules applicable to special government employees, and shall be free from bias or prejudice with respect to the issues involved. A member of a Board may be a full-time or part-time Federal government employee or may serve on a Food and Drug Administration advisory committee but, except with the agreement of all parties, shall not currently be a full-time or part-time employee of the Food and Drug Administration or otherwise act as a spe-

cial government employee of the Food and Drug Administration.

(b) The director of the bureau of the Food and Drug Administration responsible for the matter which is the subject of a public hearing before a Board, the other parties to the proceeding, and any person whose petition is the subject of the hearing, shall, within 30 days after publication of the notice of hearing in the FEDERAL REGISTER, each submit to the Hearing Clerk the names and full curricula vitae of five nominees for members of the Board. Nominations shall state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) Any two or more persons entitled to submit nominees may in consulation with each other agree upon a joint list of five qualified nominees.

(2) In addition to being filed with the Hearing Clerk, the lists of nominees and comments thereon shall be submitted to the persons who are entitled to submit a list of nominees pursuant to this paragraph but not to all participants. They shall be held in confidence by the Hearing Clerk as part of the administrative record of the proceeding and shall not be available for public disclosure, and shall similarily be held in confidence by all persons who submit or receive them. This portion of the administrative record shall remain confidential but shall be available for judicial review in the event that it becomes relevant to any issue before a court.

(3) Within 10 days after receipt of such names of nominees, such persons may submit comments to the Hearing Clerk on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section.

(c) After reviewing the lists of nominees and any comments thereon, the Commissioner shall choose three qualified persons as members of a Board. One member shall be chosen from the lists of nominees submitted by the director of the bureau responsible for the matter and by any person whose petition is the subject of the hearing. The second member shall be chosen from the lists of nominees submitted by the other parties. The Commissioner shall then choose the third member from any source, who shall be the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees submitted, or if additional information is needed, the Commissioner shall request once from the party involved the submission of such additional nominees or information as is necessary to choose a qualified member of the Board nominated by that person.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified person in lieu of a person nominated by that person without further consultation with that person.

(3) The Commissioner shall announce the members of a Board by filing a memorandum in the record of the proceeding and sending a copy to each participant who has filed a notice of appearance.

(d) In lieu of the procedure for selection of the members of a Board specified in paragraphs (b) and (c) of this section, the director of the bureau, the other party or parties to the proceeding, and any person whose petition is the subject of the hearing, may, with the approval of the Commissioner, agree that any standing advisory committee listed in § 14.80 of this chapter shall constitute the Board for a particular proceeding, or that another procedure shall be used for selection of the members of the Board, or that the Board shall consist of a larger number of members.

(e) The members of a Board shall serve as consultants to the Commissioner and shall be special government employees or government employees. A Board shall function as an administrative law tribunal in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or Part 14 of this chapter.

(f) The chairman of a Board shall have the authority of a presiding officer set out in § 12.70 of this chapter.

§ 13.15 Separation of functions; ex parte communications; administrative support.

(a) All proceedings of a Board shall be subject to the provisions of § 10.55 of this chapter, relating to separation of functions and ex parte communications. Representatives of the participants in any proceeding before a Board, including any members of the Office of the Chief Counsel of the Food and Drug Administration assigned to advise the bureau responsible for the matter, shall have no contact with the members of the Board, except as participants in such proceeding, and shall not participate in the deliberations of the Board.

(b) Administrative support for a Board shall be provided only by the office of the Commissioner and the Office of the Chief Counsel for the Food and Drug Administration.

Subpart B—Public Board of Inquiry Hearing Procedures

§ 13.20 Submissions to a Public Board of Inquiry.

(a) All submissions relating to a hearing before a Board shall be filed with the Hearing Clerk pursuant to § 10.20 of this chapter.

(b) A copy of any such submission shall be sent by the person making the submission to each participant in the proceeding, except as provided in §§ 13.10 (b)(3) and 13.45 and except that submissions of documentary data and information may but are not required to be sent to each participant. Any transmittal letter, summary, statement of position, certification pursuant to paragraph (d) of this section, or similar document accompanying a submission of documentary data and information shall be sent to each participant pursuant to this paragraph.

(c) Any such submission shall be sent as required by paragraph (b) of this section by mailing it to the address shown in the notice of appearance or by personal delivery.

(d) All submissions pursuant to this section shall be accompanied by a signed certification stating the extent to which the submission has been served on each participant, or is exempt from such service, pursuant to paragraph (b) of this section.

(e) No written submission or other portion of the administrative record shall be held in confidence, except as provided in §§ 13.10(b)(3) and 13.45.

(f) Any participant who believes that compliance with the requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis.

(1) Such petition shall be pursuant to § 10.30 of this chapter, except that the heading shall be "REQUEST TO PARTICIPATE IN FORMA PAUPERIS, DOCKET NO. ____." Pursuant to the guidelines established in § 20.43 (b) and (c) of this chapter, such petition shall demonstrate that either (i) the person is indigent and his participation has a strong public interest justification, or (ii) such participation is in the public interest because it can be considered primarily as benefiting the general public.

(2) If the Commissioner grants such petition, the participant shall be permitted to file only one copy of each submission with the Hearing Clerk, and it shall be the responsibility of the Hearing Clerk to make sufficient additional copies for the administrative record and to serve a copy upon each other participant.

§ 13.25 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 13.5, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the existing administrative record of the proceeding. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be submitted to the Hearing Clerk or placed on public display and shall not be part of the administrative record of the proceeding.

(2) A list of all persons whose views will be presented orally or in writing at the hearing.

(3) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(4) All other documentary data and information on which he relies.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within the time prescribed in the notice of hearing published pursuant to § 13.5, each participant shall submit to the Hearing Clerk all data and informa-

tion specified in paragraph (a) (2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a)(1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the Board, upon a showing that the views of the persons or the material contained in the supplement were not known or reasonably available when the initial submission was made or that the relevance of the views of the persons or the material contained in the supplement could not reasonably have been foreseen.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall constitute a waiver of the right to a hearing.

(e) The Chairman of the Board shall rule on questions relating to this section. Any participant dissatisfied with any such ruling may petition the Commissioner for interlocutory review of that ruling.

§ 13.30 Proceedings of a Public Board of Inquiry.

(a) The purpose of a Board is to review medical, scientific, and technical issues fairly and expeditiously in order to reach a reasonable decision that is sound from a medical, scientific, and technical standpoint. The proceedings of a Board shall be conducted in the manner of a scientific inquiry rather than as a legal trial.

(b) Prior to the first hearing of a Board, all participants in the hearing shall have submitted to the Hearing Clerk the data and information required to be disclosed pursuant to § 13.25, subject to the sanctions specified in § 13.25(d).

(c) The Chairman of a Board shall call the first hearing of the Board at a reasonable time subsequent to receipt of the data and information specified in paragraph (b) of this section. Notice of the time and location of such hearing shall be published in the FEDERAL REGISTER at least 15 days in advance and the hearing shall be open to the public. The director of the bureau responsible for the matter, the other parties, and all other participants shall have an opportunity at the first hearing to make an oral presentation of the data, information, and views which in their opinion are pertinent to resolution of the issues being considered by a Board. The Chairman shall determine the order in which these presentations shall be made. Each initial presentation shall be made without interruption from other participants, but members of the Board may ask any questions that they wish. At the conclusion of each presentation, each of the other participants may briefly state questions and criticism of the presentation and may request that the Board conduct further questioning with respect to specified matters. The Chairman and members of the Board may then ask further questions, and the Chairman may permit any other participant in the proceeding to ask questions if he determines this will facilitate resolution of the issues.

(d) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participant may interrupt the presentation of another participant for any reason.

(e) Within the time specified by a Board after its first hearing is concluded, each participant in the proceeding may submit in writing such rebuttal data, information, and views as he believes relevant to the issues, in accordance with the requirements of § 13.30. The Chairman of the Board shall thereafter schedule a second hearing if requested and justified by any participant. A second hearing, and any subsequent hearing, shall be called only if the Chairman concludes that it is necessary for the full and fair presentation of information that cannot otherwise adequately be considered and for the proper resolution of the issues involved. Notice of the time and location of any such subsequent hearings shall be published in the FEDERAL REGISTER at least 15 days in advance of the date of such hearing and the hearings shall be open to the public.

(f) A Board may consult with any person who it concludes may have data, information, or views relevant to resolution of the issues involved.

(1) Such consultation shall occur only at an announced hearing of a Board, and all participants shall have the right to be present and to suggest or, with the permission of the Chairman, conduct questioning of such consultant and to present rebuttal data, information, and views, as provided in paragraphs (c) and (d) of this section, except that written statements may be submitted to the Board with the consent of all participants.

(2) Any participant may submit to the Board a request that it consult with a specific person who may have data, information, or views relevant to the resolution of the issues. Such requests shall state the reasons why the person named should be consulted and why the views of that person cannot reasonably be furnished to the Board by any means other than having the Food and Drug Administration arrange for his appearance at a hearing of the Board. The Board may, in its discretion, grant or deny such a request.

(g) All hearings of a Board at which data, information, and views are presented shall be transcribed. All such hearings shall be open to the public, except that the presentation of data and information which are prohibited from public disclosure pursuant to the provisions of § 10.20(j)(3) of this chapter shall be closed to all persons except the persons making and participating in the presentation and Federal Government Executive Branch employees and special government employees. At least a majority of the members of the Board shall be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, shall be closed and shall not be transcribed. The report of the Board shall be voted upon by all members of the Board.

(h) All legal questions shall be referred to the Chief Counsel for the Food and Drug Administration for resolution. Any advice on any matter of procedure or any question of legal authority provided by the Chief Counsel shall be transmitted in writing and made a part of the record or presented in open session and transcribed.

(i) After the conclusion of all public hearings a Board shall announce that the record is closed with respect to the gathering of data and information. The Board shall provide an opportunity for all participants to submit a written statement of their positions, with proposed findings and conclusions, and may, in its discretion, provide an opportunity for participants to summarize their positions orally to assist the Board in its deliberations on the issues involved.

(j) At the conclusion of its deliberations, a Board shall prepare its decision on all of the issues, which shall include specific findings and references supporting and explaining its conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report stating additional or dissenting views.

Subpart C—Records of a Public Hearing Before a Public Board of Inquiry

§ 13.40 Administrative record of a Public Board of Inquiry.

(a) The administrative record of a hearing before a Board shall consist of the following:

(1) All relevant FEDERAL REGISTER notices.

(2) All written submissions pursuant to § 13.20.

(3) The transcripts of all hearings of the Board.

(4) The recommended or initial decision of the Board.

(b) The record of the administrative proceeding shall be closed:

(1) With respect to the gathering of information and data, at the time specified in § 13.30(i).

(2) With respect to pleadings, at the time specified in § 13.30(i) for the filing of a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time prior to the filing of a recommended or initial decision.

§ 13.45 Examination of administrative record.

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing shall be governed by the provisions of § 10.20(j) of this chapter. Each document which is available for public examination or copying

shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

(b) Lists of nominees and comments thereon submitted pursuant to § 13.10 (b)(3) shall be subject to the provisions of § 10.20(j)(3) of this chapter.

§ 13.50 Record for administrative decision.

The administrative record of the hearing specified in § 13.40(a) shall constitute the exclusive record for decision.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

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AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-609 as amended (21 U.S.C. 41-50); sec. 1 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1295 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 14.1 Scope.

(a) This part governs the practices and procedures applicable whenever:

(1) The Commissioner concludes, in his discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee, hereinafter an "advisory committee" or "committee," to hold a public hearing and to review and make recommendations with respect to any matter or class of matters of importance pending before the Food and Drug Administration, and for interested persons to present data, information, and views at an oral public hearing before the advisory committee.

(2) Pursuant to specific provisions in other sections of this chapter, a matter pending before the Food and Drug Administration is subject to a public hearing before an advisory committee. Such specific provisions are:

(i) Section 14.120 relating to review of a performance standard for an electronic product by the Technical Electronic Product Radiation Safety Standards Committee.

(ii) Section 14.140 relating to review of the safety of color additives.

(iii) Section 14.160 relating to review of the safety and effectiveness of human prescription drugs.

(iv) Section 330.10 of this chapter relating to review of the safety and effectiveness of over-the-counter drugs.

(v) Section 601.25 of this chapter relating to review of the safety and effectiveness of biological drugs.

(3) A person who has a right to an opportunity for a formal evidentiary public hearing under Part 12 of this chapter waives that opportunity and in lieu thereof requests pursuant to § 12.32 of this chapter a public hearing before a public advisory committee pursuant to this subpart, and the Commissioner, in his discretion, accepts this request.

(b) In determining whether a group is a "public advisory committee" as defined in § 10.3(a)(14) of this chapter and thus subject to the requirements of this part and of the Federal Advisory Committee Act, the following guidelines shall be used:

(1) An advisory committee may be a standing advisory committee or an ad hoc advisory committee. All standing advisory committees shall be listed in § 14.100.

(2) An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific technical or scientific issues, which may relate to regulatory decisions before the agency.

(3) An advisory committee includes any subgroup thereof when it is working on behalf of the committee. Section 14.40 (d) describes when a subgroup will be established as an advisory committee separate and independent from the parent committee.

(4) A committee composed entirely of full-time Federal government employees is not an advisory committee.

(5) An advisory committee shall ordinarily have a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, e.g., a chairman and staff, and shall serve as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest.

(i) A group of persons convened on an ad hoc basis to discuss a matter of current interest to the agency, but which has no continuing function or organization, does not involve substantial special preparation, and does not as a group issue a report to or advise the agency, is not an advisory committee.

(ii) A group of two or more agency consultants meeting with the agency on an ad hoc basis is not an advisory committee.

(iii) A group of experts who are employed by a private company or a trade association which has been requested by the agency to provide its views on a regulatory matter pending before the agency is not an advisory committee.

(iv) A consulting firm hired by the agency to provide advice regarding a matter is not an advisory committee.

(6) An advisory committee which is utilized by the agency is subject to the requirements of this subpart even though it was not established by the agency. In general, a committee is "utilized" by the agency when the agency requests advice or recommendations from the committee on a specific matter in order to obtain an independent review and consideration of the matter, and not when the agency is merely seeking the comments of all interested persons or of persons who have a specific interest in the matter involved.

(i) A committee formed by an independent scientific or technical organization is utilized by the agency if the agency requests the advice of that committee rather than of the parent organization, or if the circumstances show that the advice given is that of the committee and not of the parent organization. A committee formed by an independent scientific or technical organization is not utilized by the agency if the agency requests advice of the organization rather than of a committee and if the recommendations of any committee formed in response to the agency's request for advice are subject to substantial independent policy and factual review by the governing body of the parent organization.

(ii) A committee is not utilized by the agency if it provides only data and information, as contrasted with advice or opinions or recommendations.

(iii) The Food and Drug Administration is charged with seeking out the views of all segments of the public on enforcement of the laws administered by the Commissioner. The fact that a group of individuals or a committee meets regularly with the agency, e.g., a monthly meeting with consumer representatives, does not make that group or committee an advisory committee. Thus, the provisions of this subpart are not applicable to routine meetings, discussions, and other dealings, including exchanges of views, between the agency and any committee representing or advocating the particular interests of consumers, industry, professional organizations, or others.

(7) The inclusion of one or two agency consultants who are special government employees on an internal agency committee does not make that committee an advisory committee.

(8) A Public Board of Inquiry established under Part 13 of this chapter or other similar group convened by agreement between the parties to a regulatory proceeding pending before the Food and Drug Administration, to review and prepare an initial decision on the issue in lieu of a formal evidentiary public hearing, is acting as an administrative law tribunal and is not an advisory committee.

(9) An open public conference or meeting conducted pursuant to § 10.65(b) of this chapter is not an advisory committee meeting.

(c) The provisions of this part apply only when a committee convenes to conduct committee business. Site visits, social gatherings, informal discussions by telephone or during meals or while traveling or at other professional functions, or other similar activities do not constitute a meeting.

(d) An advisory committee which is utilized but not established by the Food and Drug Administration shall be subject to the provisions of this part only to the extent of such utilization, and not with respect to any other activities of such committee.

(e) Any conference or meeting between an employee of the Food and Drug Administration and a committee or group which is not an advisory committee shall be subject to the provisions of § 10.65 of this chapter or other provisions specifically applicable to such committee or group, e.g., Part 13 of this chapter for a Public Board of Inquiry.

(f) The provisions of this part shall apply to all Food and Drug Administration advisory committees, except to the extent that specific statutory requirements provide otherwise for a particular committee, e.g., the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), the Board of Tea Experts, and advisory committees established under the Medical Device Amendments of 1976.

§ 14.5 Purpose of proceedings before a public advisory committee.

(a) An advisory committee shall be utilized to conduct public hearings on matters of importance that come before the Food and Drug Administration, to review the issues involved, and to provide advice and recommendations to the Commissioner on such matters.

(b) The Commissioner shall have sole discretion with respect to action to be taken and policy to be expressed on any matter considered by an advisory committee.

§ 14.7 Administrative remedies.

Any person who alleges noncompliance by the Commissioner or an advisory committee with any provision of this part or the Federal Advisory Committee Act may pursue the following administrative remedies.

(a) If the person objects to any action, including a failure to act, other than denial of access to an advisory committee document, he shall submit a petition in the form and pursuant to the requirements specified in § 10.30 of this chapter. The provisions of § 10.45 of this chapter relating to exhaustion of administrative remedies shall be applicable.

(1) If the person objects to past action, the petition shall be submitted within 30 days after the action objected to. If the Commissioner determines that there was noncompliance with any provision of this subpart or of the Federal Advisory Committee Act, he shall grant any appropriate relief and shall take appropriate steps to prevent its recurrence in the future.

(2) If the person objects to proposed future action, the Commissioner shall expedite his review of the petition and shall make a reasonable effort to render a decision prior to the action which is the subject of the petition.

(3) If the person objects to action that is imminent or is occurring and which could not reasonably have been anticipated in advance, e.g., the closing of a portion of a meeting which is made known for the first time on the day of the meeting, the matter may be handled by an oral petition in lieu of a written petition.

(b) If the person objects to a denial of access to an advisory committee document, administrative review shall be pursued in accordance with the procedures established by the Department of Health, Education, and Welfare under 45 CFR 5.82.

§ 14.10 Applicability to Congress.

The provisions of this part shall apply to Congress, individual members of Congress, and other employees or representatives of Congress in the same way that they apply to any other member of the public, except that disclosure of advisory committee records to Congress shall be governed by the provisions of § 20.87 of this chapter.

§ 14.15 Committees working pursuant to a contract with the Food and Drug Administration.

(a) The Food and Drug Administration may enter into contracts with independent scientific or technical organizations to obtain advice and recommendations on particular matters, and such organizations may in turn undertake such work through existing or new committees. Whether a particular committee working pursuant to such a contract is a public advisory committee and thus subject to all of the provisions of the Federal Advisory Committee Act and this subpart will depend upon application of the criteria and principles established in § 14.1(b).

(b) The following minimum standards shall apply to any committee of an independent scientific or technical organization which is working pursuant to a contract initially executed with the Food and Drug Administration subsequent to July 1, 1975, but which is determined not to be a public advisory committee:

(1) The committee shall give public notice of its meetings and agenda, and shall provide any interested person an opportunity to submit data, information, and views, in writing at any time, and orally at specified times, relevant to the matter which is the subject of the contract. Such notice may be published in the FEDERAL REGISTER or disseminated by any other reasonable means, and shall in any event be filed with the Hearing Clerk not less than 15 days before the meeting. The length of time permitted for oral presentations and the extent to which the committee meets in open session other than for such oral presenta-

tions is in the discretion of the committee.

(2) Minutes of all open sessions shall be maintained, to which shall be attached all written submissions made to the committee in open session. After approval, such minutes shall be forwarded to the Hearing Clerk and placed on public display. The extent to which the committee maintains minutes of closed sessions is at the discretion of the committee.

(3) In selecting the members of the Committee, the organization involved shall apply the same principles relating to conflicts of interest as the Food and Drug Administration does in establishing a public advisory committee. Such principles are set out or cross-referenced in this part and in Part 19 of this chapter. Upon request, the Food and Drug Administration will assist or provide guidance to any such organization in meeting this requirement.

§ 14.19 Application of anticancer clauses.

Whenever the Commissioner concludes that it is appropriate to obtain an independent review of any scientific issue involving application of the anticancer clauses in section 409(c)(3)(A), 512(d)(1)(H), or 706(b)(5)(B) of the act, including whether a substance has been found to induce cancer when ingested by man or animal, and whether a substance has been found, after appropriate tests other than ingestion, to induce cancer in man or animal, he shall ordinarily refer such matter to the Toxicology Advisory Committee which shall hold a public hearing and provide advice and recommendations to the Commissioner on such matter, except as specifically required by the provisions of section 706(b)(5)(C) of the act and § 14.147(a)(2) relating to color additives.

Subpart B—Public Advisory Committee Meeting Procedures

§ 14.20 Notice of public hearing before a public advisory committee.

(a) Before the first day of each month, and at least 15 days before any meeting so announced, the Commissioner shall publish a notice in the FEDERAL REGISTER containing information on all advisory committee meetings to be held during the subsequent month. Any advisory committee meetings for that month called subsequent to the publication of the general monthly notice shall be announced in the FEDERAL REGISTER on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to the notice requirements of this section in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice shall be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the FEDERAL REGISTER.

(b) The FEDERAL REGISTER notice shall include:

(1) The name of the advisory committee.

(2) The date, time, and place of the meeting.

(3) The general function of the advisory committee.

(4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting.

(5) If any portion of the meeting is closed, a statement of the time of the open and closed portions.

(6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting.

(7) The time specifically set aside for oral statements by interested persons and for other public participation.

(8) The name, address, and telephone number of the advisory committee executive secretary and any other agency employee designated as responsible for the administrative support for the advisory committee.

(9) A statement that written submissions may be made to the advisory committee, through the executive secretary, at any time, unless a cutoff date has been established under § 14.35(c)(2).

(10) Where a notice is published in the FEDERAL REGISTER less than 15 days before a meeting, an explanation for the lateness of the notice.

(c) If a public hearing before a public advisory committee is being used in lieu of a formal evidentiary public hearing as provided in § 14.1(a)(3), an initial notice of hearing shall be published separately in the FEDERAL REGISTER containing all the information described in § 12.32(e) of this chapter. Such a separate notice may also be published in the FEDERAL REGISTER with respect to any other public hearing before a public advisory committee when the Commissioner concludes, in his discretion, that it would be informative to the public.

(d) A list of public advisory committee meetings shall be distributed to the press by the Assistant Commissioner for Public Affairs.

(e) All public advisory committee meetings shall be included on the public calendar described in § 10.100(a) of this chapter.

§ 14.22 Meetings of a public advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or his alternate. No such meeting shall be held in the absence of such designated Federal employee.

(1) If any matter is added to the agenda after its publication in the FEDERAL REGISTER pursuant to § 14.5(b)(4), an attempt shall be made to so inform any person known to be interested in such matter, and the addition of such matter shall be announced at the beginning of the open portion of the meeting.

(2) The advisory committee meeting shall be conducted in accordance with the approved final agenda insofar as is practical.

(b) Advisory committee meetings shall be held at places that are reasonably accessible to members of the public. All advisory committee meetings shall be held in Washington, DC, or Rockville, MD, or the immediate vicinity, unless the Commissioner receives a written request from the advisory committee for, and approves, a different location. A different location may be approved when one or more of the following applies:

(1) The total cost of the meeting to the government will be reduced.

(2) A substantial number of the advisory committee members will be at the location at no expense to the Food and Drug Administration for other reasons, e.g., for a meeting of a professional association.

(3) It is a central location which is more readily accessible to advisory committee members.

(4) There is a need for increased participation available at that location.

(5) The advisory committee wishes to review work or facilities in a specific location.

(6) The advisory committee is concerned with matters that functionally or historically occur in some other location; e.g., the Board of Tea Experts and the National Center for Toxicological Research, Science Advisory Board will generally hold meetings in Brooklyn, NY and in the Little Rock, AR vicinity, respectively.

(c) Advisory committee members may, with the approval of the Food and Drug Administration, conduct onsite visits relevant to the work of the advisory committee.

(d) A quorum for an advisory committee shall be a majority of the current voting members of the advisory committee, except as provided in § 14.125(c) for TEPRSSC. Any matter before the advisory committee shall be decided by a majority vote of the voting members present at the time, except that the designated Federal official may require that any final report be voted upon by all current voting members of the advisory committee. Any current voting member of the advisory committee may file a separate report with additional or minority views.

(e) Subject to availability of space, any interested person may attend any portion of any advisory committee meeting which is not closed.

(f) Whenever feasible, meetings shall be held in government facilities or other facilities involving the least expense to the public. The size of the meeting room shall be reasonable, considering such factors as the size of the advisory committee, the number of members of the public who could be expected to attend a particular meeting, the number of persons who attended or sought to attend similar meetings in the past, and the resources and facilities available.

(g) Any portion of a meeting shall be closed by the advisory committee chairman only when matters which have been determined by the Commissioner to be closed in accordance with § 14.60 are to be discussed. Where a portion of the meeting is closed, the closed portion shall be held after the conclusion of the open portion whenever practicable.

(h) Any advisory committee member may take notes during advisory committee meetings and report and discuss ad-

visory committee deliberations after a meeting is completed and before official minutes or a report are available, within such rules and regulations as are adopted by the Food and Drug Administration and by the advisory committee with the concurrence of the Food and Drug Administration, including all of the following:

(1) There shall be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There shall be no reporting or discussion with respect to any particular matter where the advisory committee or the Food and Drug Administration specifically so directs, e.g., where deliberations are incomplete or involve a sensitive regulatory decision which requires preparation for implementation.

(3) There shall be no reporting or discussion with respect to data or information prohibited from public disclosure pursuant to § 14.75.

(4) Any notes or minutes kept or report prepared by any advisory committee member shall have no status or effect whatever unless adopted as so incorporated into the official minutes or report by the advisory committee. It shall be the responsibility of each advisory committee member to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting he attended.

§ 14.25 Portions of public advisory committee meetings.

An advisory committee meeting shall have the following separable portions:

(a) *The open public hearing.* Every advisory committee meeting shall include an open portion which shall constitute a public hearing during which any interested person may present data, information, or views, orally or in writing, relevant to the advisory committee's agenda or other work. Such hearing shall be conducted in accordance with § 14.29.

(b) *The open committee discussion.* An advisory committee shall discuss any matter pending before it in an open portion of its meeting unless the meeting has been closed with respect to that matter pursuant to § 14.27. To the maximum extent feasible, consistent with the policy expressed in § 14.27, an advisory committee shall conduct its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the chairman of the advisory committee.

(c) *The closed presentation of data.* Data and information which are prohibited from public disclosure pursuant to the provisions of Part 20 of this chapter and the regulations referenced therein shall be presented to the advisory committee in a closed portion of its meeting. If such data and information are presented in the form of a summary which is not prohibited from public disclosure, such presentation shall not be made in a closed portion of its meeting.

(d) *The closed committee deliberations.* Deliberations with respect to matters pending before an advisory committee may be made in a closed portion of its meeting only upon an appropriate determination by the Commissioner pursuant to § 14.27.

§ 14.27 Determination to close portions of public advisory committee meetings.

(a) No advisory committee meeting shall be entirely closed. A portion of an advisory committee meeting may be closed only pursuant to a determination made in writing by the Commissioner, stating the reasons therefor, in accordance with this section.

(b) The executive secretary of an advisory committee or other designated agency employee shall prepare the initial request for a determination to close a portion of an advisory committee meeting, specifying the matter(s) to be discussed during the closed portion and the reasons why the portion should be closed. The Commissioner, based upon this request and with the concurrence of the Chief Counsel, shall determine whether to close a portion of an advisory committee meeting. The reasons for closing a portion of a meeting shall be announced in the FEDERAL REGISTER notice of the meeting published pursuant to § 14.20 in accordance with the following rules:

(1) Any determination to close a portion of a meeting shall restrict such closing to the shortest possible time consistent with the policy established in this section.

(2) A portion of a meeting may be closed only if the Commissioner determines that the closing is permitted under 5 U.S.C. 552b(c), and that the closing is necessary.

(3) Examples of portions of advisory committee meetings which ordinarily may be closed include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(4) Examples of advisory committee meetings which ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs and devices; review of data and information on specific investigational or marketed drugs and devices which have previously been made public; presentation of any other data or information which is not exempt from public disclosure pursuant to 5 U.S.C. 552b(c); and deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

(5) No portion of an advisory committee meeting devoted to matters other than those designated in paragraph (b)(1) through (3) of this section may be closed.

(6) A matter which is properly considered in an open portion of an advisory committee meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise or impinge upon the matters to be discussed in the closed portion.

(c) Attendance at a closed portion of an advisory committee meeting shall be governed by the following rules:

(1) A portion of an advisory committee meeting that has been closed for the presentation or discussion of data and information that constitute trade secrets or confidential commercial or financial information as defined in § 20.61 of this chapter, shall be attended only by voting advisory committee members, nonvoting members representing consumer interests who are also special government employees as provided in § 14.80(b), the executive secretary of the advisory committee, a transcriber, consultants, and such other regular employees of the Food and Drug Administration (including members of the Office of the Chief Counsel) as the chairman of the advisory committee may invite, and, by those persons authorized to be present, as provided in § 14.25(c), for presentation of data and information which are prohibited from public disclosure. Any person making a presentation described in § 14.25(c) may be accompanied by a reasonable number of employees, consultants, or other persons with whom he has a commercial arrangement within the meaning of § 20.81(a) of this chapter.

(2) A portion of an advisory committee meeting that has been closed for consideration of existing internal agency documents falling within § 20.62 of this chapter where premature disclosure is likely to significantly frustrate implementation of proposed agency action; consideration of personnel, medical, and similar files, disclosure of which would constitute a clearly unwarranted invasion of personal privacy within the meaning of § 20.63 of this chapter; or consideration of investigatory records compiled for law enforcement purposes as defined in § 20.64 of this chapter shall be attended only by advisory committee members (including all voting and nonvoting members), the executive secretary of the advisory committee, a transcriber, and such other regular employees of the Food and Drug Administration (including members of the Office of the Chief Counsel) as the chairman of the advisory committee may invite. Consultants, individuals performing personal service contracts, employees of other Federal agencies, and the general public may not attend such portions.

(3) If any person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section attempts to attend a closed portion of an advisory committee meeting without the approval of the executive secre-

tary and the chairman, and the matter is brought to their attention, such person will be required to leave the meeting immediately. Such inadvertent and unauthorized attendance shall not enable other unauthorized persons to attend, nor shall such attendance, of itself, constitute grounds for release of transcripts of such closed portions or any other documents otherwise exempt from disclosure under §14.75 and Part 20 of this chapter.

(4) If any person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section is allowed by the executive secretary and the chairman to attend a closed portion of an advisory committee meeting, that portion shall be open to attendance by any interested person.

§ 14.29 Conduct of a public hearing before a public advisory committee.

(a) For each advisory committee meeting, the open portion for public participation which constitutes a public hearing pursuant to §14.25(a) shall be at least 1 hour long unless the public participation does not last that long, and may last for whatever longer time the advisory committee chairman determines will facilitate the work of the advisory committee. The FEDERAL REGISTER notice published pursuant to § 14.20 shall designate the time specifically reserved for such public hearing, which shall ordinarily be the first portion of the meeting. Further public participation in any open portion of the meeting pursuant to § 14.25(b) shall be solely at the discretion of the advisory committee chairman.

(b) Any interested person who wishes to be assured of the right to make an oral presentation at a particular advisory committee hearing shall so inform the executive secretary of the advisory committee or other designated agency employee, orally or in writing, prior to the advisory committee meeting.

(1) Such person shall state the general nature of the presentation and the approximate time requested. Whenever possible, all written data and information to be discussed by that person at the advisory committee hearing shall be furnished in advance to the executive secretary or other designated agency employee. Such written material may be distributed or mailed to the advisory committee members in advance of the committee meeting if time permits, and otherwise will be distributed to the advisory committee members when they arrive for the meeting. Such mailing or distribution shall be undertaken only by the agency unless the agency specifically permits the person making the presentation to mail or distribute such material.

(2) Prior to the advisory committee hearing, the executive secretary or other designated agency employee shall determine the amount of time allocated to each person for his oral presentation and the time that oral presentation is scheduled to begin. Each such person shall be so informed in writing, or if the time prior to the hearing is short, by telephone. Joint presentations may be required by persons with common interests.

(c) The chairman of the advisory committee shall preside at the hearing pursuant to § 14.30 and shall be accompanied by other advisory committee members who shall serve as a panel in conducting the hearing.

(d) Each person may use his allotted time in whatever way he wishes, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written data, information, or views for inclusion in the record of the hearing, subject to the requirements of § 14.35(c).

(e) If a person is not present at the time specified for his presentation, the persons following will appear in order. An attempt will be made to hear any such person at the conclusion of the hearing. Any interested persons attending the hearing who did not request an opportunity to make an oral presentation shall be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the chairman of the advisory committee, to the extent that time permits.

(f) The chairman and other members of the advisory committee may question any person during or at the conclusion of his presentation. No other person attending the hearing may question a person making a presentation. The chairman may allot additional time to any person when he concludes that it is in the public interest, but may not reduce the time allotted for any person without his consent.

(g) Public participants may question an advisory committee member only with that advisory committee member's permission and only about matters before the advisory committee.

(h) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

§ 14.30 Chairman of a public advisory committee.

(a) The advisory committee chairman shall have the authority to conduct hearings and meetings, including the authority to adjourn any hearing or meeting whenever he determines adjournment to be in the public interest, to discontinue discussion of a particular matter, to conclude the open portion of a meeting, or to take any other action in furtherance of a fair and expeditious hearing or meeting.

(b) If the chairman is not a full-time employee of the Food and Drug Administration, the executive secretary of the advisory committee or other designated agency employee, or his alternate, shall be the designated Federal employee who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn any hearing or meeting whenever he determines adjournment to be in the public interest.

§ 14.31 Consultation by a public advisory committee with other persons.

(a) An advisory committee may confer with any person who may have data, information, or views relevant to any matter pending before the advisory committee.

(b) Any interested person may submit to the advisory committee a written request that it confer with specific persons who may have data, information, or views relevant to any matter pending before the advisory committee. Such request shall state why the advisory committee should confer with the person, and why the views of that person cannot reasonably be furnished to the advisory committee by any other means. The advisory committee may, in its discretion, grant or deny such a request.

(c) When an advisory committee wishes to confer with a person who is not a Federal Government executive branch employee, the committee shall only confer with the person during the open portions of a meeting. Such person may, however, submit his views in writing to the committee as part of the administrative record under § 14.70. Such person shall participate at the closed portions of a meeting only if he is appointed as a special government employee by the Commissioner as provided in paragraph (e) of this section. This paragraph (c) is not intended to bar the testimony of a person during a closed portion of a meeting relative to matters prohibited from public disclosure as provided in § 14.25 (c) and § 14.27(c).

(d) To prevent inadvertent violation of Federal conflict of interest laws and laws prohibiting disclosure of trade secrets (18 U.S.C. 208, 21 U.S.C. 331(j), 18 U.S.C. 1905), Federal executive branch employees who are not employees of the Department shall not confer, testify, or otherwise participate (other than as observers) at any portion of an advisory committee meeting unless they are appointed as special government employees by the Commissioner as provided in paragraph (e) of this section. This paragraph shall not apply to Federal executive branch employees who are appointed as members of the Technical Electronic Product Radiation Safety Standards Committee as provided in § 14.127.

(e) The Commissioner may appoint persons as special government employees to be consultants to a public advisory committee. Such consultants may be appointed to provide expertise, generally concerning a highly technical matter, not readily available from the members of the committee. Such persons may be either from outside the government or from agencies other than the Department of Health, Education, and Welfare. Reports, data, information, and other written submissions made to a public advisory committee by a consultant shall be part of the administrative record itemized in § 14.70

§ 14.33 Compilation of materials for members of a public advisory committee.

The Commissioner shall prepare and provide to all advisory committee members a compilation of materials bearing upon an advisory committee member's duties and responsibilities, including:

(a) All applicable conflict of interest laws and regulations and a summary of their principal provisions.

(b) All applicable laws and regulations relating to trade secrets and confidential commercial or financial information that may not be disclosed publicly and a summary of their principal provisions.

(c) All applicable laws, regulations, and guidelines relating to the subject matter covered by the advisory committee and a summary of their principal provisions.

(d) All applicable laws, regulations, advisory committee charters, FEDERAL REGISTER notices, curricula vitae, rules adopted by the advisory committee, and other material relating to the formation, composition, and operation of the advisory committee, and a summary of their principal provisions.

(e) Instructions on whom to contact when any questions arise.

(f) Such other material relating to the Food and Drug Administration and the subject matter covered by the committee as may facilitate the work of the advisory committee.

§ 14.35 Written submissions to a public advisory committee.

(a) Ten copies of all written submissions for an advisory committee shall be sent to the executive secretary of the advisory committee, unless an applicable FEDERAL REGISTER notice or other regulations in this chapter specify otherwise. All such submissions shall be subject to the provisions of § 10.20 of this chapter, except that no copies need be sent to the Hearing Clerk.

(b) At the request of an advisory committee, or on his own initiative, the Commissioner may at any time issue in the FEDERAL REGISTER a notice requesting the submission to the advisory committee of written data, information, and views pertinent to any matter being reviewed by an advisory committee. Such notice may specify the format in which the submission shall be made, the number of copies to be submitted, and the time within which submission shall be made.

(c) At the request of an advisory committee, or on his own initiative, the Commissioner may at any time request the applicant or sponsor of an application or petition relating to a specific product on which action is pending before the Food and Drug Administration and that is being reviewed by an advisory committee, to present and/or discuss safety, effectiveness, or other data concerning the product being reviewed during a regularly scheduled meeting of the advisory committee. The request may be for an oral presentation to the committee or for a concise, well-organized written summary of pertinent information for review by the committee members prior to the meeting, or both. Unless specified otherwise, one copy of the written summary along with a proposed agenda outlining the topics to be covered and identifying the participating industry staff members or consultants that will present each topic shall be submitted to the executive secretary of the committee or other designated agency employee at least 3 weeks prior to the meeting.

(d) Any interested person may submit to an advisory committee written data, information, or views on any matter being reviewed by that advisory committee. Voluminous data shall be accompanied by a summary.

(1) Any such submission shall be distributed to each advisory committee member, either by mail or at the next advisory committee meeting, and shall be considered by the advisory committee in its review of the matter.

(2) An advisory committee may establish, and shall give public notice of, a cutoff date after which submissions relating to any matter shall no longer be received or considered.

(e) The Commissioner shall provide to an advisory committee all data and information he concludes to be relevant to any matter being reviewed by the advisory committee. Any member of the advisory committee shall, upon request, also be provided any additional material available to the Food and Drug Administration which he believes appropriate for an independent judgment on the matter, e.g., raw data underlying any summary or report, or a briefing on the legal aspects of the matter.

§ 14.39 Additional rules for a particular public advisory committee.

(a) In addition to the rules established for all Food and Drug Administration advisory committees in this subpart, any advisory committee may, with the concurrence of the designated Federal official, adopt additional rules which are not inconsistent with this subpart or with applicable legal requirements.

(b) Such additional rules shall be included in the minutes of the meeting when adopted and in the materials compiled pursuant to § 14.33 and shall be available for public disclosure pursuant to § 14.65(c).

Subpart C—Establishment of Public Advisory Committees

§ 14.40 Establishment and renewal of public advisory committees.

(a) A public advisory committee may be established or renewed whenever it is necessary or appropriate for such an advisory committee to hold a public hearing and to review and make recommendations on any matter pending before the Food and Drug Administration. Before an advisory committee is established or renewed it shall first be approved by the Department pursuant to 45 CFR Part 11 and the Office of Management and Budget pursuant to duly promulgated procedures.

(b) Upon the establishment or renewal of an advisory committee, the Commissioner shall issue in the FEDERAL REGISTER a notice certifying that the establishment or renewal of the advisory committee is in the public interest and stating the structure, function, and purposes of the advisory committee and, if it is a standing advisory committee, shall amend § 14.100 to add it to the list of standing advisory committees. The notice shall be published in the FEDERAL REGISTER at least 15 days prior to the filing of the advisory committee charter pursuant to paragraph (c) of this section.

(c) No advisory committee shall meet or take any action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act. This requirement shall be met by an advisory committee utilized by the Food and Drug Administration, even though it is not established by the agency, prior to such utilization.

(d) The regulations of the Department cited in paragraph (a) of this section provide that the charter of a parent committee may incorporate information concerning activities of a subgroup. In such instances, a subgroup will not be established as a committee distinct from the parent committee. However, a subgroup will be established as a separate committee when the charter of the parent committee does not incorporate the activities of the subgroup, or when the subgroup includes members who are not all drawn from the parent committee.

(e) An advisory committee not required by law will be established or utilized only if it is in the public interest and only if its functions could not reasonably be performed by other existing advisory committees or by the Food and Drug Administration directly.

(f) An advisory committee shall:

(1) Have a clearly defined purpose.

(2) Have a membership that is balanced fairly in terms of the points of view represented in light of the functions to be performed. Although proportional representation is not required, there shall be no discrimination on the basis of race, color, national origin, religion, age, or sex in the selection of advisory committee members.

(3) Be constituted and utilize procedures designed to assure that its advice and recommendations are not inappropriately influenced by any special interest or by the Food and Drug Administration, and are the result of the advisory committee's independent judgment.

(4) Have an adequate staff. The Commissioner shall designate an executive secretary and alternate for every advisory committee, who shall be employees of the Food and Drug Administration. The executive secretary shall be responsible for all staff support for the advisory committee unless other agency employees are specifically designated for this function with respect to particular advisory committees.

(5) Whenever feasible, or required by statute, include representatives of the public interest.

§ 14.55 Termination of public advisory committees.

(a) Except as provided in paragraph (c) of this section, a standing advisory committee shall be terminated when it is no longer needed and in any event shall terminate not later than two years following its date of establishment unless it is renewed for an additional 2-year period. An advisory committee may be renewed for as many 2-year periods as the public interest requires. The requirements for establishment of an advisory committee pursuant to § 14.40 shall also apply to renewal of an advisory committee.

(b) Upon termination of any advisory committee the Commissioner shall issue in the FEDERAL REGISTER a notice announcing the termination and the reasons therefor and, if it is a standing advisory committee, amending § 14.100 to delete it from the list of standing advisory committees.

(c) The Technical Electronic Product Radiation Safety Standards Committee is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act (42 U.S.C. 263f(f)(1)(A)), as added by the Radiation Control for Health and Safety Act of 1968, and is not subject to the termination and renewal provisions of paragraph (a) of this section, except that a new charter shall be prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the act, and the statutory medical device good manufacturing practices advisory committees established under section 520(f)(3) of the act, are specifically exempted from the normal 2-year duration period.

(d) The Board of Tea Experts is a permanent statutory advisory committee established by the Tea Importation Act (21 U.S.C. 42), and is not subject to the termination and renewal provisions of paragraph (a) of this section, except that a new charter shall be prepared and filed at the end of each 2-year period as provided in § 14.40 (c).

(e) Color additive advisory committees are required to be established under the circumstances specified in section 706(b)(5) (C) and (D) of the act. A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this part.

Subpart D—Records of Meetings and Public Hearings Before Public Advisory Committees

§ 14.60 Minutes and reports of public advisory committee meetings.

(a) The executive secretary or other designated agency employee shall prepare detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for open portions of meetings which are transcribed or recorded by the agency. Their accuracy shall be approved by the advisory committee and certified by the advisory committee chairman. Such approval and certification may be accomplished by mail and by telephone.

(b) The minutes shall include:

(1) The time and place of the meeting.

(2) The advisory committee members, committee staff, and agency employees present, and the names and affiliations or interests of public participants in the meeting.

(3) A copy of or reference to all written information made available for consideration by the advisory committee at such proceedings.

(4) A complete and accurate description of matters discussed and conclusions reached. Such description shall be kept separately for the following portions of the meeting to facilitate their public disclosure: The open portions specified in § 14.25 (a) and (b), any closed portion during which a presentation is made pursuant to § 14.25(c), and any closed deliberative portion pursuant to § 14.25(d). The minutes of a closed deliberative portion of a meeting shall not refer to advisory committee members by name, except upon their request, or to data or information described in § 14.75(b). Any such inadvertent references which do occur shall be deleted prior to public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the advisory committee.

(6) The extent to which the meeting was open and closed to the public.

(7) The extent of public participation, including a list of members of the public who presented oral or written statements.

(c) For all advisory committee meetings any portion of which is closed, either (1) the minutes of the closed portion shall be available for public disclosure pursuant to § 14.75(a)(6)(i), or (2) if pursuant to § 14.75(a)(6)(ii) such minutes are not promptly available, the executive secretary or other designated agency employee shall prepare a brief summary of the matters considered in such manner as is informative to the public, consistent with the policy of 5 U.S.C. 552(b).

(d) Where a significant portion of the meetings of an advisory committee is closed, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of 5 U.S.C. 552(b). Such report shall be a compilation of or be prepared from the individual reports on closed portions of meetings prepared pursuant to paragraph (c) of this section.

(e) The executive secretary of each advisory committee or other designated agency employee shall, with the approval of the advisory committee, prepare an annual report describing its membership, functions, recommendations, and other actions.

§ 14.61 Transcripts of public advisory committee meetings.

(a) A transcript or recording shall be made for each portion of every advisory committee meeting. Any such transcription or recording shall be arranged by the agency.

(b) A transcript or recording of an open portion of an advisory committee meeting made by the Food and Drug Administration shall be included in the record of the advisory committee proceedings.

(c) A transcript or recording of any closed portion of an advisory committee meeting made by the Food and Drug Administration shall not be included in the administrative record of the advisory committee proceedings. Such transcript or recording shall be retained as confidential by the Food and Drug Administration and shall not be discarded or erased.

(d) Any transcript or recording of an advisory committee meeting or portion thereof which is publicly available pursuant to this section shall be available at actual cost of duplication, which shall be, where applicable, the fees established in § 20.42 of this chapter. The Food and Drug Administration may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying pursuant to § 20.51 of this chapter.

(e) Any person attending any open portion of an advisory committee meeting may, consistent with the orderly conduct of the meeting, record or otherwise take his own transcript of the meeting. Such transcription shall not be part of the administrative record.

(f) No person attending any closed portion of any advisory committee meeting may record or otherwise take his own transcript of the meeting, except for an official transcript or recording arranged by the Food and Drug Administration.

§ 14.65 Public inquiries and requests for public advisory committee records.

(a) Public inquiries on general advisory committee matters, except requests for records, shall be directed to: Committee Management Officer (HFS–20), Office of the Associate Commissioner for Science, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(b) Public inquires on matters relating to a specific advisory committee, except requests for records, shall be directed to the executive secretary of the advisory committee or other designated agency employee as listed in the FEDERAL REGISTER notices published pursuant to § 14.20.

(c) All requests for public advisory committee records, including minutes, shall be made to the Food and Drug Administration Public Records and Documents Center pursuant to § 20.40 and the related provisions of Part 20 of this chapter.

§ 14.70 Administrative record of a public hearing before a public advisory committee.

(a) Advice or recommendations of an advisory committee shall be given only on matters covered in the administrative record of the advisory committee's proceedings. Except as specified otherwise in regulations in this chapter, such admin-

istrative record shall consist of all of the following:

(1) Any transcript or recording that was made of any open portion of a meeting relating to the matter.

(2) The minutes of all portions of all advisory committee meetings relating to the matter, after any deletions pursuant to § 14.60(b)(4).

(3) All written submissions made to and data and information considered by the advisory committee relating to the matter.

(4) All reports made by the advisory committee relating to the matter.

(b) The record of the administrative proceeding shall be closed at the time the advisory committee renders its advice or recommendations or at any earlier time specified by the advisory committee or in other sections in this chapter.

§ 14.75 Examination of administrative record and other advisory committee records.

(a) The administrative record and other advisory committee records shall be available for public disclosure pursuant to the provisions of Part 20 of this chapter, except as provided in paragraph (b) of this section, at the following time:

(1) The written information made available for consideration by the advisory committee at any meeting, at the same time.

(2) The transcript or recording of any open portion of a meeting, as soon as it is available.

(3) The minutes of any open portion of a meeting, after they have been approved by the advisory committee and certified by the advisory committee chairman.

(4) The brief summary of any closed portion of a meeting prepared pursuant to § 14.60(c), as soon as it is available.

(5) All written data, information, or views submitted to the advisory committee at any open portion of a meeting, as soon as they are so submitted.

(6) The minutes or portions thereof of any closed executive portion of a meeting:

(i) For any matter not directed to be maintained as confidential pursuant to § 14.22(h)(2), after they have been approved by the advisory committee and certified by the advisory committee chairman.

(ii) For any matter directed to be maintained as confidential pursuant to § 14.22(h)(2), after the advice or report of the advisory committee relevant to those minutes or portions thereof is acted upon by the Commissioner, or upon a determination by the Commissioner that such minutes or portions thereof may be made available for public disclosure without undue interference with agency or advisory committee operations.

(7) Any formal advice or report of the advisory committee, after it has been acted upon, i.e., approved, disapproved, or rejected as inadequate, by the Commisioner, or upon a determination by the Commissioner that such formal advice or report may be made available for public disclosure without undue interference with agency and/or advisory committee operations. Such formal advice or report may be retained as confidential while it is under active advisement.

(8) Any other advisory committee records relating to the matter involved, except transcripts and recordings of closed portions of advisory committee meetings, after the advice or report of the advisory committee relevant to those records is acted upon by the Commissioner, or upon a determination by the Commissioner that such records may be made available for public disclosure without undue interference with agency or advisory committee operations.

(b) The following data and information contained in the administrative record shall not be available for public examination or copying except as provided in § 12.32(g) of this chapter:

(1) Material provided to the advisory committee by the Food and Drug Administration which is exempt from public disclosure pursuant to the provisions of Part 20 of this chapter and the regulations referenced therein.

(2) Material provided to the advisory committee by a person making a presentation described in § 14.25(c) and which is prohibited from public disclosure pursuant to the provisions of Part 20 of this chapter and the regulations referenced therein.

(c) The Public Records and Documents Center shall maintain a file for each advisory committee containing the following principal records of that advisory committee for ready access by the public: The advisory committee charter, a list of advisory committee members and their curricula vitae, the minutes of advisory committee meetings, and any formal advice or report of the advisory committee.

Subpart E—Members of Public Advisory Committees

§ 14.80 Qualifications for members of standing policy and technical advisory committees.

(a) Members of policy advisory committees, which advise the Commissioner on broad and general matters, shall possess the following qualifications:

(1) Policy advisory committee members shall possess diverse interests, education, training, and experience. Technical expertise in the subject matter with which the advisory committee is involved shall not be a requirement.

(2) Policy advisory committee members are special government employees and are subject to the conflict of interest laws and regulations. The Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing such interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the government expects from them and thus is hereby exempted pursuant to 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

(3) All members of policy advisory committees shall be voting members.

(b) Members of technical advisory committees, which advise on specific regulatory issues, shall possess the following qualifications:

(1) Voting members of technical advisory committees:

(i) Shall possess expertise in the particular subject matter with which the committee is concerned. Members shall have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it.

(ii) Except for members of the Technical Electronic Product Radiation Safety Standards Committee, are special government employees, subject to the conflict of interest laws and regulations.

(2) The Commissioner shall, when required by statute, and when not required by statute, may provide for nonvoting members of a technical advisory committee to serve as representatives of and liaison with interested organizations. Nonvoting members of technical advisory committees:

(i) Shall be selected by the interested organizations, as provided in § 14.84. Technical expertise in the subject matter with which the advisory committee is involved shall not be a requirement.

(ii) May be special government employees subject to the conflict of interest laws and regulations, except as provided in § 14.84(e).

(c) No person may serve as a voting or nonvoting member on more than one Food and Drug Administration advisory committee unless the Commissioner determines in writing that such dual membership will facilitate the work of the committees involved and is in the public interest.

(d) Members of Food and Drug Administration advisory committees and the chairman thereof shall be appointed from among those nominated pursuant to §§ 14.82 and 14.86 and from any other sources by the Secretary, the Assistant Secretary for Health, or the Commissioner, pursuant to duly promulgated procedures and delegations of authority.

(e) Members appointed to an advisory committee shall continue to serve for the duration of the advisory committee, or until their terms of appointment expire, they resign, or are removed from membership by the Commissioner.

(f) An advisory committee member may be removed from membership by the Commissioner for good cause. Good cause shall include excessive unjustified absenteeism from advisory committee meetings, a demonstrated bias which interferes with the ability to render objective advice, failure to abide by the procedures established in this subpart, or violation of other applicable rules and regulations, e.g., for nonvoting members, the provisions of § 14.86(c).

(g) Consultants appointed pursuant to § 14.31(c) are not members of public advisory committees.

§ 14.82 Nominations of voting members of standing advisory committees.

(a) The Commissioner shall publish one or more notices in the FEDERAL REGISTER each year requesting nominations for voting members of all existing standing advisory committees. Each such notice shall list separately the standing advisory committees covered by the notice in which it is known that vacancies will occur during the next 12 months and in which vacancies are not expected but may occur. The notice shall invite the submission of nominations for voting members for any vacancies from any interested individual as well as from consumer, industry, and professional organizations for the advisory committees listed.

(b) The notice published in the FEDERAL REGISTER announcing the establishment of a new standing advisory committee pursuant to § 14.40(b) shall invite the submission of nominations for voting members for such advisory committee.

(c) Any interested person may nominate one or more qualified persons as a member of a particular advisory committee. Nominations shall specify the advisory committee for which the nominee is recommended. A complete curriculum vitae of the nominee shall be included. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict of interest which would preclude committee membership.

(d) Voting members of standing technical advisory committees shall serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

§ 14.84 Nominations and selection of nonvoting members of standing technical advisory committees.

(a) The provisions of this section shall apply whenever the Commissioner concludes, in his discretion, that a standing technical advisory committee should include nonvoting members in order to represent and serve as a liaison with interested individuals and organizations.

(b) Except where the Commissioner determines otherwise, nonvoting members of a standing technical advisory committee shall be selected in accordance with paragraphs (c) and (d) of this section and shall be limited to one member selected by consumer groups and organizations and one person selected by industry groups and organizations.

(c) With respect to any nonvoting member representing consumer interests, and except as provided in paragraph (c)(5) of this section, the Commissioner shall publish a notice in the FEDERAL REGISTER requesting nominations for each specific standing technical advisory committee, or subcommittee thereof, for which he has determined that nonvoting members are appropriate.

(1) A period of 30 days shall be permitted for submission of such nominations for that particular advisory committee or subcommittee. Any interested person may nominate one or more qualified persons as a nonvoting member of a particular advisory committee to represent consumer interests. Although nominations from individuals will be accepted, individuals are encouraged to submit their nominations through consumer organizations as defined in paragraph (c)(3) of this section. Nominations of qualified persons for general consideration as nonvoting members of unspecified advisory committees or subcommittees may be made at any time. All nominations shall be submitted in writing to Director, Office of Consumer Programs (HFG–1), Office of Assistant Commissioner for Professional and Consumer Programs, Food and Drug Administration, Rm. 15B–41, 5600 Fishers Lane, Rockville, MD 20857.

(2) A complete curriculum vitae of any nominee shall be included. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of an advisory committee, and appears to have no conflict of interest. If a nominee is interested only in a particular advisory committee or subcommittee, the nomination shall so state. If a nominee is interested in becoming a member of any advisory committee or subcommittee, the nomination shall so state. Nominations which do not comply with the requirements of this paragraph shall not be considered.

(3) The Director, Office of Consumer Programs, shall compile a list of organizations whose objectives are to promote, encourage, and contribute to the advancement of consumer education and to the resolution of consumer problems. All organizations listed shall be entitled to vote upon the nominees. The list will include organizations representing the public interest, consumer advocacy groups, and consumer/health branches of Federal, State, and local governments. Any organization that meets the criteria may be included on such list upon request.

(4) The executive secretary, or other designated agency employee, shall review the list of nominees and select three to five qualified nominees to be placed on a ballot. Names not selected will remain on a list of eligible nominees and reviewed periodically by the Office of Consumer Programs to determine continued interest. Upon selection of the nominees to be placed on the ballot, the curriculum vitae for each of the nominees shall be sent to each of the organizations on the list compiled pursuant to paragraph (c)(3) of this section, together with a ballot to be filled out and returned within 30 days. After the time for return of the ballots has expired, the ballots shall be counted and the nominee who has received the highest number of votes shall be selected as the nonvoting member representing consumer interests for that particular advisory committee or subcommittee. In the event of a tie, the Commissioner shall select the winner by lot from among those tied for the highest number of votes.

(5) In the event of the resignation or removal of a member representing consumer interests before termination of the advisory committee on which the member is serving, the following procedures shall be used to appoint a replacement to serve out the term of the former member.

(i) The Commissioner shall appoint the runner-up, in order of number of ballots received, on the original ballot submitted pursuant to paragraph (c)(4) of this section to fill the vacancy. If the runner-up is no longer willing to serve as a member, then the next runners-up shall be appointed.

(ii) If none of the nominees on the original ballot is willing to serve, or if there was only one nominee on the original ballot, the Office of Consumer Programs shall contact by telephone eligible individuals whose names have been submitted in the past as candidates for membership as representatives of consumer interests. A list of persons who are interested in serving on an advisory committee shall then be prepared. The curricula vitae of these persons, together with a ballot, shall be sent to a representative number of consumer organizations that have been determined to be eligible to vote for consumer representatives in accordance with paragraph (c)(3) of this section. After 4 days have elapsed, the Office of Consumer Programs shall contact the consumer organizations by telephone and elicit their votes. The candidate who has received the highest number of votes shall be selected. In the event of a tie, the Commissioner shall select the winner by lot from among those tied for the highest number of votes.

(d) With respect to any nonvoting member representing industry interests, the Commissioner shall issue in the FEDERAL REGISTER, for each specific standing technical advisory committee for which he has determined that nonvoting members are appropriate, a notice requesting that any industry organization interested in participating in the selection of an appropriate nonvoting member representing industry interests send a letter stating that interest to the Food and Drug Administration employee designated in the notice within 30 days. After the time for such expression of interest has expired, a letter shall be sent to each organization which has expressed such an interest, attaching a complete list of all such organizations, and stating that it is their responsibility to consult with each other in selecting a single nonvoting member representing industry interests for that particular advisory committee within 60 days after receipt of the letter. If no such individual is so selected within that period of time, the Commissioner shall select the nonvoting member representing industry interests to serve on that advisory committee.

(e) The Commissioner has determined that, because nonvoting members representing consumer and industry interests are included on advisory committees specifically for the purpose of representing such interests and have no vote, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the government expects from them

and thus is hereby exempted pursuant to 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

§ 14.86 Rights and responsibilities of nonvoting members of advisory committees.

(a) A nonvoting member of an advisory committee selected to represent and serve as a liaison with interested individuals, associations, and organizations, shall have the same rights as any other advisory committee member except that:

(1) A nonvoting member shall not vote on any matter before the advisory committee except such procedural matters as additional rules adopted pursuant to § 14.39(a), approval of minutes pursuant to § 14.60(a), decisions relating to transcripts pursuant to § 14.61(b), and future meeting dates.

(2) No nonvoting member who is not a representative of consumer interests and who has not also been appointed as a special government employee as provided in § 14.80(b) shall have access to data and information that constitute a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(b) A nonvoting member of an advisory committee is subject to, and shall abide by, all rules and regulations adopted by the Food and Drug Administration and the advisory committee.

(c) It is the responsibility of the nonvoting consumer and industry members of an advisory committee to represent the consumer and industry interests in all deliberations.

(1) A nonvoting member does not represent any particular organization or group, but rather represents all interested persons within the class which he is selected to represent. Accordingly, any interested person within the class represented by that nonvoting member shall, upon request, have access to all written statements or oral briefings related to the committee prepared by the nonvoting member for distribution to any person outside the advisory committee. When documents are prepared with nongovernment funds, persons desiring copies may be required to pay a reasonable fee to cover printing and similar costs.

(2) The nonvoting member shall review all official advisory committee minutes to assure their completeness and accuracy.

(3) The nonvoting member shall act as a liaison and conduit between the advisory committee and the interested persons whom he represents, and shall transmit requests for information from the committee and relevant data, information, and views to the committee. He shall take the initiative in contacting interested persons whom he represents, to seek out relevant data, information, and views, and to relate the progress of the advisory committee.

(4) A nonvoting industry member shall represent all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the committee that directly or indirectly affects the company which employs the nonvoting industry member, he shall so inform the committee but need not absent himself during the discussion or decline to participate in the discussion. A nonvoting industry member shall not discuss his company's position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company shall occur in open session, except as provided in § 14.25(c).

(5) A nonvoting member of an advisory committee shall not make any presentation to that advisory committee during a hearing conducted by that advisory committee.

(6) Although a nonvoting member is serving in a representative capacity, he shall exercise restraint in performing his functions and shall not engage in unseemly advocacy or attempt to exert undue influence over the other members of the committee.

(d) A nonvoting member of an advisory committee may be removed by the Commissioner for failure to comply with the provisions of this section as well as § 14.80(f).

§ 14.90 Ad hoc advisory committee members.

In selecting members of an ad hoc advisory committee, the Commissioner may utilize the procedures established in §§ 14.82 and 14.84 or any other procedure he concludes to be appropriate under the circumstances.

§ 14.95 Compensation of public advisory committee members.

(a) All voting advisory committee members shall, and any nonvoting members may, (1) be appointed as special government employees, except for members of the Technical Electronic Product Radiation Safety Standards Committee, and (2) receive a consultant fee and be reimbursed for their travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement is waived.

(b) An advisory committee member, notwithstanding his primary residence, while in attendance at meetings of the full committee, or of a subcommittee, will be paid whether the meetings are held in the Washington, DC area or elsewhere.

(c) An advisory committee member who participates in any agency-directed assignment will be paid at an hourly rate when he performs his work at his home, place of business, or in a Food and Drug Administration facility located within his commuting area, and at a daily rate when he is required to travel outside of his commuting area to perform his assignment. An advisory committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment which meets the following criteria:

(i) An activity which requires undertaking a definitive study. The activity must produce a tangible end product, usually a written report. Examples are (*a*) an analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA; (*b*) the performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation; (*c*) the preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and (*d*) the design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) An advisory committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of his own assignment, can be compensated. Should such preparatory work by advisory committee members collectively result in an end product of the advisory committee, this is to be considered normal meeting preparation and advisory committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when an advisory committee member has his ordinary pursuits interrupted for the substantial portion of an additional day beyond the day or days on which he performs services, and as a consequence he sustains a loss in his regular compensation. This applies on weekends and holidays if the special government employee suffers a loss in income he would otherwise earn on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

Subpart F—Standing Advisory Committees

§ 14.100 List of standing advisory committees.

The following standing advisory committees have been established for the Food and Drug Administration.

(a) *Office of the Commissioner*—(1) *Board of Tea Experts.* (i) Date established: March 2, 1897.

(ii) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States pursuant to 21 U.S.C. 42.

(2) *National Advisory Food and Drug Committee.* (i) Date established: November 15, 1974.

(ii) Function: Reviews and evaluates agency programs and advises on policy matters of national significance as they relate to the statutory mission of the Food and Drug Administration in the areas of foods, drugs, cosmetics, medical devices, biological products, and electronic products. Reviews and makes recommendations on applications for grants-in-aid for research projects relevant to the mission of the Food and Drug Administration as required by law.

(3) *Toxicology Advisory Committee.* (i) Date established: December 9, 1974.

(ii) Function: Reviews and evaluates available data relating to the evaluation of the safety of chemicals present in foods, drugs, cosmetics, and medical devices. Advises on the safety of specific human drugs, animal drugs, color and food additives, cosmetic components, and components of devices. Recommends the development of standardized methodologies for the toxicity testing of such materials.

(b) *Bureau of Biologics.* (1) Advisory review panels for biological products, and dates established. (i) *Bacterial Vaccines and Bacterial Antigens Panel.* Established December 22, 1972.

(ii) *Bacterial Vaccines and Toxoids Panel.* Established April 16, 1973.

(iii) *Viral Vaccines and Rickettsial Vaccines Panel.* Established April 16, 1973.

(iv) *Skin Test Antigens Panel.* Established August 24, 1973.

(v) *Allergenic Extracts Panel.* Established August 24, 1973.

(vi) *Blood and Blood Derivatives Panel.* Established August 24, 1973.

(2) Function: Reviews and evaluates available data concerning the safety and effectiveness of biological products.

(c) *Bureau of Drugs*—(1) *Anesthesiology Advisory Committee.* (i) Date established: March 23, 1966.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the field of anesthesiology.

(2) *Anti-Infective Agents Advisory Committee.* (i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases.

(3) *Arthritis Advisory Committee.* (i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in arthritic conditions.

(4) *Biometric and Epidemiological Methodology Advisory Committee.* (i) Date established: March 7, 1968.

(ii) Function: Reviews and evaluates scientific studies and data with respect to, and otherwise advises the Commissioner on, epidemiological and biometrical methodology.

(5) *Cardiovascular and Renal Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in cardiovascular and renal disorders.

(6) *Controlled Substances Advisory Committee.* (i) Date established: September 27, 1973.

(ii) Function: Advises the Commissioner regarding the scientific and medical evaluation of all information gathered by the Department of Justice and the Department of Health, Education, and Welfare with regard to safety, effectiveness, and abuse potential of drugs or other substances classified as stimulants, sedatives, hypnotics, or analgesics, and recommends actions to be taken with regard to control of such substances.

(7) *Dental Drug Products Advisory Committee.* (i) Date established: June 6, 1972.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the practice of dentistry.

(8) *Dermatology Advisory Committee.* (i) Date established: June 20, 1975.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the practice of dermatology.

(9) *FDA/NIDA Drug Abuse Research Advisory Committee.* (i) Date established: March 9, 1967.

(ii) Function: Advises the Food and Drug Administration on action to be taken with respect to investigational use of substances with abuse potential. Advises the National Institute on Drug Abuse on supplies of substances for clinical studies and on quantities of substances for animal and in vitro studies. Advises FDA and NIDA on development of broad outlines for studies of substances with abuse potential and on new methods and tests in animals and man by which the dependence liability of investigational drugs may be estimated.

(10) *Endocrinology and Metabolism Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in endocrine and metabolic disorders.

(11) *Gastrointestinal Drugs Advisory Committee.* (i) Date established: January 3, 1974.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in gastrointestinal diseases.

(12) *Neurologic Drugs Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in neurologic disease.

(13) *Obstetrics and Gynecology Advisory Committee.* (i) Date established: August 31, 1965.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of obstetrics and gynecology.

(14) *Oncologic Drugs Advisory Committee.* (i) Date established: October 24, 1973.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of cancer.

(15) *Ophthalmic Drugs Advisory Committee.* (i) Date established: September 20, 1971.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in diseases and disorders of the eye.

(16) *Psychopharmacological Agents Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of psychiatry and related fields.

(17) *Pulmonary-Allergy and Clinical Immunology Advisory Committee.* (i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(18) *Radiopharmaceutical Advisory Committee.* (i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the practice of nuclear medicine.

(19) *Surgical Drugs Advisory Committee.* (i) Date established: September 14, 1971.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the field of surgery.

(20) *Advisory review panels for over-the-counter (OTC) drugs.* (i) Dates established.

(*a*) *Antimicrobial Panel.* Established March 16, 1972.

(*b*) *Internal Analgesic Panel.* Established August 31, 1972.

(*c*) *Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Panel.* Established September 19, 1972.

(*d*) *Sedative, Tranquilizer, and Sleep Aid Panel.* Established September 19, 1972.

(*e*) *Laxative, Antidiarrheal, Antiemetic, and Emetic Panel.* Established December 27, 1972.

(*f*) *Topical Analgesic Panel.* Established December 27, 1972.

(*g*) *Dentifrice and Dental Care Panel.* Established December 27, 1972.

(*h*) *Hemorrhoidal Panel.* Established April 16, 1973.

(*i*) *Ophthalmic Panel.* Established April 16, 1973.

(*j*) *Contraceptive and Other Vaginal Drug Products Panel.* Established June 27, 1973.

(*k*) *Oral Cavity Panel.* Established July 16, 1973.

(*l*) *Antiperspirant Panel.* Established July 16, 1973.

(*m*) *Miscellaneous Internal Drug Products Panel.* Established July 16, 1973.

(*n*) *Miscellaneous External Drug Products Panel.* Established July 16, 1973.

(o) *Vitamin, Mineral, and Hematinic Panel.* Established July 16, 1973.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of nonprescription drug products.

(d) *Bureau of Medical Devices and Diagnostic Products.* (1) Advisory review panels for medical devices, and dates established.

(i) *Anesthesiology Device Classification Panel.* Established August 9, 1976.

(ii) *Cardiovascular Device Classification Panel.* Established August 9, 1976.

(iii) *Clinical Chemistry Device Classification Panel.* Established August 10, 1976.

(iv) *Clinical Toxicology Device Classification Panel.* Established August 10, 1976.

(v) *Dental Device Classification Panel.* Established August 9, 1976.

(vi) *Ear, Nose, and Throat Device Classification Panel.* Established August 9, 1976.

(vii) *Gastroenterological and Urological Device Classification Panel.* Established August 9, 1976.

(viii) *General and Plastic Surgery Service Classification Panel.* Established August 9, 1976.

(ix) *General Hospital and Personal Use Device Classification Panel.* Established August 9, 1976.

(x) *Hematology Device Classification Panel.* Established August 10, 1976.

(xi) *Immunology Device Classification Panel.* Established August 10, 1976.

(xii) *Microbiology Device Classification Panel.* Established August 10, 1976.

(xiii) *Neurological Device Classification Panel.* Established August 9, 1976.

(xiv) *Obstetrical and Gynecological Device Classification Panel.* Established August 9, 1976.

(xv) *Ophthalmic Device Classification Panel.* Established August 9, 1976.

(xvi) *Orthopedic Device Classification Panel.* Established August 9, 1976.

(xvii) *Pathology Device Classification Panel.* Established August 10, 1976.

(xviii) *Physical Medicine Device Classification Panel.* Established August 9, 1976.

(xix) *Radiological Device Classification Panel.* Established August 9, 1976.

(xx) *Diagnostic Products Advisory Committee.* Established August 9, 1972.

(2) Function: Reviews and evaluates available data concerning the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(3) *Device Good Manufacturing Practice Advisory Committee.* (i) Date established: August 12, 1976.

(ii) Function: Reviews proposed regulations regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations regarding feasibility and reasonableness of the proposed regulations.

(e) *Bureau of Radiological Health*—(1) *Medical Radiation Advisory Committee.* (i) Date established: October 31, 1963.

(ii) Function: Advises on the formulation of policy and development of a coordinated program related to the application of ionizing radiation in the healing arts.

(2) *Technical Electronic Product Radiation Safety Standards Committee.* (i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation pursuant to 42 U.S.C. 263f (f) (1) (A).

(f) *National Center for Toxicological Research, Science Advisory Board.* (1) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs and the Administrator, Environmental Protection Agency, in fulfilling their regulatory responsibilities.

Subpart C—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established pursuant to the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f (f) (1) (A)). The purpose of TEPRSSC is to provide consultation with the Commissioner before he prescribes any performance standard for an electronic product, as required by law.

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC:

(1) May propose electronic product radiation safety standards to the Commissioner for his consideration.

(2) Shall provide consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f.

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action with respect to performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or any amendment of an existing standard, he shall, prior to issuance of a proposed regulation in the FEDERAL REGISTER, submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting shall be sent to members whenever possible at least 2 weeks prior to the meeting.

(c) Ten members shall constitute a quorum, provided at least three members from each group specified in 42 U.S.C. 263f(f)(1)(A) and in § 14.127(a), i.e., government, industry, and the public, are present.

(d) The Chairman of TEPRSSC shall ordinarily submit to the Commissioner a report of the committee's consideration of any proposed performance standard for an electronic product within 60 days after such consideration. If the chairman believes that more time is needed, he shall so inform the Director of the Bureau of Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) The provisions of §§ 14.1 through 14.7 shall be applicable to TEPRSSC, except where other provisions are specifically included in §§ 14.120 through 14.130.

§ 14.127 Membership of TEPRSSC.

(a) The members shall be appointed by the Commissioner after consultation with public and private associations and organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC shall consist of 15 members, each of whom shall be technically qualified by training and experienced in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(1) Five members shall be selected from government agencies, including State and Federal governments.

(2) Five members shall be selected from the affected industries after consultation with industry representatives.

(3) Five members shall be selected from the general public, of whom at least one shall be a representative of organized labor.

(b) The Commissioner shall appoint a committee member as chairman of TEPRSSC.

(c) Appointments of members shall be for a term of 3 years or as specified by the Commissioner.

(1) The chairman shall be appointed for a term concurrent with his term as a member of TEPRSSC. If the chairmanship becomes vacant without adequate notice, the executive secretary may appoint a committee member as temporary chairman pending appointment of a new chairman by the Commissioner.

(2) Members shall not be reappointed for a second consecutive full term.

(d) A person otherwise qualified for membership shall not be eligible for selection as a member of TEPRSSC from government agencies or the general public if the Commissioner determines that he does not meet the requirements of the conflict of interest laws and regulations.

(e) Retention of membership is conditioned upon:

(1) The member's continued status as a member of the group from which he was selected as specified in paragraph (a) of this section.

(2) The absence of any conflict of interest during the term of membership as specified in paragraph (d) of this section.

(3) Active participation in TEPRSSC activities.

(f) Appointment as a member of TEPRSSC shall be conditioned upon a certification from the prospective member that he:

(1) Agrees to the procedures and criteria as specified in this subpart.

(2) Has no conflict of interest as specified in paragraph (d) of this section.

(3) Will notify the executive secretary of TEPRSSC prior to any change in his representative status on TEPRSSC which may be contrary to the conditions of his appointment.

(g) Members of TEPRSSC who are not full-time officers or employees of the United States shall, in accordance with 42 U.S.C. 210(c), receive compensation pursuant to the provisions of § 14.95.

§ 14.130 Conduct of TEPRSSC meetings; availability of TEPRSSC records.

(a) In accordance with 42 U.C.S. 263f (f)(1)(B), all proceedings of TEPRSSC shall be recorded, and the record of each such proceeding shall be available for public inspection.

(b) All proceedings of TEPRSSC shall be open except where the Commissioner has determined, in accordance with the procedures in § 14.27, that a portion of a meeting may be closed.

Subpart H—Color Additive Advisory Committees

§ 14.140 Establishment of a color additive advisory committee.

The Commissioner shall establish a color additive advisory committee whenever:

(a) The Commissioner concludes, in his discretion, that it would be in the public interest for a color additive advisory committee to review and make recommendations with respect to the safety of any color additive on which important issues are pending before the Food and Drug Administration, and for interested persons to present data, information, and views at an oral public hearing before a color additive advisory committee.

(b) Any person who would be adversely affected by the issuance, amendment, or repeal of a regulation listing a color additive requests that any issue relating to the safety of the color additive arising under section 706(b)(5)(B) of the act because of the color additive's potential or actual carcinogenicity and requiring the exercise of scientific judgment be referred to a color additive advisory committee.

(1) The provisions of paragraph (b) of this section are inapplicable to any issue arising under the transitional provisions in section 203 of the Color Additive Amendments of 1960 relating to provisional listing of commercially established colors. Any color additive advisory committee to consider any such matter shall be established pursuant to the provisions of paragraph (a) of this section.

(2) A request for establishment of a color additive advisory committee shall be pursuant to § 10.30 of this chapter. The Commissioner may deny any such petition if inadequate grounds are stated for establishment of a color additive advisory committee. A request for establishment of a color additive advisory committee may not rest on mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires scientific judgment and justifies a hearing before a color additive advisory committee. When it conclusively appears from the request for a color additive advisory committee that the matter is premature or that it does not involve an issue arising under section 706(b)(5)(B) of the act or there is no genuine and substantial issue of fact requiring scientific judgment or for any other reason a color additive advisory committee is not justified, the Commissioner may deny the establishment of a color additive advisory committee.

(3) Establishment of a color additive advisory committee on the request of an interested person shall be conditioned upon receipt of the applicable fee specified in § 14.155.

(4) Any person so adversely affected may request referral of such a matter to a color additive advisory committee at any time before, or within 30 days after, publication of an order of the Commissioner acting upon a color additive petition or proposal.

§ 14.142 Functions of a color additive advisory committee.

(a) A color additive advisory committee shall review all available information relating to the matter referred to it, including all data and information contained in any pertinent color additive petition and in Food and Drug Administration files. All such data and information so reviewed shall be placed on public display and available for review at the office of the Hearing Clerk.

(b) The Commissioner shall specify to the color additive advisory committee, in writing, the issues on which review and recommendations are requested.

(c) The date of the first meeting of a color additive advisory committee, following receipt of the administrative record by each of the committee members, shall be designated as the beginning of the period allowed for consideration of the matter by the color additive advisory committee. Within 60 days after that first meeting, unless the time is extended as provided in paragraph (d) of this section, the chairman of the color additive advisory committee shall certify to the Commissioner the report containing the recommendations of the color additive advisory committee, including any minority report. The report shall state the recommendations of the color additive advisory committee and the reasons or basis for such recommendations. The report shall include copies of all material considered by the color additive advisory committee in addition to the administrative record furnished to it.

(d) If the chairman concludes that the color additive advisory committee needs additional time, he shall so inform the Commissioner in writing and may certify the report of the color additive advisory committee to the Commissioner within 90 days instead of 60 days.

(e) More than one matter may be handled by a color additive advisory committee concurrently.

§ 14.145 Procedures of a color additive advisory committee.

(a) A color additive advisory committee shall be subject to all the requirements of the Federal Advisory Committee Act and this part.

(b) All interested persons shall have a right to consult with the color additive advisory committee reviewing a matter, and to submit data, information, and views to a color additive advisory committee, in accordance with the procedures established in this part.

§ 14.147 Membership of a color additive advisory committee.

(a) The members of a color additive advisory committee shall be selected in the following manner:

(1) If a color additive advisory committee is established for purposes that do not include review of an issue arising under section 706(b)(5)(B) of the act, or is established on the initiative of the Commissioner, the Commissioner may utilize the procedure established in paragraph (a)(2) of this section to select the members, or may utilize an existing standing advisory committee listed in § 14.100, or may establish a new advisory committee pursuant to the provisions of this subpart. Once the Commissioner has established a color additive advisory committee pursuant to this paragraph and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations with respect to that color additive.

(2) If the Commissioner establishes a color additive advisory committee to review an issue arising under section 706(b)(5)(B) of the act on the request of an interested person, it shall be established pursuant to the following requirements.

(i) Except as provided in paragraph (a)(2)(ii) and (iii) of this section, the Commissioner shall request the National Academy of Sciences to select the members of a color additive advisory committee from among experts qualified in the subject matter to be reviewed by the committee, and of adequately diversified professional backgrounds. The Commissioner shall appoint one of the members so selected as the chairman.

(ii) If the National Academy of Sciences is unable or refuses to select the members of a color additive advisory committee, the Commissioner shall select such members, who shall ordinarily be the Toxicology Advisory Committee in accordance with § 14.19.

(iii) If the Commissioner and the requesting party agree, the provisions of section 706(b)(5)(D) of the act may be waived and the matter may be referred to any standing advisory committee listed under § 14.100 or to any advisory committee established pursuant to any other procedure that is mutually agreeable, which shall ordinarily be the Toxi-

cology Advisory Committee in accordance with § 14.19. Once the Commissioner has so established a color additive advisory committee and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations with respect to that color additive.

(b) Members of a color additive advisory committee shall be subject to the requirements of the Federal Advisory Committee Act and this subpart, except that no member of a color additive advisory committee shall by reason of such membership alone be a special government employee or be subject to the conflict of interest laws and regulations.

§ 14.155 Fees and compensation pertaining to a color additive advisory committee.

(a) In the event of a referral of any matter to a color additive advisory committee, all costs related thereto, including personal compensation of committee members, travel, materials, and other costs shall be borne by the person requesting the referral, such costs to be assessed on the basis of actual cost to the government. The compensation of such costs shall include personal compensation of color additive advisory committee members at a rate not to exceed $128.80 per member per day.

(b) In the case of a request for referral to a color additive advisory committee a special advance deposit shall be made in the amount of $2,500.00. Where required, further advances in increments of $2,500.00 each shall be made upon request of the Commissioner. All deposits for referrals to a color additive advisory committee in excess of actual expenses shall be refunded to the depositor.

(c) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft or certified check drawn to the order of the Food and Drug Administration, collectable at par in Washington, DC. All deposits and fees shall be forwarded to the Associate Commissioner for Administration, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(d) The Commissioner may waive or refund such fees in whole or in part when, in his judgment, such action will promote the public interest. Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner pursuant to § 10.30 of this chapter to waive or refund the fees.

Subpart I—Public Advisory Committees for Human Prescription Drugs

§ 14.160 Establishment of standing technical public advisory committees for human prescription drugs.

The standing technical advisory committees for human prescription drugs are established to advise the Commissioner:

(a) Generally on the safety and effectiveness, including the labeling and advertising, and regulatory control of any of the human prescription drugs falling within the pharmacologic class covered by the advisory committee and on the scientific standards appropriate for a determination of safety and effectiveness in that class of drugs.

(b) Specifically on any particular matter involving a human prescription drug pending before the Food and Drug Administration, including whether the available data and information are adequate to support a determination that:

(1) A particular IND study may properly be conducted.

(2) A particular drug meets the statutory standard for proof of safety and effectiveness necessary for approval or continued approval for marketing.

(3) A particular drug is properly classified as a new drug, an old drug, or a banned drug.

§ 14.171 Utilization of a public advisory committee on the initiative of the Food and Drug Administration.

(a) Any matter involving a human prescription drug under review within the agency may, in the discretion of the Commissioner, be the subject of a public hearing and continuing or periodic review by the appropriate standing technical advisory committee for human prescription drugs. The Commissioner's determinations with respect to the agenda of such an advisory committee shall be based upon the priorities of the various matters pending before the agency which fall within the pharmacologic class covered by that advisory committee.

(b) High priority for such hearing and review by the appropriate standing technical advisory committee for human prescription drugs shall be given to the following types of human prescription drugs:

(1) Investigational drugs which are potential therapeutic advances over currently marketed products from the standpoint of safety or effectiveness, or which pose significant safety hazards, or which present narrow benefit-risk considerations requiring a close judgmental decision in regard to approval for marketing, or which have a novel delivery system or formulation, or which are the subject of major scientific or public controversy, or which may be subject to special regulatory requirements such as a limitation on clinical trials, a patient followup requirement, post-marketing Phase IV studies, distributional controls, or boxed warnings.

(2) Marketed drugs for which an important new use has been discovered, or which pose newly discovered safety hazards, or which are the subject of major scientific or public controversy, or which may be subject to important regulatory actions such as withdrawal of approval for marketing, boxed warnings, distributional controls, or newly required scientific studies.

(c) The advisory committee may request the Commissioner for an opportunity to hold a public hearing and to review any matter involving a human prescription drug which falls within the pharmacologic class covered by the advisory committee. The Commissioner shall, after consulting with the advisory committee on such request, grant or deny the request in light of the priorities of the other matters pending before the advisory committee. Whenever feasible, consistent with the other work of the advisory committee, such a request shall be granted.

(d) For any drug which meets any of the criteria established in paragraph (b) of this section, one or more members of or consultants to the appropriate advisory committee may be selected for more detailed monitoring of the matter and consultation with the Food and Drug Administration on behalf of the committee. Such member or consultant may be invited by the agency to attend appropriate meetings and shall assist the bureau in any briefing of the committee with respect to that matter.

(e) An advisory committee may obtain advice and recommendations from the Toxicology Advisory Committee, the Biometric and Epidemiological Methodology Advisory Committee, and from such other agency advisory committees, consultants and experts as the advisory committee and the bureau conclude would facilitate the work of the advisory committee.

(f) Presentation of all relevant data and information relating to any such matter shall be made in open session unless it relates to an IND the existence of which has not previously been disclosed to the public as defined in § 20.81 of this chapter or is otherwise prohibited from public disclosure pursuant to the provisions of Part 20 of this chapter and the regulations referenced therein. The provisions of §§ 314.14, 431.71, and 601.51 of this chapter shall determine whether, and the extent to which, relevant data and information shall be made available for public disclosure, summarized and discussed in open session but not otherwise made available for public disclosure, or not in any way discussed or disclosed in open session or otherwise disclosed to the public.

§ 14.172 Utilization of a public advisory committee at the request of an interested person.

Any interested person may request, pursuant to § 10.30 of this chapter, that a specific matter relating to a particular

human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. Any such request shall demonstrate the importance of the matter and the reasons why it should be submitted for a hearing at that time. The Commissioner may, in his discretion, grant or deny any such request.

§ 14.174 Advice and recommendations in writing.

Advice and recommendations given by an advisory committee with respect to a specific drug or a class of drugs shall ordinarily be in the form of a written report. Such written report may consist of the approved minutes of the meeting or a separate written report. Such written report shall respond to the specific issues or questions which the Commissioner has addressed to the advisory committee, and shall state the basis of the advice and recommendations of the advisory committee.

PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

Subpart A—General Provisions

Sec.
15.1 Scope.

Subpart B—Procedures for Hearing Before the Commissioner

15.20 Notice of a public hearing before the Commissioner.
15.21 Notice of appearance; schedule for hearing.
15.25 Written submission pertaining to a public hearing before the Commissioner.
15.30 Conduct of a public hearing before the Commissioner.

Subpart C—Records of a Public Hearing Before the Commissioner

15.40 Administrative record of a public hearing before the Commissioner.
15.45 Examination of administrative record.

AUTHORITY: The Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040; 21 U.S.C. 321 et seq.), the Public Health Service Act (sec. 1 et seq., 58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241; 42 U.S.C. 257a), the Controlled Substances Act (sec. 301 et seq., 84 Stat. 1253; 21 U.S.C. 821 et seq.), the Federal Meat Inspection Act (sec. 409(b), 81 Stat. 600; 21 U.S.C. 679(b)), the Poultry Products Inspection Act (sec. 24(b)), 82 Stat. 807; 21 U.S.C. 467f(b)), the Egg Products Inspection Act (sec. 2 et seq., 84 Stat. 1620; 21 U.S.C. 1031 et seq.), the Federal Import Milk Act (44 Stat. 1101; 21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406; 15 U.S.C. 401–411 notes), the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C. 1451 et seq.), and all other statutory authority delegated to the Commissioner (21 CFR 5.1).

Subpart A—General Provisions

§ 15.1 Scope.

This part governs the practices and procedures applicable whenever:

(a) The Commissioner concludes, in his discretion, that it is in the public interest to permit interested persons to present data, information, and views at a public hearing on any particular matter, or class of matters, of importance pending before the Food and Drug Administration.

(b) Pursuant to specific provisions in other sections of this chapter, a matter pending before the Food and Drug Administration is subject to a public hearing before the Commissioner. Such specific provisions are in § 330.10(a)(8) of this chapter relating to review of the safety, effectiveness, and labeling of over-the-counter drugs.

(c) A person who has right to an opportunity for a formal evidentiary public hearing under Part 12 of this chapter waives that opportunity and in lieu thereof requests pursuant to § 12.32 of this chapter a public hearing before the Commissioner pursuant to this part, and the Commissioner, in his discretion, accepts this request.

Subpart B—Procedures for Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing before the Commissioner should be held on any matter, he shall publish in the FEDERAL REGISTER a notice of hearing setting forth the following information:

(1) If the hearing is pursuant to § 15.1(a) or (b):

(i) The purpose of the hearing and the subject matter to be considered. If any written document is to be the subject matter of the hearing, it shall be published as part of the notice, or reference shall be made to it if it has already been published in the FEDERAL REGISTER, or the notice shall state that the document is available from the Hearing Clerk or an agency employee designated in the notice.

(ii) The time, date, and place of the hearing, or a statement that such information shall be contained in a subsequent notice published in the FEDERAL REGISTER.

(2) If the hearing is in lieu of a formal evidentiary hearing pursuant to § 15.1(c), all of the information described in § 12.32(e) of this chapter.

(b) The scope of the hearing shall be determined by the notice of hearing and any specific provisions in other sections of this chapter. If any such specific provision, e.g., § 330.10(a)(10) of this chapter, limits a hearing to review of an existing administrative record, data and information not already included in the record shall not be submitted or considered at the hearing.

§ 15.21 Notice of appearance; schedule for hearing.

(a) The notice of hearing shall provide interested persons an opportunity to file a written notice of appearance with the Hearing Clerk within a specified period of time in the form and pursuant to the requirements specified in § 12.45 of this chapter. If the public interest requires that such a hearing be conducted within a short period of time, the notice may name a specific Food and Drug Administration employee, together with his telephone number, to whom an oral notice of appearance shall be given. A written or oral notice of appearance shall be received by the Hearing Clerk, or other designated person, by the close of business of the day specified in the notice.

(b) A notice of appearance shall state the approximate amount of time requested by the person for his presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations.

(c) Promptly after expiration of the time specified in the notice for the filing of a notice of appearance, the Commissioner shall determine the amount of time allocated to each such person for his oral presentation and the time that oral presentation is scheduled to begin. Each such person shall be so informed in writing or, if the time prior to the hearing is short, by telephone. The Commissioner may require joint presentations by persons with common interests.

(d) The Commissioner shall prepare a hearing schedule showing the persons making oral presentations and the time allotted to each such person, which shall be filed with the Hearing Clerk and mailed or telephoned to each such person and, if time permits, published in the FEDERAL REGISTER.

§ 15.25 Written submissions pertaining to a public hearing before the Commissioner.

Any interested person may submit data, information, or views on the matter that is the subject of the hearing in writing to the Hearing Clerk, pursuant to § 10.20 of this chapter. The record of the hearing shall remain open for 15 days after the hearing is held for any additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise at the hearing.

§ 15.30 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or his designee shall preside at the hearing, except where specific provisions in other sections of this chapter require that the Commissioner preside personally. The presiding officer may be accompanied by other Food and Drug Administration employees or other Federal government employees designated by the Commissioner, who may serve as a panel in conducting the hearing.

(b) The hearing shall be transcribed.

(c) Each person may use his allotted time in whatever way he wishes, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written data, information, or views for inclusion in the record of the hearing, subject to the requirements of § 15.25.

(d) If a person is not present at the time, specified for his presentation, the persons following will appear in order. An attempt will be made to hear any such person at the conclusion of the hearing. Any other interested persons attending the hearing who did not request an opportunity to make an oral

presentation shall be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving with him as a panel may question any person during or at the conclusion of his presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may allot additional time to any person when he concludes that it is in the public interest, but may not reduce the time allotted for any person without their consent.

(f) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record of a public hearing before the Commissioner.

(a) The administrative record of a public hearing before the Commissioner shall consist of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions pursuant to § 15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding shall be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

The availability for public examination and copying of each document which is a part of the administrative record of the hearing shall be governed by the provisions of § 10.20(j) of this chapter. Each document which is available for public examination or copying shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Sec.
16.1 Scope.
16.5 Inapplicability and limited applicability.

Subpart B—Initiation of Proceedings

16.22 Regulatory hearing on the initiative of the Commissioner.
16.24 Regulatory hearing pursuant to regulation.

Subpart C—Presiding Officer and Commissioner

16.40 Presiding officer.
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Subpart D—Procedures for Regulatory Hearing

16.60 Hearing procedure.
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Subpart E—Administrative Record Decisions

Sec.
16.80 Administrative record of a regulatory hearing.
16.85 Examination of administrative record.
16.95 Record for administrative decision.

Subpart F—Reconsideration and Stay

16.119 Reconsideration and stay of action.

Subpart G—Judicial Review

16.120 Judicial review.

AUTHORITY: The Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040; 21 U.S.C. 321 et seq.), the Public Health Service Act (sec. 1 et seq., 58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241; 42 U.S.C. 257a), the Controlled Substances Act (sec. 301 et seq., 84 Stat. 1253; 21 U.S.C. 821 et seq.), the Federal Meat Inspection Act (sec. 409(b), 81 Stat. 600; 21 U.S.C. 679(b)), the Poultry Products Inspection Act (sec. 24(b), 82 Stat. 807; 21 U.S.C. 467f(b)), the Egg Products Inspection Act (sec. 2 et seq., 84 Stat. 1620; 21 U.S.C. 1031 et seq.), the Federal Import Milk Act (44 Stat. 1101; 21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406; 15 U.S.C. 401–411 notes), the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C. 1451 et seq.), and all other statutory authority delegated to the Commissioner (21 CFR 5.1).

Subpart A—General Provisions

§ 16.1 Scope.

This part governs the practices and procedures applicable whenever:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, in his discretion, on his own initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before he makes a decision or takes action.

(b) Any provision in any regulation of this chapter provides any person with an opportunity for a hearing with respect to any regulatory action, including proposed action, and such regulation either specifically provides an opportunity for a regulatory hearing pursuant to this subpart or provides an opportunity for a hearing but does not specify the procedures for such hearing and such procedures are not specified in other provisions of this chapter. Such sections are:

(1) Section 202.1(j)(5), relating to approval of prescription drug advertisements.

(2) Section 80.31(b), relating to refusal to certify a batch of a color additive.

(3) Section 80.34(b), relating to suspension of certification service for a color additive.

(4) Section 71.37(a), relating to use of food containing a new color additive.

(5) Section 130.17(l), relating to a temporary permit to vary from a food standard.

(6) Section 170.17(b), relating to use of food containing an investigational food additive.

(7) Section 511.1(b)(5), relating to use of food containing an investigational new animal drug.

(8) Section 511.1(c)(1), relating to termination of an INAD for an investigator.

(9) Section 511.1 (c)(4) and (d), relating to termination of an INAD for a sponsor.

(10) Section 514.210, relating to suspension of certification service for a veterinary antibiotic drug.

(11) Section 312.1(c)(1), relating to whether an investigator is entitled to receive investigational new drugs.

(12) Section 312.1 (c)(4) and (d), relating to termination of an IND for a sponsor.

(13) Section 312.9(c), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

(14) Section 429.50, relating to suspension of certification service for an insulin drug.

(15) Section 431.52, relating to suspension of certification service for an antibiotic drug.

(16) Section 433.2(d), relating to exemption from certification for an antibiotic drug.

(17) Section 433.12(b)(5), relating to an exemption from labeling for a certifiable antibiotic drug.

(18) Section 433.13(b), relating to an exemption from manufacturing use for a certifiable antibiotic drug.

(19) Section 433.14(b), relating to an exemption for storage for a certifiable antibiotic drug.

(20) Section 433.15(b), relating to an exemption for processing for a certifiable antibiotic drug.

(21) Section 433.16(b), relating to an exemption for repacking for a certifiable antibiotic drug.

(22) Section 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

(23) Section 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.

(24) Section 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.

(25) Section 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

(26) Any other provision in the regulations in this chapter under which a party who is adversely affected by regulatory action is entitled to an opportunity for a hearing, and no other procedural provisions in this part are by regulation applicable to such hearing.

§ 16.5 Inapplicability and limited applicability.

(a) The provisions of this part are inapplicable to the following:

(1) Informal presentation of views before reporting a criminal violation pursuant to section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31 of this chapter.

(2) A hearing with respect to a refusal of admission of a food, drug, device, or cosmetic pursuant to section 801(a) of

the act and § 1.94 of this chapter, or of an electronic product pursuant to section 360(a) of the Public Health Service Act and § 1005.20 of this chapter.

(3) Factory inspections, recalls, regulatory letters, and similar compliance activities related to law enforcement.

(b) The provisions of this subpart are applicable to hearings conducted pursuant to specific procedural provisions in other sections of this chapter to the extent that the provisions of this subpart are in addition to the provisions in such other sections and not in conflict with them, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review. Such other sections include Subpart A of Part 108 of this chapter, relating to emergency permit control.

Subpart B—Initiation of Proceedings

§ 16.22 Regulatory hearing on the initiative of the Commissioner.

(a) A regulatory hearing on the initiative of the Commissioner pursuant to § 16.1(a) shall be initiated by a notice of opportunity for hearing from the Food and Drug Administration.

(1) Such notice shall be sent by registered mail, telegram, telex, personal delivery, or any other mode of written communication.

(2) Such notice shall specify the facts and the action that are the subject of the opportunity for a hearing.

(3) Such notice shall state that the notice of opportunity for hearing and the hearing are governed by the provisions of this subpart.

(4) Such notice shall state the time within which a hearing shall be requested, shall be signed by the Food and Drug Administration employee who will be the presiding officer in the event a hearing is held, and shall state the name, address, and telephone number of the presiding officer.

(b) Any person offered an opportunity for a hearing shall have the amount of time specified in the notice, which shall be not less than 3 working days after receipt of such notice, within which to request a hearing. Such request may be filed by registered mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the presiding officer. If no response is filed within such time, the offer shall be deemed to have been refused and no hearing shall be held.

(c) If a hearing is requested, such hearing shall take place at a time and location agreed upon by the party requesting the hearing and the presiding officer or, if such agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section shall not operate to delay or stay any administrative action, including enforcement action of any kind, by the agency unless the Commissioner, in his discretion, determines that delay or a stay is in the public interest.

§ 16.24 Regulatory hearing pursuant to regulation.

(a) A regulatory hearing pursuant to a regulation listed in § 16.1(b) shall be initiated by a notice of opportunity for hearing from the Food and Drug Administration.

(1) Such notice shall be sent by registered mail, telegram, telex, personal delivery, or any other mode of written communication.

(2) Such notice shall specify the facts and the action that are the subject of the opportunity for hearing, and shall state whether the action is or is not being taken pending the hearing pursuant to paragraph (f) of this section.

(3) Such notice shall state that the notice of opportunity for hearing and the hearing are governed by the provisions of this subpart.

(4) Such notice shall state the time within which a hearing shall be requested, and shall state the name, address, and telephone number of the Food and Drug Administration employee to whom any request for hearing shall be addressed.

(b) Any person offered an opportunity for hearing shall have the amount of time specified in the notice, which shall be not less than 3 working days after receipt of such notice, within which to request a hearing. Such request may be filed by registered mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the presiding officer. If no response is filed within such time, the offer shall be deemed to have been refused and no hearing shall be held.

(c) If a hearing is requested, the Commissioner shall designate a presiding officer and such hearing shall take place at a time and location agreed upon by the party requesting the hearing and the presiding officer or, if such agreement cannot be reached, at a reasonable time and location designated by the presiding officer. The hearing may not be required to be held at a time less than two working days subsequent to receipt of the request for hearing.

(d) Before the hearing, the Food and Drug Administration shall give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by the Food and Drug Administration at the hearing in support of such decision or action. Such information may be given orally or in writing, in the discretion of the Commissioner.

(e) The Food and Drug Administration and the party requesting the hearing shall, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy shall also be provided in advance if the other participant could not reasonably be expected to have or able to obtain a copy. If written notice or a copy is not so provided, the presiding officer shall, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission with respect to the article or information.

(f) The Commissioner may take such action pending a hearing pursuant to this section as he concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, shall be conducted on an expedited basis.

(g) On the basis of the administrative record of the hearing specified in § 16.80(a), the Commissioner shall issue a written decision stating the reasons for his administrative action and the basis in the record.

Subpart C—Presiding Officer and Commissioner

§ 16.40 Presiding officer.

(a) Any Food and Drug Administration employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer at and conduct a regulatory hearing pursuant to the provisions of this subpart.

(b) The presiding officer shall be free from bias or prejudice and shall not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c) A different presiding officer may be substituted for the one originally designated pursuant to §§ 16.22 and 16.24 without notice to the parties.

§ 16.42 Commissioner.

Whenever the Commissioner has delegated authority under Part 5 of this chapter with respect to a matter for which a regulatory hearing is available under this subpart, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated.

Subpart D—Procedures for Regulatory Hearing

§ 16.60 Hearing procedure.

(a) A regulatory hearing shall be a public hearing, except when the Commissioner determines that all or part of a hearing should be closed in order to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure pursuant to § 20.61 of this chapter; or to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure pursuant to § 20.64 of this chapter.

(1) The Commissioner may determine that a regulatory hearing shall be closed either on his initiative or pursuant to a request by the party asking for a regulatory hearing, at the time he requests such hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, his counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 20.81(a) of this chapter, and Food and Drug Administration representatives, shall be entitled to attend.

(3) If the hearing is a public hearing, it shall be announced on the public calendar described in § 10.100(a) of this chapter whenever feasible, and any interested person who attends the hearing may participate to the extent of presenting relevant information.

(b) A regulatory hearing shall be conducted by a presiding officer. Employees of the Food and Drug Administration shall first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing shall then have the right to present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement with respect to the matter at the hearing.

(c) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The Commissioner may, in his discretion, order the hearing to be transcribed. The party requesting the hearing shall have the right to have the hearing transcribed, at his expense, in which case a copy of such transcription shall be furnished to the Food and Drug Administration and included with the presiding officer's report of the hearing. Any transcription of the hearing shall be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing shall be attached to the report. Whenever time permits, the parties to the hearing shall be given the opportunity to review and offer corrections to the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of his report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer shall have the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this subpart pertaining to the conduct of hearings. The presiding officer may direct that the hearing shall be conducted in any suitable manner permitted by law and these regulations.

§ 16.62 Right to counsel.

Any party to a hearing pursuant to this part shall have the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record Decisions

§ 16.80 Administrative record of a regulatory hearing.

(a) The record of the regulatory hearing shall consist of the following:

(1) The notice of opportunity for hearing and the response thereto.

(2) All written data, information, and views submitted to the presiding officer at the hearing or thereafter if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and corrections of the report submitted pursuant to § 16.60(e).

(b) The record of the regulatory hearing shall be closed with respect to the submission of data, information, and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

(c) The record of the administrative proceeding shall consist of the record of the regulatory hearing, the Commissioner's decision referred to in § 16.24(g), and the other data and information referred to in § 16.95(a).

§ 16.85 Examination of administrative record.

The availability for public disclosure of each document which is a part of the administrative record of a regulatory hearing shall be governed by the provisions of Part 20 of this chapter and the regulations referenced therein.

§ 16.95 Record for administrative decision.

(a) With respect to any matter which is subject to an opportunity for a hearing pursuant to §§ 16.1(a) and 16.22, the administrative record of the hearing specified in § 16.80(a) shall be considered by the Commissioner together with all other relevant data and information available to the Food and Drug Administration in determining whether regulatory action should be taken and, if so, what form of regulatory action should be taken.

(b) With respect to any matter which is subject to an opportunity for a hearing pursuant to §§ 16.1(b) and 16.24, the administrative record of the hearing specified in § 16.80(a) shall constitute the exclusive record for decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

Following any final administrative action which is the subject of a hearing pursuant to this part or any provision referenced in § 16.5(b), any party may petition the Commissioner for reconsideration of any part or all of such decision or action pursuant to § 10.33 of this chapter or may petition for a stay of such decision or action pursuant to § 10.39 of this chapter.

Subpart G—Judicial Review

§ 16.120 Judicial review.

The availability of judicial review with respect to any regulatory action which is the subject of a hearing pursuant to this subpart shall be governed by the provisions of § 10.45 of this chapter.

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

Subpart A—General Provisions

Sec.
19.1 Scope.
19.5 Reference to Department regulations.
19.6 Code of ethics for government service.
19.10 Food and Drug Administration Conflict of Interest Review Board.

Subpart B—Reporting of Violations

19.21 Duty to report violation.

Subpart C—Disqualification Conditions

19.45 Temporary disqualification of former employees.
19.55 Permanent disqualification of former employees.

AUTHORITY: The Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040; 21 U.S.C. 321 et seq.), the Public Health Service Act (sec. 1 et seq., 58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241; 42 U.S.C. 257a), the Controlled Substances Act (sec. 301 et seq., 84 Stat. 1253; 21 U.S.C. 821 et seq.), the Federal Meat Inspection Act (sec. 409(b), 81 Stat. 600; 21 U.S.C. 679(b)), the Poultry Products Inspection Act (sec. 24(b), 82 Stat. 807; 21 U.S.C. 467f(b)), the Egg Products Inspection Act (sec. 2 et seq., 84 Stat. 1620; 21 U.S.C. 1031 et seq.), the Federal Import Milk Act (44 Stat. 1101; 21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406; 15 U.S.C. 401–411 notes), the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C. 1451 et seq.), and all other statutory authority delegated to the Commissioner (21 CFR 5.1).

Subpart A—General Provisions

§ 19.1 Scope.

This part governs the standards of conduct for, and establishes regulations to prevent conflicts of interest by, all Food and Drug Administration employees.

§ 19.5 Reference to Department regulations.

(a) The provisions of 45 CFR Part 73, establishing standards of conduct for all Department employees, are fully applicable to all Food and Drug Administration employees, except that such regulations shall be applicable to special government employees, i.e., consultants to the Food and Drug Administration, only to the extent stated in Subpart L of 45 CFR Part 73.

(b) The provisions of 45 CFR Part 73a supplement the Department standards of conduct and apply only to Food and Drug

Administration employees except special government employees.

§ 19.6 Code of ethics for government service.

The following code of ethics, adopted by Congress on July 11, 1958, shall apply to all Food and Drug Administration employees:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.

3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.

4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

5. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.

6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

7. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.

8. Never use any information coming to him confidentially in the performance of governmental duties as a means for making private profit.

9. Expose corruption wherever discovered.

10. Uphold these principles, ever conscious that public office is a public trust.

§ 19.10 Food and Drug Administration Conflict of Interest Review Board.

(a) The Commissioner shall establish a permanent five-member Conflict of Interest Review Board, which shall review and make recommendations to the Commissioner on all specific or policy matters relating to conflicts of interest arising within the Food and Drug Administration that are forwarded to it by (1) the Associate Commissioner for Administration or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Administration on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Personnel Management, Office of the Associate Commissioner for Administration, shall serve as executive secretary of the Review Board.

(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for Administration for resolution, except that reporting of apparent violations of law are governed by § 19.21.

(c) All general policy relating to conflicts of interest shall be established in guidelines pursuant to the provisions of § 10.90(b) of this chapter and whenever feasible shall be incorporated in regulations in this subpart.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Public Records and Documents Center, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of personal privacy in violation of § 20.63 of this chapter.

Subpart B—Reporting of Violations

§ 19.21 Duty to report violations.

(a) The Policy Management Staff, Associate Commissioner for Administration, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

(b) Any Food and Drug Administration employee who has factual information showing or who otherwise believes that any present or former Food and Drug Administration employee has violated or is violating any provision of this subpart or of 45 CFR Parts 73 or 73a or of any statute listed in Appendix A to 45 CFR Part 73 should report such information directly to the Policy Management Staff. Any such reports shall be in writing or shall with the assistance of the Policy Management Staff be reduced to writing, and shall be promptly investigated.

(c) Any report pursuant to paragraph (b) of this section and any records relating to an investigation of such reports shall be maintained in strict confidence in the files of the Policy Management Staff, shall be exempt from public disclosure, and may be reviewed only by authorized Food and Drug Administration employees who are required to do so in the performance of their duties.

Subpart C—Disqualification Conditions

§ 19.35 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee, shall appear personally before the Food and Drug Administration or other federal agency or court as agent or attorney for any person other than the United States in connection with any proceeeding or matter in which the United States is a party or has a direct and substantial interest and which was under his official responsibility at any time within one year preceding termination of such responsibility. The term "official responsibility" means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct government action.

§ 19.55 Permanent disqualification of former employees.

No former Food and Drug Administration employee, including a special government employee, shall knowingly act as agent or attorney for anyone other than United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially through decision, approval, disapproval, recommendation, rendering of advice, investigation, or otherwise as a Food and Drug Administration employee.

PART 20—PUBLIC INFORMATION

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20.109 Data and information obtained by contract.
20.110 Data and information about Food and Drug Administration employees.
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20.113 Voluntary product defect reports.
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20.115 Product codes for manufacturing or sales dates.
20.116 Drug listing information.
20.117 New drug information.
20.118 Advisory committee records.
20.119 Lists of names and addresses.

AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 et seq., as amended (42 U.S.C. 201 et seq.); Pub. L. 90-23, 81 Stat. 54-56 as amended by 88 Stat. 1561-1565 (5 U.S.C. 552).

Subpart A—Official Testimony and Information

§ 20.1 Testimony by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health, Education, and Welfare, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.

(b) Whenever a subpena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: *Provided*, That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpena, and testify with respect thereto.

§ 20.2 Production of records by Food and Drug Administration employees.

(a) Any request for records of the Food and Drug Administration, whether it be by letter or by a subpena duces tecum or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part, and shall comply with the rules governing public disclosure established in Subparts C, D, E, and F of this part and in other regulations cross-referenced in § 20.100 (c).

(b) Whenever a subpena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer or employee shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

§ 20.3 Certification and authentication of Food and Drug Administration records.

(a) Upon request, the Food and Drug Administration will certify the authenticity of copies of records that are requested to be disclosed pursuant to this part or will authenticate copies of records previously disclosed.

(b) A request for certified copies of records or for authentication of records shall be sent in writing to the Public Records and Documents Center (HFC-18), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

Subpart B—General Policy

§ 20.20 Policy on disclosure of Food and Drug Administration records.

(a) The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) Except where specifically exempt pursuant to the provisions of this part, all Food and Drug Administration records shall be made available for public disclosure.

(c) Except as provided in paragraph (d) of this section, all nonexempt records shall be made available for public disclosure upon request regardless whether any justification or need for such records have been shown.

(d) Under § 21.71 of this chapter, a statement of the purposes to which the record requested is to be put, and a certification that the record will be so used, may be requested when:

(1) The requested record is contained in a Privacy Act Record System as defined in § 21.3(c) of this chapter;

(2) The requester is a person other than the individual who is the subject of the record that is so retrieved or a person acting on his behalf; and

(3) The disclosure is one that is discretionary, i.e., not required under this part.

§ 20.21 Uniform access to records.

Any record of the Food and Drug Administration that is disclosed in an au-

thorized manner to any member of the public is available for disclosure to all members of the public, except that:

(a) Data and information subject to the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information, and in § 20.63 for personal privacy, shall be disclosed only to the persons for the protection of whom these exemptions exist.

(b) The limited disclosure of records permitted in § 7.87(c)(1) of this chapter for section 305 hearing records, in § 20.80(b) regarding certain limitations on exemptions, in § 20.103(b) for certain correspondence, and in § 20.104(b) for certain summaries of oral discussions, shall be subject to the special rules stated therein.

(c) Disclosure of a record about an individual, as defined in § 21.3(a) of this chapter, that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter, shall be subject to the special requirements of Part 21 of this chapter. Disclosure of such a record to an individual who is the subject of the record does not invoke the rule established in this section that such records shall be made available for disclosure to all members of the public.

§ 20.22 Partial disclosure of records.

If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining record will be disclosed unless the two are so inextricably intertwined that it is not feasible to separate them or release of the disclosable information would compromise or impinge upon the nondisclosable portion of the record.

§ 20.23 Request for existing records.

(a) Any written request to the Food and Drug Administration for existing records not prepared for routine distribution to the public shall be deemed to be a request for records pursuant to the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and shall be governed by the provisions of this part.

(b) Records or documents prepared by the Food and Drug Administration for routine public distribution, e.g., pamphlets, speeches, and educational materials, shall be furnished free of charge upon request as long as the supply lasts. The provisions of this part shall not be applicable to such requests except when the supply of such material is exhausted and it is necessary to reproduce individual copies upon specific request.

(c) All existing Food and Drug Administration records are subject to routine destruction according to standard record retention schedules.

§ 20.24 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Food and Drug Administration pursuant to the procedures established in Subpart C of this part.

(b) The Commissioner may, in his discretion, prepare new records in order to respond adequately to a request for information when he concludes that it is in the public interest and promotes the objectives of the act and the agency.

§ 20.25 Retroactive application of regulations.

The provisions of this part apply to all records in Food and Drug Administration files.

§ 20.26 Indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, for the following Food and Drug Administration records:

(1) Final orders published in the FEDERAL REGISTER with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretation adopted by the agency and still in force and not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(b) A copy of each such index is available at cost from the Public Records and Documents Center (HFC–18), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

§ 20.27 Submission of records marked as confidential.

Marking records submitted to the Food and Drug Administration as confidential, or with any other similar term, raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to review them pursuant to the procedures established in § 20.44, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

§ 20.28 Food and Drug Administration determinations of confidentiality.

A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 20.44.

§ 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.

Except pursuant to the procedure established in § 20.44 for presubmission review of records, no person may withdraw records submitted to the Food and Drug Administration. All Food and Drug Administration records shall be retained by the agency until disposed of pursuant to routine record disposal procedures.

§ 20.30 Food and Drug Administration Public Records and Documents Center.

(a) The office responsible for agency compliance with the Freedom of Information Act and this part is:

Public Records and Documents Center (HFC–18)
Food and Drug Administration
Rm. 4–62
5600 Fishers Lane
Rockville, MD 20857

(b) All requests for agency records shall be sent in writing to this office.

§ 20.31 Permanent file of requests for Food and Drug Administration records.

The Food and Drug Administration shall maintain a permanent file of all requests for Food and Drug Administration records and all responses thereto, including a copy of all of the records furnished in response to a request. This file is available for public review during working hours.

§ 20.32 Disclosure of Food and Drug Administration employee names.

The names of Food and Drug Administration employees will not be deleted from disclosable records except where such deletion is necessary to prevent disclosure of an informant or danger to the life or physical safety of the employee or under other extraordinary circumstances.

Subpart C—Procedures and Fees

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be filed in writing by mailing the request or delivering it to the Public Records and Documents Center (HFC–18), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, Maryland 20857. Requests should state in a prominent place on the envelope containing the request, if any, and on the request itself, "FOI request."

(b) A request for Food and Drug Administration records shall reasonably describe the records beng sought, in a way that they can be identified and located. A request should include all pertinent details that will help identify the records sought.

(1) If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and indicate the additional information needed to identify the records requested.

(2) Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

(c) Upon receipt of a request for records, the Public Records and Documents Center shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the records requested, the action taken on the request, the date of the determination letter sent pursuant to § 20.41(b) and the date(s) any records are subsequently furnished.

(d) A request by an individual, as defined in § 21.3(a) of this chapter, for a record about himself shall be subject to:

(1) The special requirements of Part 21 of this chapter (the privacy regulations), and not to the provisions of this subpart, if the record requested is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter.

(2) The provisions of this subpart if the record requested is not retrieved by the individual's name or other personal identifier, whether or not the record is contained in a Privacy Act Record System.

§ 20.41 Time limitations.

(a) All time limitations prescribed pursuant to this section shall begin as of the time at which a request for records is logged in by the Public Records and Documents Center pursuant to § 20.40 (c). An oral request for records shall not begin any time requirement. A written request for records sent elsewhere within the agency shall not begin any time requirement until it is redirected to the Public Records and Documents Center and is logged in there in accordance with § 20.40(c).

(b) Within 10 working days (excepting Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Public Records and Documents Center, a letter shall be sent to the person making the request determining whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons therefor.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all of the records requested, the letter shall so state.

(2) If all of the records have not been located or a final determination has not yet been made with respect to disclosure of all of the records requested, e.g., because it is necessary to consult the person affected pursuant to § 20.45, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.

(3) In the following unusual circumstances, the time for sending this letter may be extended for up to an additional 10 working days by written notice to the person making the request setting forth the reasons for such extension and the time within which a determination is expected to be dispatched:

(i) The need to search for and collect the requested records from field facilities or other establishments that are separate from the Public Records and Documents Center.

(ii) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request.

(iii) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the Food and Drug Administration having substantial subject-matter interest therein.

(4) If any record is denied, the letter shall state the right of the person requesting such records to appeal any adverse determination to the Assistant Secretary for Health, Department of Health, Education, and Welfare, in accordance with the provisions of 45 CFR 5.82.

(5) If the request for records will result in a fee of more than $25.00, the letter shall specify or estimate the fee involved and shall require prepayment, as well as payment of any amount not yet received as a result of any previous request, before the records are made available. If the fee is less than $25.00, prepayment shall not be required unless payment has not yet been received for records disclosed as a result of a previous request.

(c) Whenever possible, the determination letter required by paragraph (b) of this section, relating to a request for records that involves a fee of less than $25.00, shall be accompanied by the requested records. Where this is not possible, the records shall be forwarded as soon as possible thereafter, consistent with other obligations of the agency.

(d) For requests for records involving a fee of more than $25.00, the records shall be forwarded as soon as possible after receipt of prepayment from the person requesting the records, consistent with other obligations of the agency.

§ 20.42 Fees.

(a) Unless waived in accordance with the provisions of § 20.43, the following fees shall be imposed for disclosure of any record pursuant to this part.

(1) *Copying of records.* Ten cents per copy of each page.

(2) *Copying of microfilm or microfiche.* Fifty cents per microfilm frame or microfiche.

(3) *Computerized records.* The sum of the actual costs of:

(i) The computer time involved, based upon the prevailing level of cost to government organizations and upon the particular types of computer and associated equipment and the amounts of time on such equipment that are utilized.

(ii) The supplies or materials necessary to produce the requested records.

(iii) The services of the personnel in accordance with paragraph (a) (4) and (5) of this section.

(4) *Clerical searches.* $3.00 for each hour spent by clerical personnel searching for and producing a requested record, including time spent copying any record.

(5) *Nonclerical searches.* $3.00 for each hour spent by professional or managerial personnel searching for and producing a requested record, including time spent copying any record.

(6) *Certification or authentication of records.* $3.00 per certification or authentication.

(7) *Forwarding material to destination.* Postage, insurance, and special fees will be charged on an actual cost basis.

(b) No charge shall be made for the time spent in resolving legal or policy issues or in examining records for the purpose of deleting nondisclosable portions thereof.

(c) Payment shall be made by check or money order payable to "Food and Drug Administration," and shall be sent to the Accounting Operations Branch (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 20.43 Waiver of fees.

(a) No fee shall be charged for disclosure of records pursuant to this part where:

(1) The cost of providing the records is less than $5.00. In making this determination, the cost of other requests by the same individual or organization, or related individuals or organizations, shall be aggregated.

(2) The records are requested by a congressional committee or subcommittee or the General Accounting Office.

(3) The records are requested by a Federal department or agency.

(4) The records are requested by a Federal court.

(5) The records are requested by a foreign government or by a State or local government or any agency thereof for purposes that are in the public interest and will promote the objectives of the act and the agency.

(b) The Assistant Commissioner for Public Affairs may waive payment of fees when he determines, based upon a petition, that the person making the request for records is indigent and that the disclosure has a strong public interest justification. All statements made in any such petition are subject to the False Reports to the Government Act, 18 U.S.C. 1001. A person shall be deemed to be indigent for the purposes of this section if he does not have income or resources sufficient to pay the fees involved. Determinations pursuant to this provision will be made within the discretion of the agency.

(c) The Assistant Commissioner for Public Affairs may reduce or waive payment of fees when he determines, based upon a verified petition, that such reduction or waiver is in the public interest because furnishing the information can be considered primarily as benefiting the general public.

(1) Any such petition shall contain a statement of the intended purpose to which the records requested will be put, showing how it will primarily benefit the general public, and, if the total fee would otherwise exceed $25.00, a statement of the reason why the volume of records requested is necessary and a statement of the income and financial resources available to the person making the request.

(2) The Assistant Commissioner for Public Affairs may make available part of the records requested, or different records from those requested, in response to any such request for waiver of fees where he concludes that such records adequately meet that part of the request which is in the public interest.

(3) In making a determination of the broad public interest involved, the Assistant Commissioner for Public Affairs will

weigh the agency resources involved against the likely benefit to the public.

(4) Determinations pursuant to this provision will be made within the discretion of the agency.

(d) No fee shall be charged if a record requested is not found or for any record that is totally exempt from disclosure.

§ 20.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.

(a) Any person who is considering submission of data or information voluntarily to the Food and Drug Administration may forward to the Director of the Bureau involved, or to the Associate Commissioner for Compliance, a request for presubmission review of the records involved to determine whether the Food and Drug Administration will or will not make part or all of them available for public disclosure upon request if they are submitted. Any such request shall state why the data or information involved fall within an exemption from public disclosure set out in Subpart D of this part and shall enclose the records involved.

(b) Pending a determination upon such request, the records involved shall be held confidentially and separately by the Food and Drug Administration and shall not be received as part of Food and Drug Administration files.

(c) Pursuant to such a request, the Food and Drug Administration shall make a determination whether part or all of the records involved will be made available for public disclosure upon request if they are submitted. A determination of confidentiality will be made only if it is concluded that the data or information involved fall within an exemption from public disclosure set out in Subpart D of this part and are relevant to and important for agency activity.

(d) After a determination is made pursuant to this section, the Food and Drug Administration shall receive as part of its files the records for which a request for confidentiality has been granted and shall so mark or designate those records. The person requesting the presubmission review shall have the option of submitting or withdrawing the records for which a request for confidentiality has been denied. No copy or summary of records withdrawn pursuant to this section, or any correspondence or memoranda or records relating thereto, shall be retained in Food and Drug Administration files.

(e) A determination of confidentiality pursuant to this section is subject to the limitations established in Subpart E of this part except that the data or information involved shall not be subject to discretionary release pursuant to § 20.82. Such a determination of confidentiality by the Food and Drug Administration means that the Food and Drug Administration will not make the data or information involved available for public disclosure unless ordered to do so by a court.

(f) A determination based upon a presubmission review pursuant to this section shall be made in writing and shall be signed only by the Assistant Commissioner for Public Affairs.

(g) Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(h) No request under this section shall be accepted if the status of the records involved is already determined by § 20.111 or by any other regulation published or cross-referenced in this part.

§ 20.45 Situations in which confidentiality is uncertain.

In situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, the Food and Drug Administration will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure.

§ 20.46 Judicial review of proposed disclosure.

Where the Food and Drug Administration consults with a person who will be affected by a proposed disclosure of data or information contained in Food and Drug Administration records pursuant to § 20.45, and rejects the person's request that part or all of the records not be made available for public disclosure, the decision constitutes final agency action that is subject to judicial review pursuant to 5 U.S.C. chapter 7. The person affected will be permitted 5 days after receipt of notification of such decision within which to institute suit in a United States District Court to enjoin release of the records involved. If suit is brought, the Food and Drug Administration will not disclose the records involved until the matter and all related appeals have been concluded.

§ 20.47 Denial of request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs.

(b) The name and title or position of each person who participated in the denial of a request for records shall be set forth in the letter denying the request. This requirement may be met by attaching a list of such individuals to the letter.

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Assistant Secretary for Health, Department of Health, Education, and Welfare, pursuant to the provisions of 45 CFR 5.82.

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

§ 20.48 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Nonspecific requests or requests for a large number of documents that require the deployment of a substantial amount of agency manhours to search for and compile will be processed taking into account the staff-hours required, the tasks from which these resources must be diverted, the impact that this diversion will have upon the agency's consumer protection activities, and the public policy reasons justifying the requests. A decision on the processing of such a request for information shall be made after balancing the public benefit to be gained by the disclosure against the public loss that will result from diverting agency personnel from their other responsibilities. In any situation in which it is determined that a request for voluminous records would unduly burden and interfere with the operations of the Food and Drug Administration, the person making the request will be asked to be more specific and to narrow the request, and to agree on an orderly procedure for the production of the requested records, in order to satisfy the request without disproportionate adverse effects on agency operations.

§ 20.49 Referral to primary source of records.

Upon receipt of a request for a record or document which is contained in Food and Drug Administration files but which is available elsewhere at a lower cost, the person requesting the record or document shall be referred to the primary source of the record or document.

§ 20.50 Availability of records at National Technical Information Service.

The Food and Drug Administration is furnishing a number of records to the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22152, which reproduces and distributes such information to the public at cost. A single copy of each such record shall be available for public review at the Food and Drug Administration. All persons requesting copies of such records shall be answered by referring the person requesting the records to NTIS.

§ 20.51 Use of private contractor for copying.

The Food and Drug Administration may furnish requested records to a private contractor for copying after deletion of all nondisclosable data and information. Under these circumstances, the Food and Drug Administration will charge the person requesting the records for all of the fees involved pursuant to § 20.42.

§ 20.52 Request for review without copying.

(a) A person requesting disclosure of records shall be permitted an opportunity to review them without the necessity for copying them where the records involved contain only disclosable data and information. Under these circumstances, the Food and Drug Administration will

charge only for the costs of searching for the records.

(b) Where a request is made for review of records without copying, and the records involved contain both disclosable and nondisclosable information, the records containing nondisclosable information shall first be copied with the nondisclosable information blocked out and the Food and Drug Administration will charge for the costs of searching and copying.

§ 20.53 Indexing trade secrets and confidential commercial or financial information.

Whenever the Food and Drug Administration denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data and information under § 20.61, and the person requesting the record subsequently contests the denial in the courts, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record. If a court requires the Food and Drug Administration to itemize and index such records, the Food and Drug Administration will so inform the person affected and will require that such person undertake the itemization and indexing of the records. The failure of the affected person to intervene to defend the exempt status of the records and to itemize and index the disputed records will constitute a waiver by such person of such exemption, and the Food and Drug Administration will promptly make them available for public disclosure.

Subpart D—Exemptions

§ 20.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in Subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in Subpart F of this part or of another regulation cross-referenced in § 20.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in Subpart E of this part. For example, correspondence that is ordinarily disclosable under § 20.103 is not disclosable to the extent that it contains trade secrets exempt from disclosure under § 20.61 and is not subject to discretionary release under § 20.82.

(b) Where application of one or more exemptions results in a record being disclosable in part and nondisclosable in part, the rule established in § 20.22 shall apply.

§ 20.61 Trade secrets and commercial or financial information which is privileged or confidential.

(a) A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.

(b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(c) Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

§ 20.62 Inter- or intra-agency memoranda or letters.

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure.

§ 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(c) Requests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 20.61.

(d) Names of individuals conducting investigations, studies, or tests on products or ingredients shall not be deleted prior to disclosure of any record to the public unless extraordinary circumstances are shown.

(e) A request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless accompanied by the written consent of the individual named.

§ 20.64 Investigatory records compiled for law enforcement purposes.

(a) An investigatory record for law enforcement purposes may be withheld from public disclosure pursuant to the provisions of this section to the extent that disclosure of such records would:

(1) Interfere with enforcement proceedings.

(2) Deprive a person of a right to a fair trial or an impartial adjudication.

(3) Constitute an unwarranted invasion of personal privacy.

(4) Disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source.

(5) Disclose investigative techniques and procedures.

(6) Endanger the life or physical safety of law enforcement personnel.

(b) Investigatory records include all records relating to regulatory enforcement action, including both administrative and court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any investigatory record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in Subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

(d) Investigatory records for law enforcement purposes shall be subject to the following rules:

(1) No such record is available for public disclosure prior to the consideration of regulatory enforcement action based upon that record's being closed, except as provided in § 20.82. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 20.82 prior to consideration of criminal prosecution being closed only very rarely and only under circumstances that demonstrate a compelling public interest.

(2) After the consideration of regulatory enforcement action is closed, such records shall be made available for public disclosure except to the extent that other exemptions from disclosure in this subpart are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(i) If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United

States attorney based upon that record, or a recommendation has been finally refused by a United States attorney, or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events described in both paragraph (d)(3) (i) and (ii) of this section have occurred.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(e) Names and other information that would identify a Food and Drug Administration employee shall be deleted from investigatory records prior to public disclosure only pursuant to § 20.32.

Subpart E—Limitations on Exemptions

§ 20.80 Applicability of limitations on exemptions.

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in accordance with the provisions in Subpart D of this part is available for such disclosure to the extent that it falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in § 20.86, in camera disclosure in administrative or court proceedings, in § 20.87(b), Congress, in § 20.88, State and local government officials, in § 20.89, foreign government officials, and in § 20.90, contractors, which does not result in disclosure of the record to any member of the public in an authorized manner, shall not invoke the rule established in § 20.21.

(c) Disclosure to government employees and special government employees of records exempt from public disclosure shall subject those persons to the same restrictions with respect to the disclosure of such records as any Food and Drug Administration employee.

(d) In the case of a record in a Privacy Act Record System, as defined in § 21.3(c) of this chapter:

(1) The availability to an individual, as defined in § 21.3(a), of a record about himself that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System shall be subject to the special requirements of Part 21 of this chapter (the privacy regulations) and shall not be subject to the exemptions in Subpart D of this part except that where the system is exempt and the requested record is not available under § 21.61 of this chapter, the provisions of this part shall apply.

(2) The availability of a record about an individual to persons other than the individual who is the subject of the record shall be subject to the special requirements of Part 21, Subpart G, of this chapter (restrictions on disclosure in the privacy regulations), and shall not be subject to the limitations on exemptions in this subpart except as provided in Part 21, Subpart G, of this chapter.

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to Subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by § 312.1(a)(3) of this chapter or other regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

(b) Any data or information furnished to the Food and Drug Administration for a presubmission review pursuant to the procedure established in § 20.44 shall be accompanied by a statement that the information has not previously been published or disclosed to anyone other than as provided in paragraph (a) of this section.

(c) Any statement relating to prior public disclosure is subject to the False Reports to the Government Act, 18 U.S.C. 1001.

§ 20.82 Discretionary disclosure by the Commissioner.

(a) Except as provided in paragraph (b) of this section, the Commissioner may, in his discretion, disclose part or all of any Food and Drug Administration record that is otherwise exempt from disclosure pursuant to Subpart D of this part. The Commissioner shall exercise his discretion to disclose such records whenever he determines that such disclosure is in the public interest, will promote the objectives of the act and the agency, and is consistent with the rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) The Commissioner shall not make available for public disclosure any record that is:

(1) Exempt from public disclosure pursuant to § 20.61.

(2) Exempt from public disclosure pursuant to § 20.63.

(3) Prohibited from public disclosure pursuant to 21 U.S.C. 331(j), 42 U.S.C. 263g(d), 42 U.S.C. 263l, or 18 U.S.C. 1905.

(4) Contained in a Privacy Act Record System where disclosure would constitute a clearly unwarranted invasion of personal privacy or is otherwise in violation of 5 U.S.C. 552a(b), as applied in Part 21, Subpart G, of this chapter (restrictions on disclosure in the privacy regulations).

(c) Discretionary disclosure of a record pursuant to this section shall invoke the requirement that the record shall be disclosed to any person who requests it pursuant to § 20.21, but shall not set a precedent for discretionary disclosure of any similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record that is exempt from disclosure.

§ 20.83 Disclosure required by court order.

(a) Records of the Food and Drug Administration which the Commissioner has determined are not available for public disclosure, either in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 20.44, shall nevertheless be made available for public disclosure in compliance with a final court order requiring such disclosure.

(b) Where the Food and Drug Administration record ordered disclosed under paragraph (a) of this section is a record about an individual that is not available for public disclosure under § 20.63, the Food and Drug Administration shall attempt to notify the individual who is the subject of the record of the disclosure, by sending a notice to the individual's last known address.

(c) Paragraph (b) of this section shall not apply where the name or other personal identifying information is deleted prior to disclosure.

§ 20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§ 20.85 Disclosure to other Federal government departments and agencies.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets prohibited by 21 U.S.C. 331(j) from disclosure outside the Department of Health, Education, and Welfare may be disclosed only to a department or agency that has concurrent jurisdiction over the matter and separate legal authority to obtain the specific information involved. Any disclosure under this section shall be pursuant to an agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.

§ 20.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter or court proceedings, where the data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

§ 20.87 Disclosure to Congress.

(a) All records of the Food and Drug Administration shall be disclosed to Congress upon an authorized request, except for trade secrets prohibited by 21 U.S.C. 331(j) from disclosure outside the Department of Health, Education, and Welfare.

(b) An authorized request for Food and Drug Administration records by Congress shall be made by the chairman of a committee or subcommittee of Congress acting pursuant to committee business.

(c) An individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member of the public.

§ 20.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in § 20.64.

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

§ 20.89 Communications with foreign government officials.

Communications with foreign government officials shall have the same status as communications with any member of the public, except that:

(a) Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the foreign government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(b) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

§ 20.90 Disclosure to contractors.

(a) Data and information otherwise exempt from public disclosure may be disclosed to contractors with the Food and Drug Administration and their employees for use only in their work for the Food and Drug Administration. Contractors and their employees are thereafter subject to the same legal restrictions and penalties with respect to the disclosure of such data and information as Food and Drug Administration employees.

(b) A written agreement between the Food and Drug Administration and any contractor shall be entered into before data and information otherwise exempt from public disclosure may be disclosed to the contractor. The contractor shall agree to establish and follow security precautions considered by the Food and Drug Administration to be necessary to ensure proper and confidential handling of the data and information. The written agreement shall include, where appropriate, provisions establishing:

(1) Restrictions on access to the data and information by the contractor, its employees, or other persons;

(2) Physical storage requirements;

(3) Requirements for the handling and accountability of the data and information by the contractor and its employees;

(4) Limitations on reproduction, transmission, and disclosure of the data and information;

(5) A requirement of advance approval by the Food and Drug Administration of the use by the contractor of subcontractors, vendors, or suppliers;

(6) Procedures to be followed when the contractor employs time-shared computer operations;

(7) Methods of destroying source documents or related waste material; and

(8) The period during which the contractor may retain such data and information.

§ 20.91 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or in-

formation, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.

Subpart F—Availability of Specific Categories of Records

§ 20.100 Applicability; cross-reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (c) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in Subpart D of this part and the limitations on exemptions established in Subpart E of this part shall be applicable to all Food and Drug Administration records, as provided in §§ 20.60 and 20.80. Accordingly, a record that is ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in Subpart D of this part except as provided by the limitations on exemptions specified in Subpart E of this part.

(b) The Commissioner, on his own initiative or on the petition of any interested person, may amend this subpart or promulgate and cross-reference additional regulations to state the status of additional categories of documents to settle pending questions or to reflect court decisions.

(c) In addition to the provisions of this part, rules on the availability of the following specific categories of Food and Drug Administration records are established by regulations in this chapter:

(1) Section 305 hearing records, in § 7.87(c) of this chapter.

(2) Flavor ingredient records and notes, in § 101.22(i)(4)(iv) of this chapter.

(3) Environmental impact analysis reports and draft and final environmental impact statements, in §§ 25.1(h) and 25.30 of this chapter.

(4) Color additive petitions, in § 71.15 of this chapter.

(5) Food standard temporary permits, in § 130.17(k) of this chapter.

(6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in § 108.35(l) of this chapter.

(7) Food additive petitions, in § 171.1 (h) of this chapter.

(8) Action levels for natural and unavoidable defects in food for human use, in § 110.99(e) of this chapter.

(9) Drug establishment registrations and drug listings, in § 207.37 of this chapter.

(10) Investigational new animal drug notices, in § 514.12 of this chapter.

(11) New animal drug application files, in § 514.11 of this chapter.

(12) Investigational new animal drug notice and a new animal drug application file for an antibiotic drug, in § 514.10 of this chapter.

(13) Methadone patient records, in § 310.505(g) of this chapter.

(14) Investigational new drug notice, in § 312.5 of this chapter.

(15) Labeling for and lists of approved new drug applications, in § 314.10 of this chapter.

(16) Master files for new drug applications, in § 314.11 of this chapter.

(17) New drug application file, in § 314.14 of this chapter.

(18) Data and information submitted for in vitro diagnostic products, in § 809.4 of this chapter.

(19) Data and information submitted for OTC drug review, in § 330.10(a)(2) of this chapter.

(20) Investigational new drug notice for an antibiotic drug, in § 431.70 of this chapter.

(21) Antibiotic drug file, in § 431.71 of this chapter.

(22) Data and information submitted for biologics review, in § 601.25(b)(2) of this chapter.

(23) Investigational new drug notice for a biological product, in § 601.50 of this chapter.

(24) Applications for establishment and product licenses for biological products, in § 601.51 of this chapter.

(25) Cosmetic establishment registrations, in § 710.7 of this chapter.

(26) Cosmetic product ingredient and cosmetic raw material composition statements, § 720.8 of this chapter.

(27) Cosmetic product experience reports, in § 730.7 of this chapter.

(28) Electronic product information, in §§ 1002.4 and 1002.42 of this chapter.

§ 20.101 Administrative enforcement records.

(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD–483 and FD–2275 furnished to companies after factory inspection, and similar records.

(b) To the extent that any of such records fall within the exemption for investigatory records established in § 20.64, the Commissioner determines that they are subject to discretionary release pursuant to § 20.82.

(c) Records relating to administrative enforcement action that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for disclosure established in § 20.64. For example, an establishment inspection report is an investigatory record and thus subject to § 20.64 except insofar as the Commissioner exercises his discretion to release it pursuant to § 20.82.

§ 20.102 Court enforcement records.

(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The Food and Drug Administration will make available for public disclosure such records or documents if the agency can determine that it has an accurate copy of the actual record or document filed in the court. If the Food and Drug Administration cannot determine whether it has an accurate copy of such a record or document, the person requesting a copy shall be referred to the court involved.

(b) After a recommendation for court action has been finally refused by a United States attorney, the correspondence with the United States attorney and the Department of Justice with respect to that recommendation, including the pleadings recommended for filing with the court, is available for public disclosure. Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

§ 20.103 Correspondence.

(a) All correspondence to and from members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal Government and special government employees, is available for public disclosure.

(b) Any such correspondence is available for public disclosure at the time that it is sent or received by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., correspondence relating to an IND notice or an NDA in § 314.14(e)(7) of this chapter.

§ 20.104 Summaries of oral discussions.

(a) All written summaries of oral discussions, whether in person or by telephone, with members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal government or special government employees, are available for public disclosure.

(b) Any such summary is available for public disclosure at the time that it is prepared by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., summaries of oral discussions relating to a food additive petition in § 171.1(h)(3) of this chapter.

(c) If more than one summary of an oral discussion exists in a Food and Drug

Administration file, all such summaries shall be disclosed in response to any request for such summary.

§ 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of "markers" to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

§ 20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.

(a) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are available for public disclosure upon their acceptance by the responsible agency official:

(1) Quarterly and annual reports of the agency.

(2) External investigations or review of agency needs and performance.

(3) Surveys, compilations, and summaries of data and information.

(4) Consumer surveys.

(5) Compliance surveys.

(6) Compliance programs, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the program is completed.

(7) Work plans prepared by Food and Drug Administration bureaus, field offices, and other components, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the plan is completed.

(b) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are not available for public disclosure:

(1) Internal audits of agency needs and performance.

(2) Records relating to the internal planning and budget process.

(3) Legislative proposals or comments prior to submission to Congress.

§ 20.107 Food and Drug Administration manuals.

(a) All Food and Drug Administration staff manuals and instructions to staff that affect a member of the public are available for public disclosure. An index of all such manuals is available at the Food and Drug Administration Public Records and Documents Center in accordance with § 20.26.

(b) Manuals relating solely to internal personnel rules and practices are not available for public disclosure except to the extent that the Commissioner determines that they should be disclosed pursuant to § 20.82.

(c) All Food and Drug Administration action levels which are used to determine when the agency will take regulatory action against a violative product, limits of sensitivity and variability of analytical methods which are used in determining whether a product violates the law, and direct reference levels above which Food and Drug Administration field offices may request legal action directly to the office of the General Counsel, are available for public disclosure.

§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

(a) All written agreements and understandings signed by the Food and Drug Administration and other departments, agencies, and organizations are available for public disclosure.

(b) A permanent file of all such agreements and understandings is available for public review during working hours in the Food and Drug Administration Public Records and Documents Center.

(c) In accordance with the notice published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697), all such agreements and understandings shall be published in the FEDERAL REGISTER.

§ 20.109 Data and information obtained by contract.

(a) All data and information obtained by the Food and Drug Administration by contract, including all progress reports pursuant to a contract, are available for public disclosure when accepted by the responsible agency official except to the extent that they remain subject to an exemption established in Subpart D of this part, e.g., they relate to law enforcement matters as provided in § 20.88(b).

(b) Upon the awarding of a contract by the Food and Drug Administration, the technical proposal submitted by the successful offeror will be available for public disclosure. All cost proposals and the technical proposals of unsuccessful offerors submitted in response to a request for proposals are exempt from disclosure as confidential commercial or financial information pursuant to § 20.61.

§ 20.110 Data and information about Food and Drug Administration employees.

(a) The name, title, grade, position description, salary, work address, and work telephone number for every Food and Drug Administration employee are available for public disclosure. The home address and home telephone number of any such employee are not available for public disclosure.

(b) Statistics on the prior employment experience of present agency employees, and subsequent employment of past agency employees, are available for public disclosure.

§ 20.111 Data and information submitted voluntarily to the Food and Drug Administration.

(a) The provisions of this section shall apply only to data and information submitted voluntarily to the Food and Drug Administration, whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(b) A determination that data or information submitted voluntarily will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 20.44.

(c) The following data and information submitted voluntarily to the Food and Drug Administration are available for public disclosure unless extraordinary circumstances are shown:

(1) All safety, effectiveness, and functionality data and information for a marketed ingredient or product, except as provided in § 330.10(a)(2) of this chapter for OTC drugs.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established in § 20.61 for trade secrets and confidential commercial or financial information.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

(i) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that would identify the person submitting the information.

(ii) If submitted by the manufacturer of the product, the record is available for public disclosure after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved

with the report, such as a physician or hospital or other institution.

(c) Names and any other information that would identify the manufacturer or the brand designation of the product, but not the type of product or its ingredients.

(iii) If submitted by a third party, such as a physician or hospital or other institution, the record is available for public disclosure after deletion of:

(a) Names and any information that would identify the person using the product.

(b) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) If obtained through a Food and Drug Administration investigation, the record shall have the same status as the initial report which led to the investigation, i.e., it shall be disclosed in accordance with paragraph (c)(3)(i) through (iii) of this section.

(v) Any compilation of data, information, and reports prepared in a way that does not reveal data or information which is not available for public disclosure under this section is available for public disclosure.

(vi) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report. The record will be disclosed to the individual who is the subject of the report upon request.

(4) A list of all ingredients contained in a food or cosmetic, whether or not it is in descending order of predominance, or a list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 20.81 contained in a drug, or a list of all ingredients or components in a device. A particular ingredient or component or group of ingredients or components shall be deleted from any such list for a cosmetic or device prior to public disclosure upon a determination made pursuant to § 20.44 that the ingredient or ingredients fall within the exemption established in § 20.61 for trade secrets and confidential commercial information, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61.

(d) The following data and information submitted voluntarily to the Food and Drug Administration are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61:

(1) All safety, effectiveness, and functionality data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in § 20.81.

(2) Manufacturing methods or processes, including quality control procedures.

(3) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(4) Quantitative or semiquantitative formulas.

(e) For purposes of this regulation, safety, effectiveness, and functionality data include all studies and tests of an ingredient or a product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

§ 20.112 Voluntary drug experience reports submitted by physicians and hospitals.

(a) A voluntary drug experience report to the Food and Drug Administration on Form FD-1639 shall be handled in accordance with the rules established in § 20.111(c)(3)(iii).

(b) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report.

§ 20.113 Voluntary product defect reports.

Voluntary reports of defects in products subject to the jurisdiction of the Food and Drug Administration are available for public disclosure:

(a) If the report is submitted by the manufacturer, after deletion of data and information falling within the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information and in § 20.63 for personal privacy.

(b) If the report is submitted by any person other than the manufacturer, after deletion of names and other information that would identify the person submitting the report and any data or information falling within the exemption established in § 20.63 for personal privacy.

§ 20.114 Data and information submitted pursuant to cooperative quality assurance agreements.

Data and information submitted to the Food and Drug Administration pursuant to a cooperative quality assurance agreement shall be handled in accordance with the rules established in § 20.111.

§ 20.115 Product codes for manufacturing or sales dates.

Data or information in Food and Drug Administration files which provide a means for deciphering or decoding a manufacturing date or sales date or use date contained on the label or in labeling or otherwise used in connection with a product subject to the jurisdiction of the Food and Drug Administration are available for public disclosure.

§ 20.116 Drug listing information.

Information submitted to the Food and Drug Administration pursuant to section 510 of the act (21 U.S.C. 360) shall be subject only to the special disclosure provisions established in § 207.37 of this chapter.

§ 20.117 New drug information.

(a) The following computer printouts are available for public inspection in the Food and Drug Administration Public Records and Documents Center:

(1) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and, where applicable, the date the approval was withdrawn and the date the Food and Drug Administration was notified that marketing of the product was discontinued.

(2) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved, showing the same information as is specified in paragraph (a)(1) of this section except that it does not show a withdrawal date.

(b) Other computer printouts containing IND and NDA information are available to the extent that they do not reveal data or information prohibited from disclosure under §§ 20.61, 312.5, and 314.14 of this chapter.

§ 20.118 Advisory committee records.

All advisory committee records shall be handled in accordance with the rules established in Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 20.119 Lists of names and addresses.

Names and addresses of individuals in Food and Drug Administration records shall not be sold or rented. Names and addresses shall not be disclosed if disclosure is prohibited as a clearly unwarranted invasion of personal privacy, e.g., lists of names and home addresses of Food and Drug Administration employees, which shall not be disclosed under § 20.110.

PART 21—PROTECTION OF PRIVACY

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Subpart A—General Provisions

§ 21.1 Scope.

(a) This part establishes procedures to implement the Privacy Act of 1974 (5 U.S.C. 552a). It applies to records about individuals that are maintained, collected, used, or disclosed by the Food and Drug Administration and contained in Privacy Act Record Systems.

(b) This part does not:

(1) Apply to Food and Drug Administration record systems that are not Privacy Act Record Systems or make available to an individual records that may include references to him but that are not retrieved by his name or other personal identifier, whether or not contained in a Privacy Act Record System. Part 20 of this chapter (the public information regulations) and other regulations referred to therein determine when records are made available in such cases.

(2) Make any records available to persons other than (i) individuals who are the subjects of the records, (ii) persons accompanying such individuals under § 21.43, (iii) persons provided records pursuant to individual consent under § 21.72, or (iv) persons acting on behalf of such individuals as legal guardians under § 21.75. Part 20 of this chapter (the public information regulations) and other regulations referred to therein determine when Food and Drug Administration records are disclosable to members of the public generally. Subpart G of this part limits the provisions of Part 20 of this chapter with respect to disclosures of records about individuals from Privacy Act Record Systems to persons other than individuals who are the subjects of the records.

(3) Make available information compiled by the Food and Drug Administration in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such information to any member of the public, including any subject individual or party to such litigation or proceeding shall be governed by applicable constitutional principles, rules of discovery, and Part 20 of this chapter (the public information regulations).

(4) Apply to personnel records maintained by the Division of Personnel Management, Food and Drug Administration, except as provided in § 21.32. Such records are subject to regulations of the Civil Service Commission in 5 CFR Parts 293, 294, and 297.

§ 21.3 Definitions.

As used in this part:

(a) "Individual" means a natural living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. Individual does not include sole proprietorships, partnerships, or corporations engaged in the production or distribution of products regulated by the Food and Drug Administration or with which the Food and Drug Administration has business dealings. Any such business enterprise that is identified by the name of one or more individuals is not an individual within the meaning of this part. Employees of regulated business enterprises are considered individuals. Accordingly, physicians and other health professionals who are engaged in business as proprietors of establishments regulated by the Food and Drug Administration are not considered individuals; however, physicians and other health professionals who are engaged in clinical investigations, employed by regulated enterprises, or the subjects of records concerning their own health, e.g., exposure to excessive radiation, are considered individuals. Food and Drug Administration employees, consultants, and advisory committee members, State and local officials, and consumers are considered individuals.

(b) "Records about individuals" means items, collections, or groupings of information about individuals contained in Privacy Act Record Systems, including, but not limited to education, financial transactions, medical history, criminal history, or employment history, that contain names or personal identifiers.

(c) "Privacy Act Record System" means a system of records about individuals under the control of the Food and Drug Administration from which information is retrieved by individual names or other personal identifiers. The term includes such a system of records whether subject to a notice published by the Food and Drug Administration, the Department, or another agency. Where records are retrieved only by personal identifiers other than individual names, a system of records is not a Privacy Act Record System if the Food and Drug Administration cannot, by reference to information under its control, or by reference to records of contractors that are subject to this part under § 21.30, ascertain the identity of individuals who are the subjects of the records.

(d) "Personal identifiers" includes individual names, identifying numbers, symbols, or other identifying designations assigned to individuals. "Personal identifiers" does not include names, numbers, symbols, or other identifying designations that identify products, establishments, or actions.

(e) "Personnel records" means any personal information maintained in a Privacy Act Record System that is needed for personnel management programs or processes such as staffing, employee development, retirement, and grievances and appeals.

(f) "Department" means Department of Health, Education, and Welfare.

§ 21.10 Policy concerning records about individuals.

Information about individuals in Food and Drug Administration records shall be collected, maintained, used, and disseminated so as to protect the right to privacy of the individual to the fullest possible extent consistent with laws relating to disclosure of information to the general public, the law enforcement responsibilities of the agency, and administrative and program management needs.

Subpart B—Food and Drug Administration Privacy Act Record Systems

§ 21.20 Procedures for notice of Food and Drug Administration Privacy Act Record Systems.

(a) The Food and Drug Administration shall issue in the FEDERAL REGISTER on or before August 30 of each year a notice concerning each Privacy Act Record System as defined in § 21.3(c) that is not covered by a notice published by the Department, the Civil Service Commission, or another agency.

(b) The notice shall include the following information:

(1) The name and location(s) of the system.

(2) The categories of individuals about whom records are maintained in the system.

(3) The categories of records maintained in the system.

(4) The authority for the system.

(5) Each routine use of the records contained in the system (i.e., use outside the Department of Health, Education, and Welfare that is compatible with the purpose for which the records were collected and described in the notice)

including the categories of users and the purposes of such use.

(6) The policies and practices of the Food and Drug Administration regarding storage, retrievability (i.e., how the records are indexed and what intra-agency uses are made of the records), access controls, retention, and disposal of the records in that system.

(7) The title and business address of the official who is responsible for the system of records.

(8) The notification procedure, i.e., the address of the FDA Privacy Coordinator, whom any individual can contact to seek notification whether the system contains a record about him.

(9) The record access and contest procedures, which shall be the same as the notification procedure except that a reference shall be included to any exemption from access and contest.

(10) Where any records in the system are subject to an exemption under § 21.61, a reference to this exemption.

(11) The categories of sources of records in the system.

§ 21.21 Changes in systems and new systems.

(a) The Food and Drug Administration shall notify the designated Department official, the Office of Management and Budget (Information Systems Division), and the Congress of proposals to change or establish Privacy Act Record Systems in accordance with procedures of the Department and the Office of Management and Budget.

(b) The Food and Drug Administration shall issue a notice, in accordance with paragraph (d) of this section and § 21.20(b), of any change in a Privacy Act Record System which:

(1) Increases the number or types of individuals about whom records are maintained;

(2) Expands the type or amount of information about individuals that is maintained;

(3) Increases the number of categories of agencies or other persons who may have access to those records;

(4) Alters the manner in which the records are organized so as to change the nature or scope of those records, such as the combining of two or more existing systems;

(5) Modifies the way in which the system operates or its location(s) in a manner that alters the process by which individuals can exercise their rights under this part, such as the ways in which they seek access or request amendment of a record; or

(6) Changes the equipment configuration on which the system is operated so as to create the potential for greater access, such as adding a telecommunications capability.

(c) The Food and Drug Administration shall issue a notice of its intention to establish new Privacy Act Record Systems in accordance with paragraph (d) of this section and § 21.20(b).

(d) Notices under paragraphs (b) and (c) of this section shall be published in the FEDERAL REGISTER for comment at least 30 days prior to implementation of the proposed changes or establishment of new systems. Interested persons shall have the opportunity to submit written data, views, or arguments on such proposed new uses or systems.

Subpart C—Requirements for Specific Categories of Records

§ 21.30 Records of contractors.

(a) Systems of records that are required to be operated, or as a matter of practical necessity must be operated, by contractors to accomplish Food and Drug Administration functions, from which information is retrieved by individual names or other personal identifiers, may be subject to the provisions of this part. If the contract is agreed to on or after September 27, 1975, the criminal penalties set forth in 5 U.S.C. 552a(i) are applicable to such contractor, and any employee of such contractor, for disclosures prohibited in § 21.71 or for maintenance of a system of records without notice as required in § 21.20.

(b) A contract is considered to accomplish a Food and Drug Administration function if the proposal or activity it supports is principally operated on behalf of and is under the direct management of the Food and Drug Administration. Systems of records from which information is retrieved by individual names or other personal identifiers and that are operated under contracts to accomplish Food and Drug Administration functions are deemed to be maintained by the agency and shall be subject to the procedures and requirements of this part.

(c) A contract is not considered to accomplish a Food and Drug Administration function if the program or activity it supports is not principally operated on behalf of, or is not under the direct management of, the Food and Drug Administration. For example, this part does not apply to systems of records:

(1) Operated under contract with the Food and Drug Administration by State or local government agencies, or organizations representing such agencies, when such agencies or organizations are also performing State or local government functions.

(2) Operated by contractors with the Food and Drug Administration by individuals or organizations whose primary function is delivery of health services, such as hospitals, physicians, pharmacists, and other health professionals, and that report information concerning products, e.g., injuries or product defects, to the Food and Drug Administration. Before such contractors submit information to the Food and Drug Administration, the names and other personal identifiers of patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted, unless the contract provides otherwise. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(3) Relating to individuals whom the contractor employs, or with whom the contractor otherwise deals, in the course of providing goods and services to the Food and Drug Administration.

(4) Operated under grants.

(d) The requirements of this part shall apply when a contractor who operates a system of records not subject to this part reports to the Food and Drug Administration information that is a system of records about individuals from which personal information is retrieved by names or other personal identifiers. Where the information would be a new Privacy Act Record System, or a change in an existing Privacy Act Record System of a type described in § 21.21, the Food and Drug Administration shall comply with the requirements of § 21.21.

(e) The Food and Drug Administration will review all contracts before award to determine whether operation of a system from which information is retrieved by individual names or other personal identifiers will be required of the contractor, by the terms of the contract or as a matter of practical necessity. If such operation will be required, the solicitation and contract shall include the following clause, or a clause of similar effect:

> Whenever the contractor or any of his employees is required by this contract to operate a system of records from which information is retrieved by individual names or other personal identifiers in order to accomplish a Food and Drug Administration function, the contractor and every employee is considered to be an employee of the Food and Drug Administration and shall operate such system of records in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), regulations of the Food and Drug Administration in 21 CFR Part 21, and rules of conduct that apply to Food and Drug Administration employees who work with such systems of records. The contractor and his employees are subject to the criminal penalties set forth in 5 U.S.C. 552a(i) for violations of the Privacy Act.

§ 21.31 Records stored by the General Services Administration and archival records.

(a) Food and Drug Administration records that are stored, processed, and serviced by the General Services Administration in accordance with 44 U.S.C. 3103 shall be considered to be maintained by the Food and Drug Administration. The General Services Administration shall not disclose the record except to authorized Food and Drug Administration employees.

(b) Each Food and Drug Administration record pertaining to an identifiable individual that was transferred to the National Archives of the United States as a record determined by the National Archives to have sufficient historical or other value to warrant its continued preservation shall be considered to be maintained by the National Archives and shall not be subject to the provisions of this part.

§ 21.32 Personnel records.

(a) Present and former Food and Drug Administration employees desiring access to personnel records about themselves should consult system notices applicable to the agency's personnel records that are published by the Civil

Service Commission and the Department as well as any notice issued by the Food and Drug Administration.

(b)(1) The procedures of the Civil Service Commission at 5 CFR Parts 293, 294, and 297, rather than the procedures in § 21.33 and Subparts D through F of this part, govern systems of personnel records about Food and Drug Administration employees that are subject to notices published by the Commission, i.e., systems that:

(i) The Commission maintains.

(ii) Are maintained by the Division of Personnel Management, Food and Drug Administration.

(iii) Are maintained by Department Regional Offices, concerning field employees.

(2) The Commission's procedures may, if necessary, be supplemented in the Food and Drug Administration Staff Manual Guide. Current Food and Drug Administration employees should mail or deliver written requests under the Privacy Act for access to personnel records described in this paragraph to the Commission in accordance with 5 CFR 297.106, the Director, Division of Personnel Management (HFA–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the personnel officer in the servicing HEW Regional Personnel Office. An employee may consult with or direct his request to the FDA Privacy Coordinator (HFC–18). Requests for access to personnel records of former employees that are located in Federal records centers should be directed to the Commission. Requests under the Privacy Act for amendment of personnel records should be directed to these same officials who are responsible for access to personnel records under this paragraph.

(3) With respect to records subject to paragraph (b)(1) of this section:

(i) Refusal to grant access to a record or refusal to amend a record upon request of an employee, shall only be made by the Associate Commissioner for Administration or his designate; and

(ii) Appeals of refusals under paragraph (b)(3)(i) of this section may be made to the Civil Service Commission in accordance with 5 CFR 297.108(g)(3) and 297.113(b).

(c) Any other Privacy Act Record Systems that contain personnel records, or records that otherwise concern agency employees, that are maintained by offices of the Food and Drug Administration rather than the Division of Personnel Management but which are not subject to the Department's notice for personnel records in operating offices are subject to this part, except that refusals under this part to grant access to or amend records about present or former employees shall be made by the Associate Commissioner for Administration rather than the Associate Commissioner for Compliance.

(d) The following procedures shall govern requests under the Privacy Act for personnel records that are maintained by the operating offices of the Food and Drug Administration in which employees work:

(1) An employee shall upon request be told whether records about him are maintained. An employee shall be given access to records about himself that are subject to this paragraph in response to an oral or written request and through informal procedures, rather than the procedures specified in §§ 21.40 through 21.43.

(2) Employee identity may be verified, if necessary, by an FDA ID card rather than in accordance with § 21.44.

(3) Generally no fee shall be charged for records requested under this paragraph. However, in cases where the records requested are voluminous, a fee may be charged in accordance with § 21.45.

(4) Records that are subject to this paragraph shall be available for access to an individual, except to the extent that access is refused by the Associate Commissioner for Administration or his designate on the ground that the record is subject to an exemption under § 21.61 or 5 CFR 297.111.

(5) Requests under the Privacy Act for amendment of records subject to this paragraph should be directed to the Director, Division of Personnel Management (HFA–400). Such requests shall be reviewed in accordance with Subpart E of this part. Refusal to amend a record subject to this paragraph (d)(5) shall only be made by the Associate Commissioner for Administration or his designate.

(6) Appeals of refusals under paragraph (d)(4) or (5) of this section may be made to the Commissioner of Food and Drugs, except where the Associate Commissioner for Administration or his designate indicates with his refusal that the appeal should be made to the Civil Service Commission.

(7) Disclosures of records subject to this paragraph are subject to Subpart G of this part.

§ 21.33 Medical records.

(a) In general, an individual is entitled to have access to any medical records about himself in Privacy Act Record Systems maintained by the Food and Drug Administration.

(b) The Food and Drug Administration may apply the following special procedures in disclosing medical records to an individual:

(1) The agency may review the records to determine whether disclosure of the record to the individual who is the subject of the records might have an adverse effect on him. If it is determined that disclosure is not likely to have an adverse effect on the individual, the record shall be disclosed to him. If it is determined that disclosure is very likely to have an adverse effect on the individual, he may be requested to designate, in writing, a representative to whom the record shall be disclosed. Such representative may be a physician, other health professional, or other responsible person who would be willing to review the record and discuss it with the individual.

(2) The availability of the record may be subject to any procedures for disclosure to an individual of medical records about himself under Part 20 of this chapter, in addition to or in lieu of the procedures in paragraph (b)(1), that are not inconsistent with § 21.41(f).

Subpart D—Procedures for Notification of and Access to Records in Privacy Act Record Systems

§ 21.40 Procedures for submitting requests for notification and access.

(a) An individual may request that the Food and Drug Administration notify him whether a Privacy Act Record System contains records about him that are retrieved by reference to his name or other personal identifier. An individual may at the same time, or after receiving notification that such a record about him exists, request that he be given access to the record.

(b) An individual desiring notification or access to records shall mail or deliver a request for records in any Food and Drug Administration Privacy Act Record System to the FDA Privacy Coordinator (HFC–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Requests shall be in writing and shall name the Privacy Act Record System or Systems concerning which the individual requests notification of whether there are records about him that are retrieved by reference to his name or other personal identifier. To help assure a prompt response, an individual should indicate that he is making a "Privacy Act Request" on the envelope and in a prominent manner in the letter.

(d) An individual who merely wishes to be notified whether a Privacy Act Record System contains a record about him ordinarily need not provide any verification of his identity other than his name. The mere fact that the Food and Drug Administration has a record about an individual in any of its Privacy Act Records Systems would not be likely to constitute a clearly unwarranted invasion of personal privacy. Where mere disclosure of the fact that a record about the individual exists would be a clearly unwarranted invasion of personal privacy, further verification of the identity of the individual shall be required.

(e) An individual who requests that he be given access to a copy of records about himself, if any exist, should indicate whether he prefers (1) to have copies of any such records mailed to him in accordance with § 21.43(a)(1), which may involve a fee under § 21.45, including information to verify his identity under § 21.44 or (2) to use the procedures for access in person under § 21.43(a)(2).

(f) A request for notification and access may be submitted under this subpart concerning any Privacy Act Record System that is exempt under § 21.61, as indicated in the notice for the system. An individual seeking access to records under § 21.65(b)(2) to investigatory records compiled for law enforcement purposes other than criminal law enforcement purposes should submit a description of the right, benefit, or privilege that he believes he was denied as the result of the Food and Drug Administration's maintenance of the records.

Where the system is exempt under § 21.61, and access to the requested records is not granted under § 21.65, the request shall be handled under the provisions of Part 20 of this chapter (the public information regulations).

(g) The Public Records and Documents Center shall maintain and make available copies of the forms (OF–203, Privacy Act Request forms) to assist individuals in filing requests under § 21.40.

§ 21.41 Processing of requests.

(a) An individual or his guardian under § 21.75 shall not be required to show any justification or need to obtain notification under § 21.42 or access to a record under § 21.43.

(b) The Food and Drug Administration will determine whether a request by an individual for records about himself is appropriately treated as a request under this subpart, or under the provisions of Part 20 of this chapter (the public information regulations), or both. Where appropriate, the Food and Drug Administration will consult with the individual concerning the appropriate treatment of the request.

(c) The FDA Privacy Coordinator (HFC–18) in the Public Records and Documents Center shall be responsible for the handling of Privacy Act requests received by the Food and Drug Administration. Requests mailed or delivered to any other office shall be promptly redirected to the FDA Privacy Coordinator. Where this procedure would unduly delay the agency's response, however, the agency employee who received the request should consult with the FDA Privacy Coordinator and obtain advice as to whether the employee can respond to the request directly.

(d) Upon receipt of a request by the FDA Privacy Coordinator, a record shall promptly be made that a request has been received and the date.

(e) A letter in accordance with § 21.42 responding to the request for notification shall issue as promptly as possible after receipt of the request by the Food and Drug Administration. Upon determination by the Public Records and Documents Center that a request for access to records is appropriately treated as a request under Part 20 rather than this Part 21, or under both parts, the time limitations prescribed in § 21.41 of this chapter shall apply. In any case, access to available records shall be provided as promptly as possible.

(f) Except as provided in § 21.32, an individual's access to records about himself that are retrieved by his name or other personal identifiers and contained in any Privacy Act Record System may only be denied by the Associate Commissioner for Compliance or his designate. An individual shall not be denied access to any record that is otherwise available to him under this part except on the grounds that it is exempt under § 21.61 and not required to be disclosed under § 21.65(a)(2), that it was compiled in reasonable anticipation of court litigation of formal administrative proceedings, or to the extent that it is exempt or prohibited from disclosure because it includes a trade secret or commercial or financial information that is privileged or confidential information the disclosure of which would constitute a clearly unwarranted invasion of the personal privacy of another individual.

(g) The FDA Privacy Coordinator shall assure that records are maintained of the number, status, and disposition of requests under this subpart, including the number of requests for records exempt from access under this subpart and other information required for purposes of the annual report to Congress under the Privacy Act. These temporary administrative management records shall not be considered to be Privacy Act Record Systems. All records required to be kept under this paragraph shall only include requesting individuals' names or personal identifiers for so long as any request for notification, access, or amendment is pending. The identity of individuals making requests under this subppart shall be regarded as confidential and shall not be disclosed under Part 20 of this chapter (the public information regulations) to any other person or agency except as is necessary for the processing of requests under this subpart.

§ 21.42 Responses to requests.

(a) The FDA shall respond to an individual's request for notification as to whether a Privacy Act Record System contains records about him that are retrieved by his name or other personal identifier by sending a letter under this paragraph.

(1) If there are no records about the individual that are retrieved by his name or other personal identifier in the named Privacy Act Record System, or the requester is not an "individual" under § 21.3(a), the letter shall so state. Where appropriate, the letter shall indicate that the Food and Drug Administration's public information regulations in Part 20 of this chapter prescribe general rules governing the availability of information to members of the public, and that a request may be made in accordance with Part 20 of this chapter for records that are not retrieved by the requester's name or other personal identifier from a Privacy Act Record System.

(2) If there are records about the individual that are retrieved by his name or other personal identifier and the named Privacy Act Record System is not exempt from individual access and contest under § 21.61, or the system is exempt but access is allowed or required under § 21.65, the letter shall inform him that the records exist and shall either:

(i) Enclose a copy of the records under § 21.43(a)(1) or indicate that the records will be sent under separate cover, where there has been adequate verification of the identity of the individual under § 21.44 and the fees under § 21.45 do not exceed $25, or

(ii) Inform the individual of the procedures to obtain access to the records by mail or in person under § 21.43(a)(2), as well as the approximate dates by which the requested records can be provided (if the records are not then available), the locations at which access in person may be had, and the information needed, if any, to verify the identity of the individual under § 21.44.

(3) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, and the system is exempt from individual access and contest under § 21.61 and access is not allowed or required under § 21.65, the letter should inform him that the records are exempted from access and contest by § 21.61. The letter shall also inform him if the records sought are not available because they were compiled in reasonable anticipation of court litigation or formal administrative proceedings or are otherwise not available under § 21.41(b). Where appropriate, the letter shall also indicate whether the records are available under Part 20 of this chapter (the public information regulations), and it may disclose the records in accordance with Part 20.

(4) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, but a final determination has not yet been made with respect to disclosure of all of the records covered by the request, e.g., because it is necessary to consult another person or agency having an interest in the confidentiality of the records, the letter shall explain the circumstances and indicate when a final answer will be given.

(b) Except as provided in § 21.32, access to a record may only be denied by the Associate Commissioner for Compliance or his designate. If access to any record is denied, wholly or in substantial part, the letter shall state the right of the individual to appeal to the Commissioner of Food and Drugs.

(c) If a request for a copy of the records will result in a fee of more than $25, the letter shall specify or estimate the fee involved. Where the individual has requested a copy of any records about him and copying the records would result in a fee of over $50, the Food and Drug Administration shall require advance deposit as well as payment of any amount not yet received as a result of any previous request by the individual for a record about himself, under this subpart or Part 20 of this chapter (the public information regulations) before the records are made available. If the fee is less than $50, prepayment shall not be required unless payment has not yet been received for records disclosed as a result of a previous request by the individual for a record about himself under this subpart or Part 20 of this chapter.

§ 21.43 Access to requested records.

(a) Access may be granted to requested records by:

(1) Mailing a copy of the records to the requesting individual, or

(2) Permitting the requesting individual to review the record in person between 8 a.m. and 4:30 p.m. at the office of the FDA Privacy Coordinator, at the

Public Records and Documents Center at the address shown in § 20.30 of this chapter, or at any Food and Drug Administration field office listed in § 5.115 of this chapter, or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangements for such review can be made by consultation between the FDA Privacy Coordinator and the individual. An individual seeking to review records in person shall generally be permitted access to the file copy, except that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. Where the individual is not given a copy of the record to retain, no charge shall be made for the costs of copying a record to make it available to an individual who reviews a record in person under this paragraph.

(b) An individual may request that a record be disclosed to or discussed in the presence of another individual, such as an attorney. The individual may be required to furnish a written statement authorizing the disclosure or discussion in such other individual's presence.

(c) The Food and Drug Administration will make every reasonable effort to assure that records made available under this section can be understood by the individual, such as by providing an oral or written explanation of the records.

§ 21.44 Verification of identity.

(a) An individual seeking access to records in a Privacy Act Record System may be required to comply with reasonable requirements to enable the Food and Drug Administration to determine his identity. The identification required shall be suitable considering the nature of the records sought. No identification shall be required to receive access to information that is required to be disclosed to any member of the public under Part 20 of this chapter (the public information regulations).

(b) An individual who appears in person for access to records about himself shall be required to provide at least one document to identify himself, e.g., driver's license, passport, or alien or voter registration card to verify his identity. If an individual does not have any such document or requests access to records about himself without appearing in person under circumstances in which his identity cannot be verified from the request itself, he shall be required to certify in writing that he is the individual he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a $5,000 fine.

(c) In making requests under § 21.75, a parent of a minor child or legal guardian of an incompetent individual may be required to verify his relationship to the minor child or the incompetent individual, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other evidence of guardianship.

(d) Where an individual seeks access to particularly sensitive records, such as medical records, the individual may be required to provide additional information beyond that specified in paragraph (b) or (c) of this section, such as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation, or the specific times the individual received medical treatment.

§ 21.45 Fees.

(a) Where applicable, fees for copying records shall be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual has requested that a copy be made of a record to which he is granted access. No fee may be charged for making a search of a Privacy Act Record System whether the search is manual, mechanical, or electronic. Where a copy of the record must be made to provide access to the record, e.g., computer printout where no screen reading is available, the copy shall be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual under § 21.33, no fee will be charged.

(b) The fee schedule is as follows:

(1) Copying of records susceptible to photocopying—$.10 per page.

(2) Copying of records not susceptible to photocopying, e.g., punch cards or magnetic tapes—at actual cost to be determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying for an individual does not exceed $25.

(c) When a fee is to be assessed, the individual shall be notified prior to the processing of the copies, and be given an opportunity to amend his request. Payment shall be made by check or money order made payable to the "Food and Drug Administration," and shall be sent to the Accounting Operations Branch (HFA-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Advance deposit shall be required where the total amount exceeds $50.

Subpart E—Procedures for Requests for Amendment of Records

§ 21.50 Procedures for submitting requests for amendment of records.

(a) An individual who received access to a record about himself under Subpart D of this part may request that the record be amended if he believes that the record or an item of information is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete.

(b) Amendments under this subpart shall not violate existing statute, regulation, or administrative procedure.

(1) This subpart does not permit alteration of evidence presented in the course of judicial proceedings or Food and Drug Administration adjudicatory or rule making proceedings or collateral attack upon that which has already been the subject of any such proceedings.

(2) If the accuracy, relevancy, timeliness, or completeness of the records may be contested in any other pending or imminent agency proceeding, the Food and Drug Administration may refer the individual to the other proceeding as the appropriate means to obtain relief. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another agency proceeding, the request under this section shall be disposed of in accordance with the decision in the other proceeding, absent unusual circumstances.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Coordinator in accordance with § 21.40(b). Such requests shall include information sufficient to enable the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested amendment. An edited copy of the record showing the described amendment may be included. Verification of identity should be provided in accordance with § 21.44.

(d) Written acknowledgement of the receipt of a request to amend a record shall be provided within 10 working days to the individual who requested the amendment. Such acknowledgement may request any additional information needed to verify identity or make a determination. No acknowledgement need be made if the request can be reviewed, processed, and the individual notified of the agency's agreement with the request or refusal within the 10-day period.

§ 21.51 Responses to requests for amendment of records.

(a) The Food and Drug Administration shall take one of the following actions on a request for amendment of records as promptly as possible:

(1) Amend any portion of the record which the agency has determined, based upon a preponderance of the evidence, is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete, and, in accordance with paragraph (d)(3) of this section, inform the individual and previous recipients of the record that has been amended of the amendment.

(2) Inform the individual of its refusal to amend any portion of the record in the manner requested, the reason for the refusal, and the opportunity for administrative appeal to the Commissioner of Food and Drugs. Except as provided in § 21.32, such refusal may only be issued by the Associate Commissioner for Compliance or his designate.

(3) Where another agency was the source of and has control of the record, refer the request to that agency.

(b) The agency may, for good cause, extend the period for taking action an additional 30 working days if notice is provided to the individual explaining the circumstances of the delay.

(c) The officials charged with reviewing a record to determine how to respond

to a request to amend it, shall assess its accuracy, relevance to a Food and Drug Administration purpose, timeliness, or completeness. The determination shall be made in the light of the purpose for which the records or system is used, the agency's need for the record, and the possible adverse consequences to the individual from the record if not amended. Whenever the Food and Drug Administration receives a request for deletion of a record, or portions of a record, it shall consider anew whether the contested information in the record is relevant and necessary to a Food and Drug Administration purpose.

(d) If the Food and Drug Administration agrees with an individual's request, it shall take the following actions:

(1) So inform the individual in writing.

(2) In accordance with statute, regulation, or procedure, amend the record to make it accurate, relevant to a Food and Drug Administration purpose, timely, or complete, making note of the date and fact of the amendment.

(3) If an accounting was made under § 21.71(d) of a disclosure of the record under § 21.71(a), provide a copy of the record as amended, to all previous recipients of the record.

§ 21.52 Administrative appeals of refusals to amend records.

(a) If an individual disagrees with a refusal under § 21.51(a)(2) to amend a record, he may appeal that refusal to the Commissioner of Food and Drugs, Rm. 14–81, 5600 Fishers Lane, Rockville, MD 20857.

(b) If, upon appeal, the Commissioner upholds the refusal to amend the record as requested, he shall inform the individual:

(1) Of his decision and the reasons for it.

(2) Of the individual's right to file with the Food and Drug Administration a concise statement of the individual's reasons for disagreeing with the agency's decision not to amend the record as requested.

(3) That the statement of disagreement will be made available to all persons listed in an accounting as having previously received the record and any person to whom the record is subsequently disclosed together with, in the discretion of the Food and Drug Administration, a brief statement summarizing its reasons for refusing to amend the record. Any individual who includes false information in the statement of disagreement filed with the Food and Drug Administration may be subject to penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

(4) That the individual has a right to seek judicial review of the refusal to amend the record.

(c) If the Commissioner on administrative appeal or a court on judicial review determines that the record should be amended in accordance with the individual's request, the Food and Drug Administration shall proceed in accordance with § 21.51(d).

(d) A final determination on the individual's administrative appeal of the initial refusal to amend the record shall be concluded within 30 working days of the request for such review under paragraph (a) of this section, unless the Commissioner extends such period for good cause and informs the individual in writing of the reasons for the delay and of the approximate date on which a decision of the appeal can be expected.

§ 21.53 Notation and disclosure of disputed records.

When an individual has filed a statement of disagreement under § 21.52(b)(2), the Food and Drug Administration shall:

(a) Mark any portion of the record that is disputed to assure that the record will clearly show that portion is disputed whenever the record is disclosed.

(b) In any subsequent disclosure under § 21.70 or § 21.71(a), provide a copy of the statement of disagreement and, if the Food and Drug Administration deems it appropriate, a concise statement of the agency's reasons for not making the amendment(s) requested. While the individual shall have access to any such statement, it shall not be subject to a request for amendment under § 21.50.

(c) If an accounting was made under § 21.71(d) and (e) of a disclosure of the record under § 21.71(a), provide to all previous recipients of the record a copy of the statement of disagreement and the agency statement, if any.

§ 21.54 Amended or disputed records received from other agencies.

Whenever the Food and Drug Administration is notified that a record that it received from another agency was amended or is the subject of a statement of disagreement, the Food and Drug Administration shall:

(a) Discard the record, or clearly note the amendment or the fact of disagreement in its copy of the record, and

(b) Refer persons who subsequently request the record to the agency that provided it.

(c) If an accounting was made under § 21.71 (d) and (e) of the disclosure of the record under § 21.71(a), inform all previous recipients of the record about the amendment or provide to them the statement of disagreement and the agency statement, if any.

Subpart F—Exemptions

§ 21.60 Policy.

It is the policy of the Food and Drug Administration that record systems should be exempted from the Privacy Act only to the extent essential to the performance of law enforcement functions under the laws that are administered and enforced by the Food and Drug Administration or that govern the agency.

§ 21.61 Exempt systems.

(a) Investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, in the Food and Drug Administration Privacy Act Record Systems listed in paragraph (b) of this section are exempt from the following provisions of the Privacy Act (5 U.S.C. 552a) and of this part:

(1) Such records are exempt from 5 U.S.C. 552a(c)(3) and § 21.71(e)(4), requiring that an individual be provided with the accounting of disclosures of records about himself from a Privacy Act Record System.

(2) Except where access is required under 5 U.S.C. 552a(k)(2) and § 21.65(a)(2), (such records are exempt from 5 U.S.C. 552a (d)(1) through (4) and (f)) and §§ 21.40 through 21.54, requiring procedures for an individual to be given notification of and access to records about himself in a Privacy Act Record System and to be allowed to challenge the accuracy, relevance, timeliness, and completeness of such records.

(3) Such records are exempt from 5 U.S.C. 552a(e)(4) (G) and (H) and § 21.20(b)(10) requiring inclusion in the notice for the system of information about agency procedures for notification, access, and contest.

(4) Such records are exempt from 5 U.S.C. 552a(e)(3) requiring that individuals asked to supply information be provided a form outlining the authority for the request, the purposes for which the information will be used, the routine uses in the notice for the Privacy Act Record System, and the consequences to the individual of not providing the information, but only with respect to records compiled by the Food and Drug Administration in a criminal law enforcement investigation where the conduct of the investigation would be prejudiced by such procedures.

(b) Records in the following Food and Drug Administration Privacy Act Record Systems that concern individuals who are subject to Food and Drug Administration enforcement action and consist of investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, are exempt under 5 U.S.C. 552a(j)(2) and (k)(2) from the provisions enumerated in paragraph (a) of this section:

(1) Clinical Investigator Records, FDA–3.

(2) Regulated Industry Employee Enforcement Records, FDA–10.

(3) Employee Conduct Investigative Records, FDA–13.

(4) Service Contractor Employees Investigative Records, FDA–14.

(c) The systems described in paragraph (b)(3) and (4) of this section include investigatory records compiled solely for the purpose of determining suitability, eligibility, or qualification for Federal civilian employment, military service, Federal contracts, and access to classified information. These records are exempt from disclosure under 5 U.S.C. 552a(k)(5) to the extent that the disclosure would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished after September 27, 1975. Any individual who is refused access to a record that

would reveal a confidential source shall be advised in a general way that the record includes information that would reveal a confidential source.

§ 21.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt and the requested records are unavailable under § 21.61, an individual may nevertheless make a request under § 21.40 for notification concerning whether any records about him exist and request access to such records where they are retrieved by his name or other personal identifier.

(b) An individual making a request under paragraph (a) of this section:

(1) May be given access to the records where available under Part 20 of this chapter (the public information regulations) or the Commissioner may, in his discretion, entertain a request under any or all of the provisions of §§ 21.40 through 21.54; and

(2) Shall be given access upon request if the records requested are subject to 5 U.S.C. 552a(k)(2) and not to 5 U.S.C. 552a(j)(2) (i.e., because they consist of investigatory material compiled for law enforcement purposes other than criminal law enforcement purposes) and maintenance of the records resulted in denial to the individual of any right, benefit, or privilege to which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible. An individual given access to a record under this paragraph (b)(2) is not entitled to seek amendment under Subpart E of this part. The FDA may refuse to disclose a record that would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished on or after September 27, 1975. Any individual refused access to a record that would reveal a confidential source shall be advised in a general way that the record contains information that would reveal a confidential source.

(c) The Commissioner shall not make available any record that is prohibited from public disclosure under § 20.82(b) of this chapter.

(d) Discretionary disclosure of a record pursuant to paragraph (b)(1) of this section shall not set a precedent for discretionary disclosure of a similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record in a system that is exempt under § 21.61.

Subpart G—Disclosure of Records in Privacy Act Record Systems to Persons Other Than the Subject Individual

§ 21.70 Disclosure and intra-agency use of records in Privacy Act Record Systems; no accounting required.

(a) A record about an individual which is contained in a Privacy Act Record System may be disclosed:

(1) To the individual who is the subject of the record, or his legal guardian under § 21.75;

(2) To a third party pursuant to a written request by, or with a written consent of, the individual to whom the record pertains, or his legal guardian under § 21.75;

(3) To any person:

(i) Where the names and other identifying information are first deleted, and under circumstances in which the recipient is unlikely to know the identity of the subject of the record;

(ii) Where disclosure is required by Part 20 of this chapter (the public information regulations); or

(4) Within the Department of Health, Education, and Welfare to officers and employees who have a need for the record in the performance of their duties in connection with the laws administered and enforced by the Food and Drug Administration or that govern the agency. For purposes of this section, officers or employees of the Department shall include the following categories of individuals, who shall thereafter be subject to the same restrictions with respect to disclosure as any Food and Drug Administration employee: Food and Drug Administration consultants and advisory committees, State and local government employees for use only in their work with the Food and Drug Administration, and contractors and their employees to the extent that the records of such contractors are subject to the requirements of this part under § 21.30.

(b) No accounting is required for any disclosure or use under paragraph (a) of this section.

§ 21.71 Disclosure of records in Privacy Act Record Systems; accounting required.

(a) Except as provided in § 21.70, a record about an individual that is contained in a Privacy Act Record System shall not be disclosed by any method of communication except under any of the following circumstances, which are subject to the limitations of paragraphs (b) and (c) of this section and to the accounting requirement of paragraph (d) of this section:

(1) For a use described as a "routine use" in the notice for the system under § 21.20(b)(5) that is compatible with the purpose for which the record was collected.

(2) To the Bureau of Census for a census, survey, or a related activity pursuant to Title 13 of the United States Code.

(3) To a recipient who has provided advance assurance, pursuant to paragraph (c)(2) of this section that the record will be used solely as a statistical research or reporting record and will not be communicated by the recipient to any other person except in a form that is not individually identifiable.

(4) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation, or to the General Services Administration for evaluation to determine whether the record has such value.

(5) To a Federal, State, or local agency for purposes of a law enforcement activity that is authorized by law, upon written request by the head of the agency specifying the particular portion of the record that is desired and the law enforcement purpose for which the record is sought. Disclosures under this paragraph are in addition to any disclosures for law enforcement purposes described as a "routine use" in a notice for a Privacy Act Record System.

(6) To a person pursuant to a showing of compelling circumstances affecting the health and safety of an individual, not necessarily the individual to whom the record pertains. Upon such disclosure, the Food and Drug Administration shall mail a notification of the fact of disclosure to the last known address of the individual who is the subject of the record.

(7) To either House of Congress, or to any Subcommittee or Committee thereof, to the extent that the subject matter of the record falls within its jurisdiction.

(8) To the General Accounting Office.

(9) Pursuant to an order of the court of competent jurisdiction. Upon such court-ordered disclosure, the Food and Drug Administration shall make reasonable efforts to notify the individual in accordance with § 20.83(b) of this chapter.

(b) The Food and Drug Administration may in its discretion refuse to make a disclosure permitted under paragraph (a) of this section, if the disclosure would in the judgment of the agency, invade the privacy of the individual or be inconsistent with the purpose for which the information was collected.

(c) The Food and Drug Administration may require any person requesting a disclosure of a record under paragraph (a) of this section to provide:

(1) Information about the purposes to which the disclosed record is to be put, and

(2) A written statement certifying that the record will be used only for the stated purposes and will not be further disclosed without the written permission of the Food and Drug Administration.

Under 5 U.S.C. 552a(i)(3), any person who knowingly or willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000. Such person may also be subject to prosecution under the False Reports to the Government Act, 18 U.S.C. 1001.

(d) An accounting shall be made, in accordance with paragraph (e) of this section, of any disclosure under paragraph (a) of this section of a record that is not a disclosure under § 21.70.

(e) Where an accounting is required under paragraph (d) of this section, the Food and Drug Administration shall:

(1) Record the name and address of the person or agency to whom the disclosure is made and the date, nature, and purpose of the disclosure. The accounting shall not be considered a Privacy Act Record System.

(2) Retain the accounting for 5 years or for the life of the record, whichever is longer, following the disclosure.

(3) Notify those recipients listed in the accounting of amendments or disputes concerning the records previously

disclosed to them pursuant to §§ 21.51(d)(3), 21.53(c), or 21.54(c).

(4) Except when the record is exempt from individual access and contest under § 21.61 or to the extent that the accounting describes a transfer for a law enforcement purpose pursuant to paragraph (a)(5) of this section, make the accounting available to the individual to whom the record pertains, in accordance with procedures of Subpart D of this part.

(f) A single accounting may be used to cover disclosure(s) that consist of a continuing dialogue between two agencies over a prolonged period, such as discussion of an enforcement action between the Food and Drug Administration and the Department of Justice. In such cases, a general notation may be made that, as of a certain date, contact was initiated, to continue until resolution of the matter.

§ 21.72 Individual consent to disclosure of records to other persons.

(a) Individuals may consent to disclosure of records about themselves to other persons in several ways, for example:

(1) An individual may give consent at the time that the information is collected for disclosure for specific purposes or to specific persons.

(2) An individual may give consent for disclosure of his records to a specific person.

(3) An individual may request the Food and Drug Administration to transcribe a specific record for submission to another person.

(b) In each case the consent shall be in writing and shall specify the individual, organizational unit, or class of individuals or organizational units to whom the record may be disclosed, which record may be disclosed, and, if applicable, for what time period. A blanket consent to release all of an individual's records to unspecified individuals or organizational units will not be honored. Verification of the identity of the individual and, where applicable, of the person to whom the record is to be disclosed shall be made in accordance with § 21.44. Consent documents shall be retained for a period of at least 2 years. If such documents are used as a means of accounting for the disclosure, they shall be retained as provided in § 21.71(e)(2).

§ 21.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.

(a) The Food and Drug Administration shall make reasonable efforts to assure that a record about an individual in a Privacy Act Record System is accurate, relevant to a Food and Drug Administration purpose, timely, and complete before such record is disclosed under § 21.71.

(b) Paragraph (a) of this section shall not apply to disclosures that are required under Part 20 of this chapter (the public information regulations) or made to other Federal Government departments and agencies. Where appropriate, the letter disclosing the information shall indicate that the Food and Drug Administration has not reviewed the record to assure that it is accurate, relevant, timely, and complete.

§ 21.74 Providing notice that a record is disputed.

Whenever an individual has filed a statement of disagreement with the Food and Drug Administration concerning a refusal to amend a record under § 21.51(a)(2) or with another agency that provides the record to the Food and Drug Administration, the Food and Drug Administration shall in any subsequent disclosure under this subpart provide a copy of the statement of disagreement and a concise statement by the agency, if one has been prepared, of the reasons for not making the amendment(s) requested.

§ 21.75 Rights of legal guardians.

For the purposes of this part, the parent of any individual who is a minor or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction may act on behalf of the individual.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart A—General Provisions

Sec.
- 25.1 Applicability.
- 25.5 Responsible agency officials.
- 25.10 Submission of comments to other agencies.

Subpart B—Administrative Procedures

- 25.20 Content and format of environmental impact statements.
- 25.25 Preparation and review procedures.
- 25.30 Public availability of environmental impact statements.

AUTHORITY: Sec. 701, 52 Stat. 1055–56 as amended by 70 Stat. 919 and 72 Stat. 948, 21 U.S.C. 371; sec. 102(2)(C), 83 Stat. 853, 42 U.S.C. 4332; the Guidelines issued by the Council on Environmental Quality (36 FR 7724); Executive Order 11514 of March 4, 1970 (35 FR 4247).

Subpart A—General Provisions

§ 25.1 Applicability.

(a) (1) An environmental impact statement shall be prepared, circulated, and filed pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 for every major agency action that significantly affects the quality of the human environment.

(2) Agency decisions shall include a careful consideration of all environmental effects of proposed actions.

(b) The need for preparing an environmental impact statement shall be considered for the following agency actions pursuant to environmental criteria established by the agency and the department:

(1) Recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved;

(2) Destruction of articles condemned after seizure or enjoined;

(3) Destruction of articles following detention or recall at agency request;

(4) Disposition of Food and Drug Administration laboratory waste materials;

(5) Issuance of licenses for biological products;

(6) Establishment by regulation of labeling or other requirements for marketing articles;

(7) Establishment by regulation of standards for articles (except food standards);

(8) Approval of new drug and abbreviated new drug applications and old drug monographs;

(9) Approval of new animal drug and abbreviated new animal drug applications and old animal drug monographs;

(10) Approval of antibiotic drug monographs;

(11) Approval of food additive petitions;

(12) Approval of color additive petitions; and

(13) Policy, regulations, and procedure making which significantly affect the quality of the human environment.

(c) An environmental impact statement will not be required for amendments to existing regulations and approvals of supplements to existing approvals unless the change is substantial.

(d) The agency has carefully considered the environmental effects of the following types of actions and has concluded that since they are not major agency actions significantly affecting the quality of the human environment, environmental impact statements are not required for them:

(1) Recommendations for court action concerning foods, drugs, devices, cosmetics, and electronic products;

(2) Factory inspections;

(3) Seafood inspections;

(4) Issuance or amendment of food standards; and

(5) Investigational new drug applications and investigational new animal drug applications, unless the agency notifies the applicant that one is required.

(e) Whenever a person submits any application or petition requesting action by the agency (except action specified in paragraph (d) of this section), he shall include an environmental impact analysis report on the requested action. Failure to include an adequate environmental impact analysis report in an application or petition shall be sufficient grounds to refuse to accept or file the application or petition.

(f) Whenever a manufacturer, distributor, or dealer proposes to destroy a food, drug, cosmetic, device, or electronic product which has been condemned, enjoined, detained, or banned by regulation, he shall submit to the agency an environmental impact analysis report analyzing the environmental impact of the disposition of such articles.

(g) An environmental impact analysis report shall be submitted to the agency in the following format:

ENVIRONMENTAL IMPACT ANALYSIS REPORT

Date: _____

Name of applicant: _____

Address: _____

1. Describe the proposed action: _____

_____

2. Discuss the probable impact of the action on the environment (including primary and secondary consequences): _____

3. Discuss the probable adverse environmental effects which cannot be avoided: _____

4. Evaluate alternatives to the proposed action: _____

5. Describe the relationship between local short-term uses of the environment with respect to the proposed action and the maintenance and enhancement of long-term productivity: _____

6. Describe any irreversible and irretrievable commitment of resources which would be involved in the proposed action should it be implemented: _____

7. Discuss the objectives raised by other agencies, organizations, or individuals which are known to the applicant: _____

8. If proposed action should be taken prior to 90 days from the circulation of a draft environmental impact statement or 30 days from the filing of a final environmental impact statement, explain why: _____

9. Analyze whether the benefit to the public of the proposed action will outweigh the action's potential risks to the environment: _____

_____ _____
(Date) (Signature of responsible official)

(h) Data and information which constitute trade secrets or confidential information under Part 20 of this chapter shall not be submitted in an environmental impact analysis report.

(i) Upon receipt of an environmental impact analysis report, the responsible agency official shall make an independent assessment as to whether an environmental impact statement shall be prepared for the proposed action.

§ 25.5 Responsible agency officials.

(a) When environmental impact statements are required, the following agency officials are responsible for preparing the statements as indicated:

(1) The office of the Commissioner is responsible for preparing a draft or final environmental impact statement on actions not delegated by the Commissioner.

(2) The director of each bureau is responsible for preparing a draft or final environmental impact statement on actions delegated to that bureau by the Commissioner under Subpart B of Part 5 of this chapter.

(3 The Executive Director for Regional Operations is responsible for preparing a draft or final environmental impact statement on the destruction of articles condemned after seizure, enjoined, under import detention, or under detention or recalled at agency request.

(b) Every action memorandum proposing an agency action included under § 25.1(b) shall contain an evaluation of the environmental impact of the proposed action and shall be accompanied by a draft or final environmental impact statement if one is required.

§ 25.10 Submission of comments to other agencies.

When the Food and Drug Administration is requested by the Office of the Secretary to comment on environmental impact statements prepared by other agencies, the Commissioner shall prepare such comments as he deems appropriate and shall submit them to the Office of the Secretary, which shall prepare an appropriate response for submission to the requesting agency and the Council on Environmental Quality.

Subpart B—Administrative Procedures

§ 25.20 Content and format of environmental impact statements.

(a) When it is determined that an environmental impact statement is required, draft and final environmental impact statements shall cover the following points:

(1) There shall be a description of the proposed action including adequate information and technical data to permit a careful assessment of the environmental impact. Where relevant, exhibits should be provided.

(2) The probable impact that the proposed action will have on the environment shall be analyzed and shall include the impact on ecological systems such as wildlife, fish, and other marine life. Both primary and secondary significant consequences for the environment should be included in the analysis.

(3) There shall be a description of any probable adverse environmental effects which cannot be avoided (such as water or air pollution, undesirable land use patterns, damage to life systems, threats to health, or other consequences adverse to the environmental goals set forth in section 101(b) of the National Environmental Policy Act).

(4) Alternatives to the proposed action must be described, in accordance with section 102(2)(D) of the National Environmental Policy Act, which requires the responsible agency to "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." A rigorous exploration and objective assessment of alternative actions that might avoid some or all of the adverse environmental effects is essential. Sufficient analysis of alternatives and their costs and impact on the environment should accompany the proposed action through the agency review process in order to avoid eliminating prematurely options which might have fewer adverse environmental effects.

(5) The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity must be discussed. Thus, realizing that each generation is trustee of the environment for succeeding generations, the agency must assess the action for cumulative and long-term effects.

(6) There must be a statement concerning any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented. This requires the agency to identify the extent to which the action curtails the range of beneficial uses of the environment.

(7) Where appropriate, there must be a discussion of the problems and objections raised by other Federal, State, and local agencies and by private organizations and individuals, and a disposition of the issues raised by these problems and objections. This section may be added at the end of the review process in the final text of the environmental statement.

(b) When it is determined that an environmental impact statement is required, draft and final environmental impact statements shall be prepared in the following format:

("DRAFT" OR "FINAL") ENVIRONMENTAL IMPACT STATEMENT, FOOD AND DRUG ADMINISTRATION (RESPONSIBLE OPERATING DIVISION)

1. Indicate administrative action or legislative action.

2. Describe the action, indicating any States or counties particularly affected.

3. Analyze the environmental impact of the proposed action.

4. Describe any unavoidable adverse environmental effects of the action.

5. Describe and assess alternative courses of action considered.

6. Describe any irreversible and irretrievable commitments of resources involved in implementing the action.

7. Where appropriate, evaluate any objections to the action raised by interested persons.

8. (a) For draft statements, state the date and form of FEDERAL REGISTER publication by which comments have been requested from all interested persons and attach a copy of the notice.

(b) For final statements, list all persons from which written comments have been received and attach a copy of each.

9. Give the date that the draft or final statement was made available to the Council on Environmental Quality and to the public.

§ 25.23 Preparation and review procedures.

(a) When it is determined that an environmental impact statement is required, the statement shall be prepared as follows:

(1) *Preparation of draft environmental impact statement.* A draft environmental impact statement shall be prepared by the responsible agency official as designated in § 25.5. When appropriate during the preparation of a draft environmental impact statement, the responsible agency official shall consult with Federal, State, and local officials and other interested persons.

(2) *Distribution of draft environmental impact statements.* After the responsible agency official has prepared a draft environmental impact statement, he shall forward 20 copies of the draft statement to the Office of the Secretary which shall thereupon forward 10 copies to the Council on Environmental Qual-

ity. At the same time the draft statement will be made available for public inspection by the Office of the Assistant Commissioner for Public Affairs and the Hearing Clerk.

(3) *Solicitation of comments.* (i) After the preparation and distribution of a draft environmental impact statement, comments will be solicited from all interested persons. Sixty days are allowed for reply, after which it is presumed that no comments will be made unless a specified extension of time is requested.

(ii) Where the subject of a draft environmental impact statement is also the subject of a notice of proposed rule making or a notice of filing published in the FEDERAL REGISTER, the FEDERAL REGISTER notice shall state that the environmental impact analysis report and the draft environmental impact statement are available upon request and shall solicit comments by all interested persons.

(iii) Where the subject of a draft environmental impact statement is not also the subject of a notice published in the FEDERAL REGISTER, a notice will be published in the FEDERAL REGISTER describing the proposed action, stating that the environmental impact analysis report and the draft environmental impact statement are available upon request, and soliciting comments by all interested persons. This notice may be published by the agency or the department, or the agency or the department may request that the Council on Environmental Quality publish it.

(iv) Comments shall be solicited from Federal agencies having jurisdiction by law or special expertise with respect to the environmental impact of a proposed action by sending them a copy of a draft environmental impact statement.

(v) All comments on draft environmental impact statements shall be submitted in quintuplicate to the Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 4–65, 5600 Fishers Lane, Rockville, MD 20857, where they shall be available for public inspection during working hours, Monday through Friday.

(vi) When the responsible agency official concludes that no environmental impact statement is necessary and the proposed action is the subject of a notice of proposed rule making or a notice of filing published in the FEDERAL REGISTER, the FEDERAL REGISTER notice shall state that no environmental impact statement is necessary and, where applicable, that the environmental impact analysis report is available upon request.

(4) *Time for consideration prior to decision.* Draft environmental impact statements shall be prepared, forwarded to the Council on Environmental Quality, and made available to the public early enough in the consideration of the proposed action to permit meaningful review of the environmental issues involved. To the maximum extent practicable, no final action shall be taken on the proposal earlier than 90 days after a draft environmental impact statement has been prepared, forwarded to the Council, and made available to the public.

(5) *Final environmental impact statements.* The final text of an environmental impact statement shall be prepared by the responsible agency official after comments on the draft statement have been reviewed and shall include an evaluation of all comments. The final statements shall receive full consideration in the agency's decisionmaking process. The responsible agency official shall forward 20 copies of the final statement to the Office of the Secretary which shall thereupon forward 10 copies to the Council on Environmental Quality, and copies of the final statement shall be made available for public inspection by the Office of the Assistant Commissioner for Public Affairs and the Hearing Clerk. To the maximum extent practicable, no agency action shall take place earlier than 30 days after the final statement has been forwarded to the Council on Environmental Quality and made available to the public.

(6) Where the subject of an environmental impact statement is an agency action governed by specific time requirements under statute or regulation, every effort shall be made to comply with the provisions of this part within the time specified, and those time requirements shall be extended only as long as is absolutely necessary to permit the agency to consider or issue an environmental impact statement of the action.

(b) When the proposed action involves destruction of condemned, enjoined, detained or recalled articles or disposition of Food and Drug Administration laboratory waste materials, the agency shall adhere to disposal guidelines consistent with Federal, State, and local regulations applicable on a case-by-case basis. This shall be reflected in environmental impact statements when they are issued on such actions.

(c) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of paragraph (a) (1) through (5) of this section impracticable. Compliance with the requirements for environmental analysis under the National Environmental Policy Act is impossible in instances which require immediate regulatory action to safeguard the public health. The responsible agency official shall give written notice to the Council on Environmental Quality of those actions having potentially significant individual environmental impact as to which no environmental impact statement is filed because public health considerations require immediate action.

§ 25.30 Public availability of environmental impact statements.

(a) All draft and final environmental impact statements and all environmental impact analysis reports shall be available for public inspection through the office of the Assistant Commissioner for Public Affairs and the Hearing Clerk.

(b) Draft and final environmental impact statements will be available immediately after preparation. An environmental impact analysis report will be available at the time a draft environmental impact statement is circulated or, if no environmental impact statement is necessary, at the time of publication of the FEDERAL REGISTER notice announcing the availability of the report.

PART 70—COLOR ADDITIVES

Subpart A—General Provisions

Sec.
70.3 Definitions.
70.5 General restrictions on use of color additives.
70.10 Color additives in standardized foods, new drugs, and antibiotics.
70.11 Related substances.
70.19 Fees for listing.

Subpart B—Packaging and Labeling

70.20 Packaging requirements for straight colors (other than hair dyes).
70.25 Labeling requirements for color additives (other than hair dyes).

Subpart C—Safety Evaluation

70.40 Safety factors to be considered.
70.42 Criteria for evaluating the safety of color additives.
70.45 Allocation of color additives.
70.50 Application of the cancer clause of section 706 of the act.
70.51 Advisory committee on the application of the cancer clause.
70.55 Request for scientific studies.

AUTHORITY: The provisions of this Part 70 issued under secs. 701, 706, 52 Stat. 1055–1056 as amended; 74 Stat. 399–407 as amended (21 U.S.C. 371, 376), unless otherwise noted.

Subpart A—General Provisions

§ 70.3 Definitions.

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

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) "Act" means the Federal Food, Drug, and Cosmetic Act as amended.

(e) "Color Certification Branch" means the unit established within the Food and Drug Administration located in the Bureau of Foods, charged with the responsibility for the mechanics of the certification procedure hereinafter described, and including the examination of samples of color additives subject to certification.

(f) A "color additive" is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the transmittal of the color to the contents of the package or any part thereof. Food ingredients such as cherries, green or red

peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as "color additives"; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a "color additive." Food ingredients as authorized by a definition and standard of identity prescribed by regulations pursuant to section 401 of the act are "color additives," where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. An ingested drug the intended function of which is to impart color to the human body is a "color additive." For the purposes of this part, the term "color" includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not "color additives."

(g) For a material otherwise meeting the definition of "color additive" to be exempt from section 706 of the act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)

(h) The exemption that applies to a pesticide chemical, soil or plant nutrient, or other agricultural chemical, where its coloring effect results solely from its aiding, retarding, or otherwise affecting directly or indirectly, the growth or other natural physiological processes of produce of the soil, applies only to color developed in such product through natural physiological processes such as enzymatic action. If the pesticide chemical, soil or plant nutrient, or other agricultural chemical itself acts as a color or carries as an ingredient a color, and because of this property colors the produce of the soil, it is a "color additive" and is not exempt.

(i) "Safe" means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

(j) The term "straight color" means a color additive listed in Parts 71 and 81 of this chapter, and includes lakes and such substances as are permitted by the specifications for such color.

(k) The term "mixture" means a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(l) The term "lake" means a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.

(m) The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

(n) The term "substratum" means the substance on which the pure color in a lake is extended.

(o) The term "pure color" means the color contained in a color additive, exclusive of any intermediate or other component, or of any diluent or substratum contained therein.

(p) The term "batch" means a homogeneous lot of color additive or color additive mixture produced by an identified production operation, which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(q) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.

(r) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(s) The term "area of the eye" means the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(t) The term "package" means the immediate container in which a color additive or color additive mixture has been packed for shipment or delivery. If the package is then packed in a shipping carton or other protective container, such container shall not be considered to be the immediate container. In the case of color additive mixtures for household use containing less than 15 percent pure color, when two or more containers of 3 ounces each or less, each containing a different color, are distributed as a unit, the immediate container for such unit shall be considered to be the package as defined in this section.

(u) The "hair dye" exemption in section 601(a) of the act applies to coal tar hair dyes intended for use in altering the color of the hair and which are, or which bear or contain, color additives derived from coal tar with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. The exemption does not apply to coloring ingredients in hair dyes not derived from coal tar, and it does not extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetic that alter the color of the hair.

(v) The terms "externally applied drugs" and "externally applied cosmetics" mean drugs or cosmetics applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

§ 70.5 General restrictions on use of color additives.

(a) *Color additives for use in the area of the eye.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in the area of the eye unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in the area of the eye, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Parts 73 and 74 of this chapter, even though such color additive is certified and/or listed for other uses.

(b) *Color additives for use in injections.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in injections unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in injections, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Parts 73 and 74 of this chapter, even though such color additive is certified and/or listed for other uses.

(c) *Color additives for use in surgical sutures.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use as a surgical suture unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use as a surgical suture, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Parts 73 and 74 of this chapter, even though such color additive is certified and/or listed for other uses.

§ 70.10 Color additives in standardized foods, new drugs, and antibiotics.

(a) *Standardized foods.* (1) Where a petition is received for issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a color additive in the standardized food, the provisions

of the regulations in this part shall apply with respect to the information that must be submitted with respect to the safety of the color additive (if such information has not previously been submitted and safety of the color additive for the intended use has not been already established), and the petition must show also that the use of the color additive in the standardized food would be in conformance with section 401 of the act or with the terms of a temporary permit issued under § 130.17 of this chapter.

(2) If a petition for a definition and standard of identity contains a proposal for a color additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a color additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this part.

(3) A regulation will not be issued allowing the use of a color additive in a food for which a definition and standard of identity is established, unless its issuance is in conformance with section 401 of the act or with the terms of a temporary permit issued under § 130.17 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the color additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

(b) *New drugs and antibiotics.* (1) Where an application for a new drug or for certification of an antibiotic drug is received and this application proposes, for coloring purposes only, the inclusion of a color additive, the provisions of the regulations in this part shall apply with respect to the information that must be submitted about the safety of the color additive, if such information has not previously been submitted and safety of the color additive for the intended use has not already been established.

(2) If an application for a new drug or certification of an antibiotic drug inferentially contains a proposal for a color additive regulation, and the applicant fails to designate it as such, the Commissioner, upon determining that the application includes a proposal for a color additive regulation, shall so notify the applicant and shall thereafter proceed in accordance with the regulations in this part.

(3) Where a petition for a color additive must be filed in accordance with paragraph (b)(2) of this section, the date of filing of the color additive petition shall be considered as the date of filing of the new-drug application or the request for certification of the antibiotic drug.

§ 70.11 Related substances.

(a) Different color additives may cause similar or related pharmacological or biological effects, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(b) Food additives may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered as having additive toxic effects.

(c) Pesticide chemicals may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(d) In establishing tolerances for color additives, the Commissioner will take into consideration, among other things, the amount of any common component permitted in other color additives, in food additives, and in pesticide chemical residues as well as the similar biological activity (such as cholinesterase inhibition) produced by such substance.

§ 70.19 Fees for listing.

(a) Each petition for the listing of a color additive shall be accompanied by a deposit of $3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition for the listing is for use in or on foods only, the deposit shall be $3,000.00.

(c) If the petition for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be $2,600.00.

(d) The provisions of paragraphs (a), (b), and (c) of this section shall be applicable, whether or not the proposal contemplates any tolerances, limitations, or other restrictions placed upon the use of the color additive.

(e) If a petition proposing the issuance of a regulation is withdrawn before it is finally accepted for filing, the deposit, less a $600.00 fee for clerical handling and administrative and technical review, shall be returned to the petitioner.

(f) If a petition proposing the issuance of a regulation is withdrawn within 30 days after filing, the deposit, less $1,800.00 if the petition is covered by paragraph (a) or (b) of this section, and less $1,600.00, if the petition is covered by paragraph (c) of this section, shall be returned to the petitioner.

(g) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of $1,800.00 for a petition filed under paragraph (a) or (b) of this section, and $1,600.00 for a petition filed under paragraph (c) of this section. If a petition is resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(h) When the resubmission pertains to a petition that had been withdrawn before acceptance for filing, a new advance deposit shall be made in full as prescribed in paragraph (a), (b), or (c) of this section.

(i) After a color additive has been listed, any request for an amendment or additional tolerance shall be accompanied by a deposit of $1,800.00 for use in the items specified in paragraphs (a) and (b) of this section, or $1,600.00 for use in items specified in paragraph (c) of this section.

(j) The fee for services in listing a diluent under § 80.35 for use in color additive mixtures shall be $250.00.

(k) Objections and request for public hearing under section 706(d) of the act or section 203(d)(2)(C) of Public Law 86-618 (74 Stat. 404; 21 U.S.C. 376, note) shall be accompanied by a filing fee of $250.00.

(l) In the event of a referral of a petition under this section to an advisory committee, all costs related thereto (including personal compensation of committee members, travel materials, and other costs) shall be borne by the person or organization requesting the referral, such costs to be assessed on the basis of actual cost to the Government: *Provided*, That the compensation of such costs shall include personal compensation of advisory committee members at a rate not to exceed $75.00 per member per day.

(m) In the case of requests of referrals to advisory committees, a special advance deposit shall be made in the amount of $2,500.00. Where required, further advance in increments of $2,500.00 each shall be made upon request of the Commissioner of Food and Drugs. All deposits for referrals to advisory committees in excess of actual expenses shall be refunded to the depositor.

(n) All requests for pharmacological or other scientific studies shall be accompanied by an advance deposit of $5,000.00. Further advance deposits shall be made upon request of the Commissioner of Food and Drugs when necessary to prevent arrears in such cost. Any deposits in excess of actual expenses will be refunded to the depositor. If a request is denied the advance deposit will be refunded less such costs as are incurred for review of the request.

(o) The person who files a petition for judicial review of an order under section 706(d) of the act shall pay the costs of preparing a transcript of the record on which the order is based.

(p) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft or certified check drawn to the order of the Food and Drug Administration, collectable at par at Washington, D.C. All deposits and fees shall be forwarded to the Division of Food and Color Additives, HFF-330, Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(q) The Commissioner of Food and Drugs may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(r) Any person who believes that payment of these fees will work a hardship

on him may petition the Commissioner of Food and Drugs to waive or refund the fees.

Subpart B—Packaging and Labeling

§ 70.20 Packaging requirements for straight colors (other than hair dyes).

Straight colors shall be packaged in containers which prevent changes in composition. Packages shall be sealed so that they cannot be opened without breaking the seal. An unavoidable change in moisture content caused by the ordinary and customary exposure that occurs in good storage, packing, and distribution practice is not considered a change in composition. If the packaging material is a food additive it shall be authorized by an appropriate regulation in Parts 170 through 189 of this chapter.

§ 70.25 Labeling requirements for color additives (other than hair dyes).

(a) *General labeling requirements.* All color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by this part and Parts 71 and 80 of this chapter. In addition to all other information required by the act, labels for color additives, except those in a form suitable for coloring the human body, shall state:

(1) The name of the straight color or the name of each ingredient comprising the color additive, if it is a mixture.

(2) A statement indicating general limitations for the use of the color additive, such as "for food use only"; "for food, drug, and cosmetic use"; "for use in drugs for external application only."

(3) Where regulations issued impose quantitative limitations for a general or specific use of a straight color, the amount of each such straight color in terms of weight per unit/volume or percent by weight.

(4) An expiration date if stability data require it.

(b) *Special labeling for color additives with tolerances.* Where tolerances are imposed for a general or specific use of a color additive, the label shall in addition provide directions for use of the color additive which if followed will preclude the food, drug, or cosmetic to which it is added from containing an amount of the color additive in excess of the tolerance.

(c) *Special labeling for color additives with other limitations.* If use of the color additive is subject to other limitations prescribed in this part, such limitations shall be stated on the label of the color additive by a plain and conspicuous statement. Examples of such limitation statements are: "Do not use in products used in the area of the eye"; "Do not use for coloring drugs for injection."

(d) *Special labeling for color additives not exempt from certification.* Color additives not exempt from the certification procedures shall in addition include in the labeling the lot number assigned by the Color Certification Branch, except that in the case of any mixture for household use which contains not more than 15 percent of pure color and which is in packages containing not more than 3 ounces there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number.

Subpart C—Safety Evaluation

§ 70.40 Safety factors to be considered.

In accordance with section 706(b)(5)(A)(iii) of the act, the following safety factor will be applied in determining whether the proposed use of a color additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor of 100 to 1 will be used in applying animal experimentation data to man; that is, a color additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum no-effect level for the most susceptible experimental animals tested. The various species of experimental animals used in the tests shall conform to good pharmacological practice.

§ 70.42 Criteria for evaluating the safety of color additives.

(a) In deciding whether a petition is complete and suitable for filing and in reaching a decision on any petition filed, the Commissioner will apply the "safe-for-use" principle. This will require the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. The Commissioner may list a color additive for use generally in or on food, in or on drugs, or in or on cosmetics when he finds from the data presented that such additive is suitable and may safely be employed for such general use; he may list an additive only for more limited use or uses for which it is proven suitable and may safely be employed; and he is authorized to prescribe broadly the conditions under which the additive may be safely employed for such use or uses. This may allow the use of a particular dye, pigment, or other substance with certain diluents, but not with others, or at a higher concentration with some than with others.

(b) The safety for external color additives will normally be determined by tests for acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded skin, and carcinogenicity by skin application. The Commissioner may waive any of such tests if data before him otherwise establish that such test is not required to determine safety for the use proposed.

(c) Upon written request describing the proposed use of a color additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a color additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 70.45 Allocation of color additives.

Whenever, in the consideration of a petition or a proposal to list a color additive or to alter an existing listing, the data before the Commissioner fail to show that it would be safe to list the color additive for all the uses proposed or at the levels proposed, the Commissioner will notify the petitioner and other interested persons by publication in the FEDERAL REGISTER that it is necessary to allocate the safe tolerance for the straight color in the color additive among the competing needs. This notice shall call for the presentation of data by all interested persons on which the allocation can be made in accordance with section 706(b)(8) of the act. The time for acting upon the petition shall be stayed until such data are presented, whereupon the time limits shall begin to run anew. As promptly as possible after presentation of the data, the Commissioner will, by order, announce the allocation and the tolerance limitations.

§ 70.50 Application of the cancer clause of section 706 of the act.

(a) *Color additives that may be ingested.* Whenever (1) the scientific data before the Commissioner (either the reports from the scientific literature or the results of biological testing) suggest the possibility that the color additive including its components or impurities has induced cancer when ingested by man or animal; or (2) tests which are appropriate for the evaluation of the safety of additives in food suggest that the color additive, including its components or impurities, induces cancer in man or animal, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, cancer has been induced and whether the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable; and if the data considered as a whole establish that the color additive will be safe under the conditions that can be specified in the applicable regulation, it may be listed for such use. But if in the judgment of the Commissioner, based on information from qualified scientists, cancer has been induced, no regulation may issue which permits its use.

(b) *Color additives that will not be ingested.* Whenever the scientific data before the Commissioner suggest the possibility that the color additive, including its components or impurities, has induced cancer in man or animals by routes other than ingestion, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, the test suggesting the possibility of carcinogenesis is appropriate for the evaluation of the color additive for a use which does not involve ingestion, cancer has been induced, and the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable to preclude external drug and cosmetic uses,

and if the data as a whole establish that the color additive will be safe under conditions that can be specified in the regulations, it may be listed for such use. But if, in the judgment of the Commissioner, based on information from qualified scientists, the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive, including its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production.* Color additives that are an ingredient of the feed for animals that are raised for food production must satisfy the requirements imposed by subpart E of Part 500 of this chapter.

§ 70.51 Advisory committee on the applicability of the anticancer clause.

All requests for and procedures governing any advisory committee on the anticancer clause shall be subject to the provisions of Part 14 of this chapter, and particularly Subpart G of that part.

§ 70.55 Request for scientific studies.

The Commissioner will consider requests by any interested person who desires the Food and Drug Administration to conduct scientific studies to support a petition for a regulation for a color additive. If favorably acted upon, such studies will be limited to pharmacological investigations, studies of the chemical and physical structure of the color additive, and methods of analysis of the pure color additive (including impurities) and its identification and determination in foods, drugs, or cosmetics, as the case may be. All requests for such studies shall be accompanied by the fee prescribed in § 70.19.

PART 71—COLOR ADDITIVE PETITIONS

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AUTHORITY: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376), unless otherwise noted.

Subpart A—General Provisions

§ 71.1 Petitions.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or cosmetic or for coloring the human body. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. The petition shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petitioner shall state the post-office address in the United States to which published notices or orders issued or objections filed pursuant to section 706 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted the information. Any reference to published information offered in support of a color additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)

Name of petitioner ----------
Post-office address ----------
Name of color additive and proposed use ----

Division of Food and Color Additives,
HFF-330, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

Dear Sir:

Petitioner submits this pursuant to section 706(b)(1) of the Federal Food, Drug, and Cosmetic Act requesting listing by the Commissioner of the color additive ----------
as suitable and safe for use in or on ----------
subject to the conditions that ----------
[Petitioner may propose a listing for general use in food, drugs, or cosmetics or, if such general listing is not believed suitable and safe, the petitioner shall describe the conditions under which he believes the additive can be safely used and for which it will be suitable. These conditions may include tolerance limitations, specifications as to the manner in which the additive may be added or used, and directions and other labeling or packaging safeguards that should be applied. The level of use proposed should not be higher than reasonably required to accomplish the intended color effect.]

Attached hereto in triplicate and constituting a part of this petition are the following:

A. The name and all pertinent information concerning the color additive, including chemical identity and composition of the color additive, its physical, chemical, and biological properties, and specifications prescribing its component(s) and identifying and limiting the reaction byproducts and other impurities.

The petition shall contain a description of the chemical and physical tests relied upon to identify the color additive and shall contain a full description of the methods used in, and the facilities and controls used for, the production of the color additive. These shall establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls, within reasonable limits, that do not affect the characteristics of the substance or the reliability of the controls may be specified.

The petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation of any straight color, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common or usual name and its complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitive statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a color additive, the petitioner shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the color additive, the expiration period that will be employed as well as any packaging and labeling precautions needed to preserve stability.

B. The amount of the color additive proposed for use and the color effect intended to be achieved, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the color additive. If the color effect results or may reasonably be expected to result from use of the color additive in packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

Typewritten or other draft-labeling copy will be accepted for consideration of the petition provided final printed labeling identical in content to the draft copy is submitted as soon as available, and prior to the marketing of the color additive. The printed labeling shall conform in prominence and conspicuousness with the requirements of the act.

If the color additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance. If the safety data will not support the use of the amount of the color additive reasonably needed to accomplish the desired color effect, the requested tolerance will not be established. Petitioners are expected to propose the use of color additives in accordance with sound color chemistry.

C.1. A description of practicable methods to determine the pure color and all intermediates, subsidiary colors, and other components of the color additive.

2. A description of practicable methods to determine the amount of the color additive in any raw, processed, and/or finished food, drug, or cosmetic in which use of the color additive is proposed. (The tests proposed shall be those that can be used for food, drug, or cosmetic control purposes and can be applied with consistent results by any properly equipped laboratory and trained personnel.)

3. A description of methods for identification and determination of any substance formed in or on such food, drug, or cosmetic because of the use of the color additive.

(If it is the petitioner's view that any such method would not be needed, under the terms of section 706(b)(5)(A)(iv), a statement shall be submitted in lieu of methods as to the basis for such view.)

D. Full reports of investigation made with respect to the safety of the color additive.

(A petition will be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the color additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any data that would influence the evaluation of the safety of the color additive).

E. Complete data which will allow the Commissioner to consider, among other things, the probable consumption of, and/or other relevant exposure from the additive and of any substance formed in or on food, drugs, or cosmetics because of such additive; and the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in the diet including, but not limited to food additives and pesticide chemicals for which tolerances or exemptions from tolerances have been established.

F. Proposed tolerances and other limitations on the use of the color additive, if tolerances and limitations are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If exemption from batch certification is requested, the reasons why it is believed such certification is not necessary (including supporting data to establish the safety of the intended use).

H. If submitting a petition to alter an existing regulation issued pursuant to section 706(b) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

I. The prescribed fee of $ _____ for admitting the color additive to listing is enclosed (unless there is an advance deposit adequate to cover the fee).

Yours very truly,

_____
(Petitioner)

By _____
(Indicate authority)

J. The petitioner is required to submit an environmental impact analysis report analyzing the manufacturing process and the ultimate use or consumption of the color additive pursuant to § 25.1 of this chapter.

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will be retained but not filed. A petition shall be retained but shall not be filed if any of the data listed in the above form are lacking or are not set forth so as to be readily understood or if the prescribed fee has not been submitted. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or authorized agent, who is a resident of the United States.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier petition.

§ 71.2 Notice of filing of petition.

(a) Except where the petition involves a new drug, the Commissioner, within 15 days after receipt, will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 706(d)(1) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. Where the petition involves a new drug or certifiable antibiotic, notification to the petitioner will be made in accordance with § 70.10(b)(3) of this chapter.

(b) The Commissioner will cause to be published in the FEDERAL REGISTER within 30 days from the date of filing of such petition a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. A copy of the notice will be mailed to the petitioner when the original document is signed.

§ 71.4 Samples; additional information.

The Commissioner may request samples of the color additive, articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, and any additional information needed to clarify a submitted method or other aspect of a petition at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the color additive, or articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the color additive present in products for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the color additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 706(d)(1) of the act shall be moved forward 1 day for each day, after mailing date of the request, taken by the petitioner to submit the information and/or sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

(a) *Extension of time for studying petitions.* If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

(b) *Substantive amendments.* After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew.

(c) *Withdrawal of petitions without prejudice.* (1) In some cases the Commissioner may notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(2) At any time before the order provided for in § 71.20 has been forwarded to the FEDERAL REGISTER for publication the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew.

§ 71.15 Confidentiality of data and information in color additive petitions.

(a) The following data and information in a color additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(1) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints,

and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(4) A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(6) All records showing the Food and Drug Administration's testing of or action on a particular lot of a certifiable color additive.

(b) The following data and information in a color additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(c) All correspondence and written summaries of oral discussions relating to a color additive petition are available for public disclosure in accordance with the provisions of Part 20 of this chapter when the color additive regulation is published in the FEDERAL REGISTER.

(d) For purposes of this regulation, safety and functionality data include all studies and tests of a color additive on animals and humans and all studies and tests on a color additive for identity, stability, purity, potency, performance, and usefulness.

§ 71.18 Petition for exemption from certification.

A manufacturer, packer, or distributor of a color additive or color additive mixture may petition for an exemption from certification pursuant to Part 10 of this chapter. Any such petition shall show why such certification is not necessary for the protection of public health.

Subpart B—Administrative Action on Petition

§ 71.20 Publication of regulation.

The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 706(d)(1) of the act):

(a) A regulation listing in Part 73 or 74 of this chapter the color additive on the appropriate list or lists as provided under section 706(b)(1).

(1) Such a regulation may list the color additive for use generally in or on foods, drugs, or cosmetics or for use in coloring the human body, as the case may be, or may prescribe the conditions under which the color additive may be safely used (including, but not limited to, specifications as to the particular food, drug, or cosmetic or classes of food, drugs, or cosmetics in or on which such color additive may be used, or for the material intended for coloring the human body; the maximum quantity of any straight color or diluent that may be used or permitted to remain in or on such food, drug, or cosmetic or article intended for coloring the human body; the manner in which such color additive may be added to or used in or on such food, drug, or cosmetic or for coloring the human body; and any directions or other labeling or packing requirements for such color additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.

§ 71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.

The Commissioner shall refuse to issue a regulation listing a color additive, if in his judgment the data before him show that such proposed use would promote deception of the consumer or would result in misbranding or adulteration within the meaning of the act. Such a finding shall be by order published in the FEDERAL REGISTER subject to the filing of objections and a request for a hearing by adversely affected parties. The issuance of a regulation for a color additive authorizing its use generally in or on a food, drug, or cosmetic shall not be construed as authorization to use the color additive in a manner that may promote deception or conceal damage or inferiority. The use of a color additive to promote deception or conceal damage or inferiority shall be considered as the use of a color additive for which no regulation has issued pursuant to section 706(b) of the act, even though the regulation is effective for other uses.

§ 71.25 Condition for certification.

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in Part 74 of this chapter. The Commissioner's order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time after which use of a color additive subject to batch certification but not from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.

§ 71.26 Revocation of exemption from certification.

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled by a notice published in the FEDERAL REGISTER.

§ 71.27 Listing and exemption from certification on the Commissioner's initiative.

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in Part 73 or 74 of this chapter.

§ 71.30 Procedure for filing objections to regulations.

(a) Objections and hearings relating to color additive regulations under section 706 (b) and (c) of the act shall be governed by Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

(b) The fees specified in § 70.19 of this chapter shall be applicable.

§ 71.37 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently,

"Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart A—Foods

Sec.
73.1 Diluents in color additive mixtures for food use exempt from certification.
73.30 Annatto extract.
73.40 Dehydrated beets (beet powder).
73.50 Ultramarine blue.
73.75 Canthaxanthin.
73.85 Caramel.
73.90 β-Apo-8'-carotenal.
73.95 β-Carotene.
73.100 Cochineal extract; carmine.
73.140 Toasted partially defatted cooked cottonseed flour.
73.160 Ferrous gluconate.
73.170 Grape skin extract (enocianina).
73.200 Synthetic iron oxide.
73.250 Fruit juice.
73.260 Vegetable juice.
73.275 Dried algae meal.
73.295 Tagetes (Aztec marigold) meal and extract.
73.300 Carrot oil.
73.315 Corn endosperm oil.
73.340 Paprika.
73.345 Paprika oleoresin.
73.450 Riboflavin.
73.500 Saffron.
73.575 Titanium dioxide.
73.600 Turmeric.
73.615 Turmeric oleoresin.

Subpart B—Drugs

73.1001 Diluents in color additive mixtures for drug use exempt from certification.
73.1010 Alumina (dried aluminum hydroxide).
73.1015 Chromium-cobalt-aluminum oxide.
73.1025 Ferric ammonium citrate.
73.1030 Annatto extract.
73.1070 Calcium carbonate.
73.1075 Canthaxanthin.
73.1085 Caramel.
73.1095 β-Carotene.
73.1100 Cochineal extract; carmine.
73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
73.1150 Dihydroxyacetone.
73.1200 Synthetic iron oxide.
73.1375 Pyrogallol.
73.1400 Pyrophyllite.
73.1550 Talc.
73.1575 Titanium dioxide.

Subpart C—Cosmetics

73.2120 Disodium EDTA-copper.
73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
73.2150 Dihydroxyacetone.
73.2180 Guaiazulene.
73.2190 Henna.
73.2250 Iron oxides.
73.2400 Pyrophyllite.
73.2575 Titanium dioxide.
73.2725 Ultramarines.
73.2775 Manganese violet.

AUTHORITY: The provisions of this Part 73 are issued under secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376), unless otherwise noted.

Subpart A—Foods

§ 73.1 Diluents in color additive mixtures for food use exempt from certification.

The following substances may be safely used as diluents in color additive mixtures for food use exempt from certification, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. If a specification for a particular diluent is not set forth in this Part 73, the material shall be of a purity consistent with its intended use.

(a) *General use.* (1) Substances that are generally recognized as safe under the conditions set forth in section 201(s) of the act.

(2) Substances meeting the definitions and specifications set forth under Subchapter B of this chapter, and which are used only as prescribed by such regulations.

(3) The following:

Substance	Definition and specification	Restrictions
Castor oil	As set forth in U.S.P. XVI	Not more than 500 p.p.m. in the finished food. Labeling of color additive mixtures containing castor oil shall bear adequate directions for use that will result in a food meeting this restriction.
Dioctylsodium sulfosuccinate	As set forth in sec. 172.810 of this chapter.	Not more than 9 p.p.m. in the finished food. Labeling of color additive mixtures containing dioctylsodium sulfosuccinate shall bear adequate directions for use that will result in a food meeting this restriction.

(b) *Special use—(1) Diluents in color additive mixtures for marking food—(i) Inks for marking food supplements in tablet form, gum, and confectionery.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, SDA-3A	As set forth in 26 CFR pt. 212	No residue.
n-Butyl alcohol		Do.
Cetyl alcohol	As set forth in N.F. XI.	
Cyclohexane		Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Ethylene glycol monoethyl ether		Do.
Isobutyl alcohol		Do.
Isopropyl alcohol		Do.
Polyoxyethylene sorbitan monooleate (polysorbate 80).	As set forth in sec. 172.840 of this chapter.	
Polyvinyl acetate	Molecular weight, minimum 2,000.	
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	
Shellac, purified	Food grade.	

(ii) *Inks for marking fruit and vegetables.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Acetone	As set forth in N.F. XI	No residue.
Alcohol, SDA-3A	As set forth in 26 CFR pt. 212	Do.
Benzoin	As set forth in U.S.P. XVI	
Copal, Manila		
Ethyl acetate	As set forth in N.F. XI	Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Methylene chloride		Do.
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	
Silicon dioxide	As set forth in sec. 172.480 of this chapter.	Not more than 2 pct of the ink solids.
Terpene resins, natural	As set forth in sec. 172.615 of this chapter.	
Terpene resins, synthetic	Polymers of α- and β-pinene	

(2) *Diluents in color additive mixtures for coloring shell eggs.* Items listed in paragraph (a) of this section and the following, subject to the condition that there is no penetration of the color additive mixture or any of its components through the eggshell into the egg:

Alcohol, denatured, formula 23A (26 CFR Part 212), Internal Revenue Service.
Damar gum (resin).
Diethylene glycol distearate.
Dioctyl sodium sulfosuccinate.
Ethyl cellulose (as identified in § 172.868 of this chapter).
Ethylene glycol distearate.
Japan wax.
Limed rosin.
Naphtha.
Pentaerythritol ester of fumaric acid-rosin adduct.
Polyethylene glycol 6000 (as identified in § 172.820 of this chapter).
Polyvinyl alcohol.
Rosin and rosin derivatives (as identified in § 172.820 of this chapter).

(3) *Miscellaneous special uses.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	In or as food-tablet coatings; limit, not more than 0.1 pct in the finished food; labeling of color additive mixtures containing polyvinylpyrrolidone shall bear adequate directions for use that will result in a food meeting this restriction.

§ 73.30 Annatto extract.

(a) *Identity.* (1) The color additive annatto extract is an extract prepared from annatto seed, *Bixa orellana* L., using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in Parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.40 Dehydrated beets (beet powder).

(a) *Identity.* (1) The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.

(2) Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive shall conform to the following specifications:

Volatile matter, not more than 4 percent.
Acid insoluble ash, not more than 0.5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.50 Ultramarine blue.

(a) *Identity.* The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700° C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo-silicate having the approximate formula $Na_8Al_6Si_6O_{24}S_2$.

(b) *Specifications.* Ultramarine blue shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(d) *Labeling requirements.* The color additive shall be labeled in accordance with the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.75 Canthaxanthin.

(a) *Identity.* (1) The color additive canthaxanthin is β-carotene-4,4′-dione.

(2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Canthaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Physical state, solid.
1 percent solution in chloroform, complete and clear.
Melting range (decomposition), 207° C. to 212° C. (corrected).
Loss on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Total carotenoids other than trans-canthaxanthin, not more than 5 percent.
Lead, not more than 10 parts per million.
Arsenic, not more than 3 parts per million.
Mercury, not more than 1 part per million.
Assay, 96 to 101 percent.

(c) *Uses and restrictions.* The color additive canthaxanthin may be safely

used for coloring foods generally subject to the following restrictions:

(1) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

Dextrose.
Invert sugar.
Lactose.
Malt sirup.
Molasses.
Starch hydrolysates and fractions thereof.
Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) Acids:

Acetic acid.
Citric acid.
Phosphoric acid.
Sulfuric acid.
Sulfurous acid.

(ii) Alkalis:

Ammonium hydroxide.
Calcium hydroxide U.S.P.
Potassium hydroxide.
Sodium hydroxide.

(iii) Salts: Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in § 172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Caramel shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 0.1 part per million.

(c) *Uses and restrictions.* Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.90 β-Apo-8'-carotenal.

(a) *Identity.* (1) The color additive is β-apo-8'-carotenal.

(2) Color additive mixtures for food use made with β-apo-8'-carotenal may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β-Apo-8'-carotenal shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Melting point (decomposition), 136° C.–140° C. (corrected).
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions.* The color additive β-apo-8'-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β-apo-8'-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.95 β-Carotene.

(a) *Identity.* (1) The color additive is β-carotene prepared synthetically or obtained from natural sources.

(2) Color additive mixtures for food use made with β-carotene may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β-carotene shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions.* The color additive β-carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.100 Cochineal extract; carmine.

(a) *Identity.* (1) The color additive cochineal extract is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)). The coloring principle is chiefly carminic acid.

(2) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)).

(3) Color additive mixtures for food use made with cochineal extract or carmine may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Cochineal extract shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25° C.
Protein (N x 6.25), not more than 2.2 percent.
Total solids, not less than 5.7 and not more than 6.3 percent.
Methyl alcohol, not more than 150 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 1.8 percent.

(2) Carmine shall conform to the following specifications:

Volatile matter (at 135° C. for 3 hours), not more than 20.0 percent.
Ash, not more than 12.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 50.0 percent.

Carmine and cochineal extract shall be pasteurized or otherwise treated to destroy all viable salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine and cochineal extract free of viable Salmonella microorganisms, which substances are not food additives as defined in section 201(s) of the act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the act.

(c) *Uses and restrictions.* Carmine and cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.140 Toasted partially defatted cooked cottonseed flour.

(a) *Identity.* (1) The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

(2) Color additive mixtures for food use made with toasted partially defatted cooked cottonseed flour may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

Arsenic: It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

Lead (as Pb), not more than 10 parts per million.

Free gossypol content, not more than 450 parts per million.

(c) *Uses and restrictions.* The color additive toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.160 Ferrous gluconate.

(a) *Identity.* The color additive ferrous gluconate is the ferrous gluconate defined in the Food Chemicals Codex, First Edition, Publication 1406 (1966), National Academy of Sciences-National Research Council, Washington, D.C.

(b) *Specifications.* Ferrous gluconate shall meet the specifications given in the Food Chemicals Codex.

(c) *Uses and restrictions.* Ferrous gluconate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.170 Grape skin extract (enocianina).

(a) *Identity.* (1) The color additive grape skin extract (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The extract is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin extract (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape skin extract (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape skin extract (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of Parts 4 and 5, Title 27, Code of Federal Regulations.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. The common or usual name of the color additive is "grape skin extract" followed, if desired, by "(enocianina)".

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for dog and cat food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Synthetic iron oxide shall conform to the following specifications, all on an "as is" basis:

Arsenic (as As), not more than 5 parts per million.

Lead (as Pb), not more than 20 parts per million.

Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.250 Fruit juice.

(a) *Identity.* (1) The color additive fruit juice is the concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible fruits, or is a water infusion of the dried fruit. The definition of fruit juice in this paragraph is for the purpose of identity as a color

additive only and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.260 Vegetable juice.

(a) *Identity.* (1) The color additive vegetable juice is the concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible vegetables. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.275 Dried algae meal.

(a) *Identity.* The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, corn-steep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) *Uses and restrictions.* The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(c) *Labeling.* The label of the color additives and any premixes prepared therefrom shall bear in addition to the information required by § 70.25 of this chapter.

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this section.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.295 Tagetes (Aztec marigold) meal and extract.

(a) *Identity.* (1) The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3 percent ethoxyquin.

(2) The color additive tagetes (Aztec marigold) extract is a hexane extract of the flower petals of the Aztec marigold (*Tagetes erecta* L.). It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3 percent ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(b) *Specifications.* (1) Tagetes (Aztec marigold) meal is free from admixture with other plant material from *Tagetes erecta* L. or from plant material or flowers of any other species of plants.

(2) Tagetes (Aztec marigold) extract shall be prepared from tagetes (Aztec marigold) petals meeting the specifications set forth in paragraph (b)(1) of this section and shall conform to the following additional specifications:

Melting point	53.5°–55.0° C.
Iodine value	132–145.
Saponification value	175–200.
Acid value	0.60–1.20.
Titer	35.5°–37.0° C.
Unsaponifiable matter	23.0 percent–27.0 percent.
Hexane residue	Not more than 25 p.p.m.

All determinations, except the hexane residue, shall be made on the initial extract of the flower petals (after drying in a vacuum oven at 60° C. for 24 hours) prior to the addition of the oils and ethoxyquin. The hexane determination shall be made on the color additive after the addition of the vegetable oils, hydrogenated vegetable oils, and ethoxyquin.

(c) *Uses and restrictions.* The color additives tagetes (Aztec marigold) meal and extract may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additives are used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additives incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(d) *Labeling requirements.* The label of the color additives and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter:

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this section.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.300 Carrot oil.

(a) *Identity.* (1) The color additive carrot oil is the liquid or the solid portion of the mixture or the mixture itself obtained by the hexane extraction of edible carrots (*Daucus carota* L.) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carotenoids naturally occurring in carrots. The definition of carrot oil in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for carrot oil or carrot oleoresin under section 401 of the act.

(2) Color additive mixtures for food use made with carrot oil may contain only those diluents listed in this subpart

as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Carrot oil shall contain no more than 25 parts per million of hexane.

(c) *Uses and restrictions.* Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless the use of added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.315 Corn endosperm oil.

(a) *Identity.* (1) The color additive corn endosperm oil is a reddish-brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain. The definition of corn endosperm oil in this paragraph is for the purpose of definition as a color additive only and shall not be construed as a food standard of identity under section 401 of the act.

(2) Color additive mixtures for food use made with corn endosperm oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Corn endosperm oil conforms to the following specifications:

Total fatty acids, not less than 85 percent.
Iodine value, 118 to 134.
Saponification value, 165 to 185.
Unsaponifiable matter, not more than 14 percent.
Hexane, not more than 25 parts per million.
Isopropyl alcohol, not more than 100 parts per million.

(c) *Uses and restrictions.* The color additive corn endosperm oil may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section.

(d) *Labeling requirements.* The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter, a statement of the concentration of xanthophyll contained therein.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.340 Paprika.

(a) *Identity.* (1) The color additive paprika is the ground dried pod of mild capsicum (*Capsicum annuum* L.). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under section 401 of the act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.345 Paprika oleoresin.

(a) *Identity.* (1) The color additive paprika oleoresin is the combination of flavor and color principles obtained from paprika (*Capsicum annuum* L.) by extraction, using any one or a combination of the following solvents:

Acetone.	Isopropyl alcohol.
Ethyl alcohol.	Methyl alcohol.
Ethylene dichloride.	Methylene chloride.
Hexane.	Trichloroethylene.

The definition of paprika oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under section 401 of the act.

(2) Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Paprika oleoresin shall contain no more residue of the solvents listed in paragraph (a)(1) of this section than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in Parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.450 Riboflavin.

(a) *Identity.* (1) The color additive riboflavin is the riboflavin defined in the Food Chemicals Codex, First Edition, Publication 1406 (1966), National Academy of Sciences—National Research Council, Washington, D.C.

(2) Color additive mixtures made with riboflavin may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* Riboflavin shall meet the specifications given in the Food Chemicals Codex.

(c) *Uses and restrictions.* Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice; except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.500 Saffron.

(a) *Identity.* (1) The color additive saffron is the dried stigma of Crocus sativus L. The definition of saffron in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for saffron under section 401 of the act.

(2) Color additive mixtures made with saffron may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.575 Titanium dioxide.

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO_2, free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods, and the following: Silicon dioxide, SiO_2 and/or aluminum oxide, Al_2O_3, as dispersing aids—not more than 2 percent total.

(b) *Specifications.* Titanium dioxide shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Antimony (as Sb), not more than 2 parts per million.
Mercury (as Hg), not more than 1 part per million.
Loss on ignition at 800° C. (after drying for 3 hours at 105° C.), not more than 0.5 percent.
Water soluble substances, not more than 0.3 percent.
Acid soluble substances, not more than 0.5 percent.
TiO_2, not less than 99.0 percent after drying for 3 hours at 105° C.

Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.600 Turmeric.

(a) *Identity.* (1) The color additive turmeric is the ground rhizome of Curcuma longa L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric under section 401 of the act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.615 Turmeric oleoresin.

(a) *Identity.* (1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (Curcuma longa L.) by extraction using any one or a combination of the following solvents:

Acetone.	Isopropyl alcohol.
Ethyl alcohol.	Methyl alcohol.
Ethylene dichloride.	Methylene chloride.
Hexane.	Trichloroethylene.

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this section than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in Parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this subpart, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs*—(1) *General use.* Diluents listed in § 73.1(a) and the following:

Substances	Definitions and specifications	Restriction
Alcohol, specially denatured	As set forth in 26 CFR, pt. 212	As set forth in 26 CFR, pt. 211.
Cetyl alcohol	As set forth in N.F. XI	
Isopropyl alcohol		In color coatings for pharmaceutical forms, no residue.
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60).	As set forth in sec. 172.836 of this chapter.	
Polyoxyethylene (20) sorbitan tristearate (Polysorbate 65).	As set forth in sec. 172.838 of this chapter.	
Polysorbate 80	As set forth in sec. 172.840 of this chapter.	
Polyvinyl-pyrrolidone	As set forth in sec. 173.55 of this chapter.	
Sorbitan monooleate	As set forth in sec. 172.842 of this chapter.	
Sorbitan monostearate		
Sorbitan trioleate		

(2) *Special use; inks for branding pharmaceutical forms.* Items listed in paragraph (a)(1) of this section, § 73.1 (b)(1)(i), and the following:

Ethyl lactate.
Polyoxyethylene sorbitan monolaurate (20).

(b) *Externally applied drugs.* Diluents listed in paragraph (a)(1) of this section and the following:

Substances	Definitions and specifications
Benzyl alcohol	As set forth in N.F. XI.
Ethyl cellulose	As set forth in § 172.868 of this chapter.
Hydroxyethyl cellulose.	— — —
Hydroxypropyl cellulose.	As set forth in § 172.870 of this chapter.

§ 73.1010 Alumina (dried aluminum hydroxide).

(a) *Identity.* (1) The color additive alumina (dried aluminum hydroxide) is a white, odorless, tasteless, amorphous powder consisting essentially of aluminum hydroxide ($Al_2O_3 \cdot X\ H_2O$).

(2) Color additive mixtures for drug use made with alumina (dried aluminum hydroxide) may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Alumina (dried aluminum hydroxide) shall conform to the following specifications:

Acidity or alkalinity: Agitate 1 gram of the color additive with 25 milliliters of water and filter. The filtrate shall be neutral to litmus paper.
Matter insoluble in dilute hydrochloric acid, not more than 0.5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.
Aluminum oxide (Al_2O_3), not less than 50 percent.

(c) *Uses and restrictions.* Alumina (dried aluminum hydroxide) may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1015 Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications.* Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3, 34–37 percent.
Cobalt, calculated as CoO, 29–34 percent.
Aluminum, calculated as AL_2O_3, 29–35 percent.
Lead (as Pb), not more than 30 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 *N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, U.S.P., for use in general surgery, subject to the following restrictions:

(1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500°–550° F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.

(2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P.

(4) When the sutures are used for the purpose specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(5) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1025 Ferric ammonium citrate.

(a) *Identity.* The color additive ferric ammonium citrate consists of complex chelates prepared by the interaction of ferric hydroxide with citric acid in the presence of ammonia. The complex chelates occur in brown and green forms, are deliquescent in air, and are reducible by light.

(b) *Specifications.* Ferric ammonium citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Iron (as Fe), not less than 14.5 percent and not more than 18.5 percent.
Lead (as Pb), not more than 20 p/m.
Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Ferric ammonium citrate may be safely used in combination with pyrogallol (as listed in § 73.1375), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery subject to the following conditions:

(1) The dyed suture shall conform in all respects to the requirements of the U.S.P.

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The labeling of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 706(c) of the act.

(Sec. 706(b)(1), (c)(2), (d); 74 Stat. 399, 402–403; 21 U.S.C. 376 (b)(1), (c)(2), (d).)

§ 73.1030 Annatto extract.

(a) *Identity and specifications.* (1) The color additive annatto extract shall conform in identity and specifications to the requirements of § 73.30(a)(1) and (b).

(2) Color additive mixtures for drug use made with annatto extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* The color additive annatto extract may be used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25 (a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in § 73.30(a)(1)(ii) of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1070 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white, synthetically prepared powder consisting essentially of precipitated calcium carbonate ($CaCO_3$).

(2) Color additive mixtures for drug use made with calcium carbonate may contain only those diluents listed in this

subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Calcium carbonate shall meet the specifications for precipitated calcium carbonate in the U.S.P.

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1075 Canthaxanthin.

(a) *Identity and specifications.* (1) The color additive canthaxanthin shall conform in identity and specifications to the requirements of § 73.75(a)(1) and (b).

(2) Color additive mixtures for ingested drug use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* Canthaxanthin may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1085 Caramel.

(a) *Identity and specifications.* (1) The color additive caramel shall conform in identity and specifications to the requirements of § 73.85(a) (1), (2), and (3) and (b).

(2) The diluents in color additive mixtures for drug use containing caramel shall be limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Caramel may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(c) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirement of section 706(c) of the act.

§ 73.1095 β-Carotene.

(a) *Identity and specifications.* (1) The color additive β-carotene shall conform in identity and specifications to the requirements of § 73.95(a)(1) and (b).

(2) The diluents in color additive mixtures for drug use containing β-carotene are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* β-Carotene may be used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1100 Cochineal extract; carmine.

(a) *Identity and specifications.* (1) The color additives cochineal extract and carmine shall conform in identity and specifications to the requirements of § 73.100(a) (1) and (2) and (b).

(2) Color additive mixtures for drug use made with carmine and cochineal extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Cochineal extract and carmine may be safely used for coloring ingested and externally applied drugs in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity.* (1) The color additive potassium sodium copper chlorophyllin is a green to black powder obtained from chlorophyll by replacing the methyl and phytyl ester groups with alkali and replacing the magnesium with copper. The source of the chlorophyll is dehydrated alfalfa.

(2) Color additive mixtures for drug use made with potassium sodium copper chlorophyllin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Potassium sodium copper chlorophyllin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Moisture, not more than 5.0 percent.
Nitrogen, not more than 5.0 percent.
pH of 1 percent solution, 9 to 11.
Total copper, not less than 4 percent and not more than 6 percent.
Free copper, not more than 0.25 percent.
Iron, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 5 parts per million.
Ratio, absorbance at 405 mμ to absorbance at 630 mμ, not less than 3.4 and not more than 3.9.
Total color, not less than 75 percent.

(c) *Uses and restrictions.* Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are drugs at a level not to exceed 0.1 percent. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1150 Dihydroxyacetone.

(a) *Identity.* (1) The color additive dihydroxyacetone is 1,3-dihydroxy-2-propanone.

(2) Color additive mixtures for drug use made with dihydroxyacetone may contain only those diluents that are listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Dihydroxyacetone shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter (at 34.6° C. for 3 hours at a pressure of not more than 30 mm. mercury), not more than 0.5 percent.
Residue on ignition, not more than 0.4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Iron (as Fe), not more than 25 parts per million.
1,3-dihydroxy-2-propanone, not less than 98 percent.

(c) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied drugs intended solely or in part to impart a color to the human body. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or

in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for drug use made with synthetic iron oxide may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Specifications.* Synthetic iron oxide shall conform to the following specifications, all on an "as is" basis:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 706(c) of the act.

§ 73.1375 Pyrogallol.

(a) *Identity.* The color additive pyrogallol is 1,2,3-trihydroxybenzene.

(b) *Specifications.* Pyrogallol shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Melting point, between 130° and 133° C.
Residue on ignition, not more than 0.1 percent.
Lead (as Pb), not more than 20 p/m (parts per million).
Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Pyrogallol may be safely used in combination with ferric ammonium citrate (as listed in § 73.1025), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the U.S.P.

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Secs. 706 (b)(1), (c)(2), (d); 74 Stat. 399, 402–403; 21 U.S.C. 376 (b)(1), (c)(2), (d).)

§ 73.1400 Pyrophyllite.

(a) *Identity.* (1) The color additive pyrophyllite is a naturally occurring mineral substance consisting predominantly of a hydrous aluminum silicate, $Al_2O_3 \cdot 4SiO_2 \cdot H_2O$, intimately mixed with lesser amounts of finely divided silica, SiO_2. Small amounts, usually less than 3 percent, of other silicates, such as potassium aluminum silicate, may be present. Pyrophyllite may be identified and semiquantitatively determined by its characteristic X-ray powder diffraction pattern and by its optical properties.

(2) Color additive mixtures made with pyrophyllite are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Pyrophyllite shall conform to the following specifications:

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the pyrophyllite for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* Pyrophyllite may be safely used in amounts consistent with good manufacturing practice to color drugs that are to be externally applied.

(d) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1550 Talc.

(a) *Identity.* (1) The color additive talc is a finely powdered, native, hydrous magnesium silicate sometimes containing a small proportion of aluminum silicate.

(2) Color additive mixtures for drug use made with talc may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Talc shall meet the specifications for talc in the U.S.P. and the following:

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the talc for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* Talc may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1575 Titanium dioxide.

(a) *Identity and specifications.* (1) The color additive titanium dioxide shall conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).

(2) Color additive mixtures for drug use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs, and the following: Silicon dioxide, SiO_2, and/or aluminum oxide, Al_2O_3, as dispersing aids—not more than 2 percent total.

(b) *Uses and restrictions.* The color additive titanium dioxide may be used for coloring ingested and externally applied drugs generally, in amounts consistent with good manufacturing practice. External application includes use in the area of the eye.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of the chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

Subpart C—Cosmetics

§ 73.2120 Disodium EDTA-copper.

(a) *Identity.* The color additive disodium EDTA-copper is disodium [[*N*,*N*'-1,2 - ethanediylbis[*N* - (carboxymethyl) glycinato]] (4-) - *N*,*N*',*O*,*O*',O^N,$O^{N'}$] cuprate(2-).

(b) *Specifications.* Disodium EDTA-copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Total copper, not less than 13.5 percent.
Total (ethylene-dinitrilo)tetraacetic acid, not less than 62.5 percent.
Free copper, not more than 100 parts per million.
Free disodium salt of (ethylene-dinitrilo) tetraacetic acid, not more than 1.0 percent.
Moisture, not more than 15 percent.
Water insoluble matter, not more than 0.2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions.* Disodium EDTA-copper may be safely used in amounts consistent with good manufacturing practices in the coloring of shampoos which are cosmetics.

(d) *Labeling requirements.* The labeling of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 706(c) of the act.

§ 73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity and specifications.* The color additive potassium sodium copper chlorophyllin shall conform in identity and specifications to the requirements of § 73.1125(a)(1) and (b).

(b) *Uses and restrictio* . Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are cosmetics subject to the following conditions:

(1) It shall not be used at a level in excess of 0.1 percent.

(2) It may be used only in combination with the following substances:

Water.
Glycerin.
Sodium carboxymethylcellulose.
Tetrasodium pyrophosphate.
Sorbitol.
Magnesium phosphate, tribasic.
Calcium carbonate.
Calcium phosphate, dibasic.
Sodium *N*-lauroyl sarcosinate.
Artificial sweeteners that are generally recognized as safe or that are authorized under Subchapter B of this chapter.
Flavors that are generally recognized as safe or that are authorized under Subchapter B of this chapter.
Preservatives that are generally recognized as safe or that are authorized under Subchapter B of this chapter.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.2150 Dihydroxyacetone.

(a) *Identity and specifications.* The color additive dihydroxyacetone shall conform in identity and specifications to the requirements of § 73.1150(a)(1) and (b).

(b) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied cosmetics intended solely or in part to impart a color to the human body.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 706(c) of the act.

(Sec. 706(b)(1), (c)(2), (d), 74 Stat. 399-402; 21 U.S.C. 376(b)(1), (c)(2), (d).)

§ 73.2180 Guaiazulene.

(a) *Identity.* (1) The color additive, guaiazulene, is principally 1,4-dimethyl-7-isopropyl-azulene.

(2) Color additive mixtures of guaiazulene for cosmetic use may contain the following diluent:

Polyethylene glycol-40 castor oil (PEG-40 castor oil).
Saponification No., 60 to 70.
Hydroxyl No., 63 to 78.
Acid No., <2.
Specific gravity, 1.05 to 1.07.

(b) *Specifications.* Guaiazulene shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Melting point, 30.5° C to 31.5° C.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 99 percent.

(c) *Uses and restrictions.* Guaiazulene may be safely used in externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.2190 Henna.

(a) *Identity.* The color additive henna is the dried leaf and petiole of *Lawsonia alba* Lam. (*Lawsonia inermis* L.). It may be identified by its characteristic odor and by characteristic plant histology.

(b) *Specifications.* Henna shall conform to the following specifications:

It shall not contain more than 10 percent of plant material from *Lawsonia alba* Lam. (*Lawsonia inermis* L.) other than the leaf and petiole, and shall be free from admixture with material from any other species of plant.

Moisture, not more than 10 percent.
Total ash, not more than 15 percent.
Acid-insoluble ash, not more than 5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions.* The color additive henna may be safely used for coloring hair only. It may not be used for coloring the eyelashes or eyebrows, or generally in the area of the eye.

(d) *Labeling.* The label for henna shall bear the information required by § 70.25 of this chapter and the following statements or their equivalent:

"Do not use in the area of the eye."
"Do not use on cut or abraded scalp."

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.2250 Iron oxides.

(a) *Identity.* The color additives iron oxides consist of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(b) *Specifications.* Iron oxides shall conform to the following specifications, all on an "as is" basis:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* Iron oxides are safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

§ 73.2400 Pyrophyllite.

(a) *Identity and specifications.* The color additive pyrophyllite shall conform in identity and specifications to the requirements of § 73.1400(a)(1) and (b).

(b) *Uses and restrictions.* Pyrophyllite may be safely used for coloring externally applied cosmetics, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to all applicable requirements

of law, including the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Secs. 706(b), (c), and (d), 74 Stat. 399-403; 21 U.S.C. 376(b), (c), and (d).)

§ 73.2575 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide shall conform in identity and specifications to the requirements on § 73.575(a) (1) and (b).

(b) *Uses and restrictions.* The color additive titanium dioxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

(Secs. 706(b), (c), and (d), 74 Stat. 399-403; 21 U.S.C. 376(b), (c), and (d).)

§ 73.2725 Ultramarines.

(a) *Identity.* The color additives, ultramarines (blue, green, pink, red, and violet) are pigments obtained by calcining at temperatures above 700° C. a mixture of kaolin, sulfur, sodium carbonate, silicious matter, sodium sulfate, and carbonaceous matter, but not necessarily all these substances, to produce a single color. The ultramarines are complex sodium aluminum sulfosilicates having a typical formula $Na(AlSiO)S$ with proportions of each element varying with each color.

(b) *Specifications.* The ultramarines shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Use and restrictions.* The ultramarine pigments may be safely used for coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The color additives and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

§ 73.2775 Manganese violet.

(a) *Identity.* The color additive manganese violet is a violet pigment obtained by reacting phosphoric acid, ammonium dihydrogen orthophosphate, and manganese dioxide at temperatures above 450° F. The pigment is a manganese ammonium pyrophosphate complex having the approximate formula: Mn (III) $NH_4P_2O_7$.

(b) *Specifications.* Manganese violet shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Ash (at 600° C), not less than 81 percent.
Volatile matter at 135° C for 3 hours, not more than 1 percent.
Water soluble substances, not more than 6 percent.
pH of filtrate of 10 grams color additive (shaken occasionally for 2 hours with 100 milliliters of freshly boiled distilled water), not more than 4.7 and not less than 2.5.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, based on Mn content in "as is" sample, not less than 93 percent.

(c) *Uses and restrictions.* Manganese violet is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necesary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart A—Foods

Sec.
74.101 FD&C Blue No. 1.
74.250 Orange B.
74.302 Citrus Red No. 2.
74.303 FD&C Red No. 3.
74.340 FD&C Red No. 40.
74.705 FD&C Yellow No. 5.

Subpart B—Drugs

74.1045 [Phthalocyaninato(2-)] copper.
74.1101 FD&C Blue No. 1.
74.1102 FD&C Blue No. 2.
74.1104 D&C Blue No. 4.
74.1109 D&C Blue No. 9.
74.1205 D&C Green No. 5.
74.1206 D&C Green No. 6.
74.1208 D&C Green No. 8.
74.1303 FD&C Red No. 3.
74.1304 FD&C Red No. 4.
74.1317 D&C Red No. 17.
74.1331 D&C Red No. 31.
74.1334 D&C Red No. 34.
74.1339 D&C Red No. 39.
74.1340 FD&C Red No. 40.
74.1602 D&C Violet No. 2.
74.1705 FD&C Yellow No. 5.
74.1707 D&C Yellow No. 7.
74.1707a Ext. D&C Yellow No. 7.
74.1708 D&C Yellow No. 8.
74.1711 D&C Yellow No. 11.

Subpart C—Cosmetics

74.2104 D&C Blue No. 4.
74.2151 D&C Brown No. 1.
74.2208 D&C Green No. 8.
74.2304 FD&C Red No. 4.
74.2317 D&C Red No. 17.
74.2331 D&C Red No. 31.
74.2334 D&C Red No. 34.
74.2340 FD&C Red No. 40.
74.2602 D&C Violet No. 2.
74.2602a Ext. D&C Violet No. 2.
74.2705 FD&C Yellow No. 5.
74.2707 D&C Yellow No. 7.
74.2707a Ext. D&C Yellow No. 7.
74.2708 D&C Yellow No. 8.
74.2711 D&C Yellow No. 11.

AUTHORITY: The provisions of this Part 74 are issued under secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376), unless otherwise noted.

Subpart A—Foods

§ 74.101 FD&C Blue No. 1

(a) *Identity.* (1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[*p*[ethyl(*m*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene] - 2,5-cyclohexadien-1-ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl[4-[*p*-[ethyl(*p*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien - 1 - ylidene] (*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl(*o*-sulfobenzyl) amino] - α - (*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien - 1 - ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Blue No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C.) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of *o*-, *m*-, and *p*-sulfobenzaldehydes, not more than 1.5 percent.
N-ethyl, *N*-(*m*-sulfobenzyl) sulfanilic acid, not more than 0.3 percent.
Subsidiary colors, not more than 6.0 percent.
Chromium (as Cr), not more than 50 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Blue No. 1 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.250 Orange B.

(a) *Identity.* (1) The color additive Orange B is principally the disodium salt of 1 - (4-sulfophenyl) -3-ethylcarboxy-4-(4-sulfonaphthylazo) - 5 - hydroxypyrazole.

(2) The diluents in color additive mixtures for food use containing Orange B are limited to those listed in Part 73 of this chapter as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Orange B shall conform to the following specifications:

Volatile matter (at 135° C.), not more than 6.0 percent.
Chlorides and sulfates (calculated as the sodium salts), not more than 7.0 percent.
Water insoluble matter, not more than 0.2 percent.
1-(4-Sulfophenyl) - 3 - ethylcarboxy - 5 - hydroxypyrazolone and 1-(4-sulfophenyl)-3-carboxy-5-hydroxypyrazolone, not more than 0.7 percent.
Naphthionic acid, not more than 0.2 percent.
Phenylhydrazine-*p*-sulfonic acid, not more than 0.2 percent.
The trisodium salt of 1-(4-sulfophenyl)-3-carboxy - 4 - (4 - sulfonaphthylazo)-5-hydroxypyrazole, not more than 6.0 percent.
Other subsidiary dyes, not more than 1.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Pure color, not less than 87.0 percent.

(c) *Uses and restrictions.* Orange B may be safely used for coloring the casings or surfaces of frankfurters and sausages subject to the restriction that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Orange B shall be certified in accordance with regulations promulgated under Part 80 of this chapter.

§ 74.302 Citrus Red No. 2.

(a) *Identity.* (1) The color additive Citrus Red No. 2 is principally 1-(2,5-dimethoxyphenylazo)-2-naphthol.

(2) The following diluents may be used in aqueous suspension, in the percentages specified, to facilitate application to oranges in accordance with paragraph (c)(1) of this section:

(i) Suitable diluents used in accordance with § 73.1(a) of this chapter.

(ii) Volatile solvents that leave no residue after application to the orange.

(iii) Salts of fatty acids meeting the requirements of § 172.863 of this chapter.

(iv) Sodium tripolyphosphate, not more than 0.05 percent.

(b) *Specifications.* Citrus Red No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100° C.), not more than 0.5 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluble in carbon tetrachloride, not more than 0.5 percent.
Uncombined intermediates, not more than 0.05 percent.
Subsidiary dyes, not more than 2.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Pure color, not less than 98 percent.

(c) *Uses and restrictions.* (1) Citrus Red No. 2 shall be used only for coloring the skins of oranges that are not intended or used for processing (or if so used are designated in the trade as "Packinghouse elimination") and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown.

(2) Oranges colored with Citrus Red No. 2 shall bear not more than 2.0 parts per million of such color additive, calculated on the basis of the weight of the whole fruit.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. To meet the requirements of § 70.25 (b) and (c) of this chapter the label shall bear:

(1) The statement (or its equivalent) "To be used only for coloring skins of oranges."

(2) Directions for use to limit the amount of the color additive to not more than 2.0 parts per million, calculated on the basis of the weight of the whole fruit.

(e) *Certification.* All batches of Citrus Red No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.303 FD&C Red No. 3.

(a) *Identity.* (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (*o*-carboxyphenyl)-6-hydroxy - 2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower iodinated fluoresceins.

(2) Color additive mixtures for food use made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
Unhalogenated intermediates, total not more than 0.1 percent.
Sodium iodide, not more than 0.4 percent.
Triiodoresorcinol, not more than 0.2 percent.
2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.
Monoiodofluoresceins not more than 1.0 percent.
Other lower iodinated fluoresceins, not more than 9.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring foods generally (including dietary supplements) in amounts consistent with good manufacturing practices except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.340 FD&C Red No. 40.

(a) *Identity.* (1) The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo] - 2 - naphthalenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(3) The listing of this color additive includes lakes prepared as described in § 82.51 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 of this chapter.

(b) *Specifications.* FD&C Red No. 40 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C.) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

Water-insoluble matter, not more than 0.2 percent.
Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.
Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.
Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo] -8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, not more than 1.0 percent.
Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.
4-Amino-5-methoxy-o-toluenesulfonic acid, not more than 0.2 percent.
Disodium salt of 6,6'-oxybis (2-naphthalenesulfonic acid), not more than 1.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 40 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.705 FD&C Yellow No. 5.

(a) *Identity.* (1) The color additive FD&C Yellow No. 5 is 5-oxo-1-(p-sulfophenyl)-4-[(p-sulfophenyl)azo]-2-pyrazoline-3-carboxylic acid, trisodium salt.

(2) Color additive mixtures for food use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practices:

Volatile matter (at 135° C.), and chlorides and sulfates (calculated as the sodium salts), total not more than 13.0 percent.
Water insoluble matter, not more than 0.2 percent.
Phenylhydrazine-p-sulfonic acid, not more than 0.2 percent.
Other uncombined intermediates, not more than 0.2 percent.
Subsidiary dyes, not more than 1.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

Subpart B—Drugs

§ 74.1045 [Phthalocyaninato(2-)] copper.

(a) *Identity.* The color additive is [phthalocyaninato(2-)] copper having the structure shown in color index No. 74160.

(b) *Specifications.* [Phthalocyaninato (2-)] copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter (135° C.), not more than 0.3 percent.
Salt content (as NaCl), not more than 0.3 percent.
Alcohol soluble matter, not more than 0.5 percent.
Organic chlorine, not more than 0.2 percent.
Aromatic amines, not more than 0.05 percent.
Lead (as Pb), not more than 40 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 98.5 percent.

(c) *Uses and restrictions.* [Phthalocyaninato (2-)]copper may be safely used to color polypropylene sutures for use in general and ophthalmic surgery subject to the following restrictions:

(1) The quantity of the color additive does not exceed 0.5 percent by weight of the suture.

(2) The dyed suture shall conform in all respects to the requirements of The United States Pharmacopeia.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug (including any other sutures) in which it is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of [phthalocyaninato(2-)] copper shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1101 FD&C Blue No. 1.

(a) *Identity and specifications.* (1) The color additive FD&C Blue No. 1 shall conform in identity and specifications to the requirements of § 74.101(a)(1) and (b).

(2) Color additive mixtures for ingested drug use made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* The color additive FD&C Blue No. 1 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1102 FD&C Blue No. 2.

(a) *Identity.* The color additive FD&C Blue No. 2 is principally the disodium salt of 5,5'-disulfo-3,3'-dioxo-$\Delta^{2,2'}$-biindoline with smaller amounts of the isomeric disodium salt of 5,7'-disulfo-3,3'-dioxo-$\Delta^{2,2'}$-biindoline.

(b) *Specifications.* FD&C Blue No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C.) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.
Water-insoluble matter not more than 0.4 percent.
Isatin-5-sulfonic acid, not more than 0.4 percent.
Isomeric colors, not more than 18.0 percent.
Lower sulfonated subsidiary colors, not more than 5.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(1) The quantity of color additive does not exceed 1 percent by weight of the suture.

(2) The dyed suture shall conform in all respects to the requirements of the U.S.P.

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, an approved new-drug application, pursuant

to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1104 D&C Blue No. 4.

(a) *Identity.* (1) The color additive D&C Blue No. 4 is principally the diammonium salt of ethyl[4-[p[ethyl(*m*-sulfobenzyl)amino] - α - (*o*-sulfophenyl)benzylidene] - 2,5 - cyclohexadien - 1 - ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric diammonium salts of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien - 1-ylidene](*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl[4-[p-[ethyl (*o*-sulfobenzyl)amino] - α - (*o*-sulfophenyl) benzylidene] - 2,5 - cyclohexadien - 1 - ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for use in externally applied drugs made with D&C Blue No. 4 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Blue No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of *o*-, *m*, and *p*-sulfobenzaldehydes, ammonium salt, not more than 1.5 percent.
N-ethyl, N-(*m*-sulfobenzyl) sulfanilic acid ammonium salt, not more than 0.3 percent.
Subsidiary colors, not more than 6 percent.
Chromium (as Cr), not more than 50 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* D&C Blue No. 4 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1109 D&C Blue No. 9.

(a) *Identity.* The color additive D&C Blue No. 9 is principally 7,16-dichloro-6,15 - dihydro - 5,9,14,18 - anthrazinetetrone.

(b) *Specifications.* D&C Blue No. 9 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C.), not more than 3 percent.
Matter extractable by alcoholic HCl (0.1 ml of concentrated hydrochloric acid per 50 ml of 95 percent ethyl alcohol), not more than 1 percent.
2-Amino anthraquinone, not more than 0.2 percent.
Organically combined chlorine in pure dye, 13.0–14.8 percent.
Lead (as Pb), not more than 20 p/m.
Arsenic (as As), not more than 3 p/m.
Pure color, not less than 97 percent.

(c) *Uses and restrictions.* D&C Blue No. 9 may be safely used for coloring cotton and silk surgical sutures, including sutures for ophthalmic use, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the U.S.P.

(2) The quantity of the color additive does not exceed 2.5 percent by weight of the suture.

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, a new-drug application approved pursuant to section 505 of the act is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 9 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1205 D&C Green No. 5.

(a) *Identity.* The color additive D&C Green No. 5 is principally the disodium salt of 2,2'-[(9,10-dihydro-9,10-dioxo-1,4 - anthracenediyl) diimino]bis[5 - methyl-benzenesulfonic acid].

(b) *Specifications.* D&C Green No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135°C) and chlorides and sulfates (calculated as sodium salts), not more than 20.0 percent.
Water-insoluble matter, not more than 0.2 percent.
1,4-Dihydroxy-anthraquinone, not more than 0.2 percent.
2-Amino-m-toluenesulfonic acid, not more than 0.2 percent.
Subsidiary colors, not more than 5.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 80.0 percent.

(c) *Uses and restrictions.* D&C Green No. 5 may be safely used to color nylon (the copolymer of adipic acid and hexamethylene diamine) nonabsorbable surgical sutures for use in general surgery subject to the following restrictions:

(1) The quantity of color additives does not exceed 0.6 percent by weight of the suture.

(2) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(4) If the suture is a new drug, an approved new-drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

(Sec. 706(b), (c), (d), 74 Stat. 399–403; 21 U.S.C. 376 (b), (c), (d).)

§ 74.1206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 is 1-4-di-*p*-toluidino anthraquinone.

(b) *Specifications.* D&C Green No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C.), not more than 2.0 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluble in carbon tetrachloride, not more than 1.5 percent.
Intermediates, not more than 0.5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Pure color, not less than 96.0 percent.

(c) *Uses and restrictions.* (1) D&C Green No. 6 may be safely used at a level, (i) not to exceed 0.75 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use; and (ii) not to exceed 0.1 percent by weight of the suture material for coloring polyglycolic acid surgical sutures, including sutures for ophthalmic use.

(2) [Reserved]

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under Part 80 of this chapter.

§ 74.1208 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the trisodium salt of 8-hydroxy-1,3,6-pyrenetrisulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C

Green No. 8 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Green No. 8 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

Volatile matter (at 135° C), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Chlorides and sulfates (calculated as sodium salt), not more than 20 percent.
The trisodium salt of 1,3,6-pyrenetrisulfonic acid, not more than 6 percent.
The tetrasodium salt of 1,3,6,8-pyrenetetrasulfonic acid, not more than 1 percent.
Pyrene, not more than 0.2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 65 percent.

(c) *Uses and restrictions.* D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1303 FD&C Red No. 3.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 3 shall conform in identity and specifications to the requirements of § 74.303(a)(1) and (b).

(2) Color additive mixtures for ingested drug used made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1304 FD&C Red No. 4.

(a) *Identity.* (1) The color additive FD&C Red No. 4 is principally the disodium salt of 3-[(2,4-dimethyl-5-sulfophenyl)azo] - 4 - hydroxy - 1 - naphthalene sulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with FD&C Red No. 4 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* FD&C Red No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C.) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
5-Amino-2,4-dimethyl - 1 - benzenesulfonic acid, sodium salt, not more than 0.2 percent.
4-Hydroxyl-1-naphthalenesulfonic acid, sodium salt, not more than 0.2 percent.
Subsidiary colors, not more than 2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* FD&C Red No. 4 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1317 D&C Red No. 17.

(a) *Identity.* (1) The color additive D&C Red No. 17 is principally 1-[(4-(phenylazo) phenyl[azo] - 2-naphthalenol.

(2) Color additive mixtures for drug use made with D&C Red No. 17 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 17 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C), not more than 5 percent.
Matter insoluble in both toluene and water, not more than 0.5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Aniline, not more than 0.2 percent.
4-Aminoazobenzene, not more than 0.1 percent.
2-Naphthol, not more than 0.2 percent.
1-(Phenylazo)-2-naphthol, not more than 3 percent.
1-[[2-(phenylazo) phenyl]azo]-2-naphthalenol, not more than 2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Red No. 17 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1331 D&C Red No. 31.

(a) *Identity.* (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy - 4-(phenylazo) - 2-naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 31 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 31 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.
Aniline, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 percent.
Subsidiary colors, not more than 1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Red No. 31 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 31 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1334 D&C Red No. 34.

(a) *Identity.* (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azo] - 2 - naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 34 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 34 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated at sodium salts), not more than 15 percent.
2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.
Subsidiary colors, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), nor more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 34 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Part 80 of this chapter.

NOTE: The provisions of § 74.1334 listing D&C Red No. 34 for use in drugs were stayed pending resolution of a question concerning the possible presence of β-naphthylamine (42 FR 12424, March 4, 1977).

§ 74.1339 D&C Red No. 39.

(a) *Identity.* (1) The color additive D&C Red No. 39 is *o*-[*p*(β,β'-dihydroxydiethylamino)-phenylazol-benzoic acid.

(2) Color additive mixtures made with D&C Red No. 39 may contain the following diluents: Water, acetone, isopropyl alcohol, and specially denatured alcohols used in accordance with 26 CFR Part 212.

(b) *Specifications.* D&C Red No. 39 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100° C.), not more than 2.0 percent.
Matter insoluble in acetone, not more than 1.0 percent.
Anthranilic acid, not more than 0.2 percent.
N,N-(β,β'-Dihydroxy-diethyl) aniline, not more than 0.2 percent.
Subsidiary colors, not more than 3.0 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Pure color, not less than 95.0 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 39 may be safely used for the coloring of quaternary ammonium type germicidal solutions intended for external application only, and subject to the further restriction that the quantity of the color additive does not exceed 0.1 percent by weight of the finished drug product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 39 shall be certified in accordance with regulations promulgated under Part 80 of this chapter.

§ 74.1340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(3) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by §§ 82.51 or 82.1051 of this chapter.

(b) *Uses and restrictions.* FD&C Red No. 40 may be safely used in coloring drugs, subject to the restrictions on use of color additives in § 70.5 of this chapter, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations, in Part 80 of this chapter.

§ 74.1602 D&C Violet No. 2.

(a) *Identity.* (1) The color additive D&C Violet No. 2 is principally 1-hydroxy - 4 - [(4 - methylphenyl) amino] - 9,10-anthracenedione.

(2) Color additive mixtures for use in externally applied drugs made with D&C Violet No. 2 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities can be avoided by good manufacturing practice:

Volatile matter (at 135° C.), not more than 2.0 percent.
Matter insoluble in both carbon tetrachloride and water, not more than 0.5 percent.
p-Toluidine, not more than 0.2 percent.
1-Hydroxy-9,10-anthracenedione, not more than 0.5 percent.
1,4 - Dihydroxy - 9,10 - anthracenedione, not more than 0.5 percent.
Subsidiary colors, not more than 1.0 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* (1) The color additive D&C Violet No. 2 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(2) D&C Violet No. 2 may be safely used for coloring glycolic-lactic acid polyester (USAN polyglactin 910) synthetic absorbable sutures for use in general and ophthalmic surgery subject to the following restrictions:

(i) The quantity of the color additive does not exceed 0.2 percent by weight of the suture.

(ii) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1705 FD&C Yellow No. 5.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705(a)(1) and (b).

(2) Color additive mixtures for ingested drug use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1707 D&C Yellow No. 7.

(a) *Identity.* (1) The color additive D&C Yellow No. 7 is principally fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 6 percent.
Matter insoluble in alkaline water, not more than 0.5 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.

2-(2,4-Dihydroxybenzoyl benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 94 percent.

(c) *Uses and restrictions.* D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1707a Ext. D&C Yellow No. 7.

(a) *Identity.* (1) The color additive Ext. D&C Yellow No. 7 is principally the disodium salt of 8-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with Ext. D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe fore use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Ext. D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
1-Naphthol, not more than 0.2 percent.
2,4-Dinitro-1-naphthol, not more than 0.03 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1708 D&C Yellow No. 8.

(a) *Identity.* (1) The color additive D&C Yellow No. 8 is principally the disodium salt of fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 8 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 8 shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in alkaline water, not more than 0.3 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(2,4-Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* D&C Yellow No. 8 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1711 D&C Yellow No. 11.

(a) *Identity.* (1) The color additive D&C Yellow No. 11 is principally 2-(2-quinolyl)-1,3-indandione.

(2) Color additive mixtures for drug use made with D&C Yellow No. 11 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 11 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C), not more than 1 percent.
Ethyl alcohol-insoluble matter, not more than 0.4 percent.
Phathalic acid, not more than 0.3 percent.
Quinaldine, not more than 0.2 percent.
Subsidiary colors, not more than 5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 96 percent.

(c) *Uses and restrictions.* D&C Yellow No. 11 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

Subpart C—Cosmetics

§ 74.2104 D&C Blue No. 4.

(a) *Identity and specifications.* The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b).

(b) *Uses and restrictions.* D&C Blue No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Blue No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2151 D&C Brown No. 1.

(a) *Identity.* The color additive D&C Brown No. 1 is a mixture of the sodium salts of 4[[5-[(dialkylphenyl)azo]-2,4-dihydroxyphenyl]azo] - benzenesulfonic acid. The alkyl group is principally the methyl group.

(b) *Specifications.* D&C Brown No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 16 percent.
Water-insoluble matter, not more than 0.2 percent.
Sulfanilic acid, sodium salt, not more than 0.2 percent.
Resorcinol, not more than 0.2 percent.
Xylidines, not more than 0.2 percent.
Disodium salt of 4[[5-[(4-sulfophenyl)-azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not more than 3 percent.
Monosodium salt of 4[5-[(2,4-dimethylphenyl)azo] - 2,4 - dihydroxyphenyl]azo] benzenesulfonic acid, not less than 29 percent and not more than 39 percent.
Monosodium salt of 4[[5-[(2,5-dimethylphenyl)azo] - 2,4 - dihydroxyphenyl]azo] benzenesulfonic acid, not less than 12 percent and not more than 17 percent.
Monosodium salt of 4[[5-[(2,3-dimethylphenyl)azo] - 2,4 - dihydroxyphenyl]azo] benzenesulfonic acid, not less than 6 percent and not more than 13 percent.
Monosodium salt of 4[[5-[(2-ethylphenyl)-azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid not less than 5 percent and not more than 12 percent.
Monosodium salt of 4[[5-[(3,4-dimethylphenyl)azo] - 2,4 - dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 9 percent.
Monosodium salt of 4[[5-[(2,6,-dimethylphenyl)azo] - 2,4 - dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 8 percent.
Monosodium salt of 4[[5-[(4-ethylphenyl) azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 2 percent and not more than 8 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.
Total color, not less than 84 percent.

(c) *Uses and restrictions.* D&C Brown No. 1 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Brown No. 1 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2208 D&C Green No. 8.

(a) *Identity and specifications.* The color additive D&C Green No. 8 shall conform in identity and specifications to the requirements of § 74.1208 (a) (1) and (b).

(b) *Uses and restrictions.* D&C Green No. 8 may be safely used for coloring externally applied cosmetics in amounts not exceeding 0.01 percent by weight of the finished cosmetic product.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2304 FD&C Red No. 4.

(a) *Identity and specifications.* The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a) (1) and (b).

(b) *Uses and restrictions.* FD&C Red No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2317 D&C Red No. 17.

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317 (a) (1) and (b).

(b) *Uses and restrictions.* D&C Red No. 17 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2331 D&C Red No. 31.

(a) *Identity and specifications.* The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a) (1) and (b).

(b) *Uses and restrictions.* D&C Red No. 31 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 31 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2334 D&C Red No. 34.

(a) *Identity and specifications.* The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 74.1334(a) (1) and (b).

(b) *Uses and restrictions.* D&C Red No. 34 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Part 80 of this chapter.

NOTE: The provisions of § 74.2334 listing D&C Red No. 34 for cosmetic use were stayed pending resolution of a question concerning the possible presence of β-naphthylamine (42 FR 12424, March 4, 1977).

§ 74.2340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 73.340 (a) (1) and (b) of this chapter.

(2) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 or § 82.1051 of this chapter.

(b) *Uses and restrictions.* FD&C Red No. 40 may be safely used in coloring cosmetics generally subject to the following restrictions:

(1) The color additive may be used in amounts consistent with good manufacturing practice.

(2) The color additive shall not be exposed to oxidizing or reducing agents which may affect the integrity of the color or any other conditions which may affect the integrity of the color.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 40 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2602 D&C Violet No. 2.

(a) *Identity and specifications.* The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.606 (a) (1) and (b).

(b) *Uses and restrictions.* The color additive D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2602a Ext. D&C Violet No. 2.

(a) *Identity.* The color additive Ext. D&C Violet No. 2 is principally the monosodium salt of 2-[(9,10-dihydro-4-hydroxy - 9,10 - dioxo - 1 - anthracenyl) amino]-5-methyl-benzensulfonic acid.

(b) *Specifications.* Ext. D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.
Water-insoluble matter, not more than 0.4 percent.
1-Hydroxy - 9,10 - anthracenedione, not more than 0.2 percent.
1,4 - Dihydroxy - 9,10 - anthracenedione, not more than 0.2 percent.
p-Toluidine, not more than 0.1 percent.
p-Toluidine sulfonic acids, sodium salts, not more than 0.2 percent.
Subsidiary colors, not more than 1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 80 percent.

(c) *Uses and restrictions.* The color additive Ext. D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Ext. D&C Violet No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2705 FD&C Yellow No. 5.

(a) *Identity and specifications.* The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705(a) (1) and (b).

(b) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring externally applied cosmetics other than hair straighteners, permanent wave preparations and depilatories in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordcordance with regulations in Part 80 of this chapter.

NOTE: The provisions of § 74.2705 listing FD&C Yellow No. 5 for use in cosmetics were stayed pending further notice (42 FR 6805, February 4, 1977).

§ 74.2707 D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2707a Ext. D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707a (a)(1) and (b).

(b) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 8 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2711 D&C Yellow No. 11.

(a) *Identity and specifications.* The color additive D&C Yellow No. 11 shall conform in identity and specifications to the requirements of § 74.1711 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 11 shall be certified in acance with regulations in Part 80 of this chapter.

PART 80—COLOR ADDITIVE CERTIFICATION

Subpart A—General Provisions

Sec.
80.10 Fees for certification services.

Subpart B—Certification Procedures

80.21 Request for certification.
80.22 Samples to accompany requests for certification.
80.31 Certification.
80.32 Limitations of certificates.
80.34 Authority to refuse certification service.
80.35 Color additive mixtures; certification and exemption from certification.
80.37 Treatment of batch pending certification.
80.38 Treatment of batch after certification.
80.39 Records of distribution.

AUTHORITY: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376), unless otherwise noted.

Subpart A—General Provisions

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j) (1) and (2), shall be 15 cents per pound of the batch covered by such requests, but no such fee shall be less than $100.00.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j) (3) and (4) shall be:

Weight of batch	*Fees*
100 pounds or less	$6.00
Over 100 pounds but not over 1,000 pounds.	$6.00 plus 4 cents for each pound over 100 pounds.
Over 1,000 pounds	$42.00 plus 1 cent per pound for each pound in excess of 1,000 pounds.

(c) *Advance desposits.* Any person regularly requesting certification services may desposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Food and Drug Administration, collectable at par at Washington, D.C. All such deposits and fees shall be forwarded to the Division of Color Technology, HFF-430, Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United States for deposit to the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(e) *Refunds from advance desposits.* Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than $5.00.

Subpart B—Certification Procedures

§ 80.21 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Commissioner of Food and Drugs.

(b) Be prepared in the manner set forth in paragraph (j) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.

(e) Show the name and post office address of the actual manufacturer in case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in § 80.10 unless the person has established with the Food and Drug Administration an advance deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by § 80.10 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in § 80.22 consisting of:

(1) Four ounces in the case of straight colors and lakes.

(2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

(1) The name of a straight color shall be the name of the color as listed in Part 74 of this chapter.

(2) The name of a lake shall be the name derived in the manner described in Part 70 of this chapter.

(3) The name of a mixture shall be the name given to such mixture by the person requesting certification.

(4) The name of a repack shall be the name described in paragraph (h) (1), (2), or (3) of this section, whichever is applicable.

(i) The information and samples enumerated in paragraphs (a) to (h), inclusive, of this section are the minimum

required. Additional information and samples shall be submitted at the request of the Food and Drug Administration when such additional information and samples are necessary to determine compliance with the requirements of § 80.31 for the issuance of a certificate.

(j) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack of a previously certified color additive, or a color additive mixture.

(1) *Request for certification of a batch of straight color additive.*

Date _____
Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color _____
(As listed in 21 CFR Part 74)
Batch number _____
(Manufacturer's number)
Batch weights _____ pounds
Batch manufactured by _____
_____ at _____
(Name and address of actual manufacturer)
How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested of this color for use in
_____
(State proposed uses)
_____
Required fee, $_____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(2) *Request for certification of a batch of color additive lake.*

Date _____
Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive lake.

Name of color _____
Batch number _____
(Manufacturer's number)
Batch weighs _____ pounds
Name of color used _____
Quantity _____ pounds
Lot number _____
(When certification of the lake for use in foods is requested)
Precipitant used _____
Substratum used _____
Quantity _____ pounds
Batch manufactured by _____
_____ at _____
(Name and address of actual manufacturer)
How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested of this color for use in _____
_____
_____
(State proposed uses)
Required fee, $_____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(3) *Request for certification of a repack of a batch of certified color additive.*

Date _____
Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive repack.

Name of color _____
(As listed in regulations and as certified; or repacker's name, if a mixture)
Original lot number _____
Certified color content _____
This color obtained from _____
Batch number _____
Batch weighs _____ pounds
How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in _____
_____
_____
(State proposed uses)
Required fee, $_____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

(4) *Request for certification of a batch of color additive mixture.*

Date _____
Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive mixture.

Name of mixture _____
(Manufacturer's trade name)
Batch number _____
(Manufacturer's number)
Weight of batch _____ pounds
Volume of batch _____ gallons
(If liquid)
Batch manufactured by _____
Constituents of the mixture:

1. Color(s). (List separately each color and each lot number.)

Name of color as certified	*Lot number*

Quantity used (in pounds)	*Obtained from*

2. List of diluents. (List separately each diluent.)

Name of diluent

_____
_____

Quantity used

By weight	*By volume (if liquid)*

Batch mixed as follows _____
(Describe in detail)
How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in _____
_____
_____
(State proposed uses)
Required fee, $_____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) _____
By _____
_____
(Title)

§ 80.22 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

(a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.

(b) Held under the control of the person requesting certification until certified.

(c) Be labeled to show:

(1) The name of the color additive.

(2) The manufacturer's batch number.

(3) The quantity of such batch.

(4) The name and post-office address of the person requesting certification of such batch.

(5) Be accompanied by any label or labeling intended to be used.

§ 80.31 Certification.

(a) If the Commissioner determines, after such investigations as he considers to be necessary, that:

(1) A request submitted in accordance with §80.21 appears to contain no untrue statement of a material fact;

(2) Such color additive conforms to the specifications and any other conditions set forth therefor in Part 74 of this chapter.

(3) The batch covered by such request otherwise appears to comply with the regulations in this part, the Commissioner shall issue to the person who submitted such request a certificate

showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by Part 74 of this chapter, is a certified batch.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with § 80.21, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating his reasons for refusal. Any person who contests such refusal shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

§ 80.32 Limitations of certificates.

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and a color additive from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever, the Commissioner learns that any certificate has been obtained through fraud or material misrepresentation, he shall notify the holder of the certificate that it is of no effect.

(b) If between the time a sample of color additive accompanying a request for certification is taken and the time a certificate covering the batch of such color additive is received by the person to whom it is issued, any such color additive becomes changed in composition, such certificates shall not be effective with respect to such changed color additive and such changed color additive shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(c) If at any time after a certificate is received by the person to whom it is issued any color additive from the batch covered by such certificate becomes changed in composition, such certificate shall expire with respect to such changed color additive. After such expiration, such color additive shall be considered to be from a batch that has not been certified in accordance with this part; except that such color additive shall not be so considered when used for coloring a food, drug, or cosmetic, or for the purpose of certifying a batch of a mixture in which such color additive was used as an ingredient, or for use in preparing a batch of a mixture for which exemption from certification has been authorized, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any color additive covered thereby if the package in which such color additive was closed for shipment or delivery is opened. After such expiration such color additive shall be considered to be from a batch that has not been certified, except that such color additive shall not be so considered when the package is opened; (1) and such color additive is used, subject to the restrictions prescribed by paragraphs (f), (g), and (h) of this section, in coloring a food, drug, or cosmetic; (2) for the purpose of certifying a batch made by repacking such color; (3) for the purpose of certifying a batch of a mixture in which such color is used as an ingredient; or (4) for the purpose of preparing a batch of a mixture for which exemption from certification has been authorized; or (5) when the package is reopened solely for repackaging by the person to whom such certificate was issued.

(e) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by § 70.25 of this chapter to appear thereon.

(f) A certificate shall not be effective with respect to a package of color additive, and such color additive shall be considered to be from a batch that has not been certified if:

(1) Such package has not been sealed in accordance with § 70.20 of this chapter.

(2) Such package has been sealed in accordance with § 70.20 of this chapter and the seal has been broken, intentionally or accidentally, unless such seal has been broken for the purpose of using color additive in accordance with § 80.38, or, such package has been opened by a duly authorized representative of the Administration or Department in the performance of his official duties, and he has immediately resealed the package in conformance with § 70.20 of this chapter.

(g) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such color additive is used in any manner other than that for which it was certified.

(h) When the listing or the specifications for a color additive are revoked or amended, the final order effecting the revocation or amendment may specify, in addition to its own effective date, a date on which all certificates for existing batches and portions of batches of such a color additive theretofore issued under such revoked or amended regulations shall cease to be effective; and any such lots of the color additive shall be regarded as uncertified after the date specified unless a new certificate can be and is obtained in conformance with the new regulations. When a certificate thus ceases to be effective for a color additive, any certificates previously issued for a color additive mixture containing that color additive shall cease to be effective on the same date. Use of such color additive or color additive mixture after such specified date without the new certificate in preparing food, drugs, or cosmetics will result in such food, drugs, or cosmetics being adulterated. When a certified color additive has been used in food, drugs, or cosmetics and the status of the color additive is thereafter changed by amendment or revocation of its listing or specification regulations, such food, drugs, and cosmetics will not be regarded as adulterated by reason of the use of such color additive, unless the hazard to health is such that existing stocks of the foods, drugs, or cosmetics cannot be safely used, in which cases findings to that effect will be made and regulations appropriate for such special cases will be issued.

§ 80.34 Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by § 80.39; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 80.39; or

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

(b) Any person who contests suspension of service shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

§ 80.35 Color additive mixtures; certification and exemption from certification.

(a) *Color additive mixtures to be certified.* Any color additive mixture that contains one or more straight colors listed in Part 74 of this chapter, together with any diluents listed in such subparts for use with such straight colors, shall be certified if intended for use in foods, drugs, or cosmetics, or in coloring the human body, as the case may be, subject to any restrictions prescribed in Parts 70 and 71 of this chapter.

(b) *Color additive mixtures exempted from certification.* A color additive mixture prepared from a previously certified batch of one or more straight colors, with or without any diluent that has been listed in Part 73 of this chapter for use in mixtures, shall be exempt from batch certification if the straight color used has not changed in composition in any manner whatsoever since its certification and if it is simply mixed with the approved diluents for exempt mixtures. The label of such color additive mixtures shall not bear the lot number assigned by the Food and Drug Administration to the certified straight color components, but shall bear the manufacturer's control number through which the history of the straight color can be determined.

(c) *Additions to the list of diluents.* A person requesting additions to the list of diluents authorized for the purposes described in paragraphs (a) and (b) of this section shall submit a petition in accordance with the provisions of § 71.1 of this chapter. Each such petition shall be accompanied by the fee prescribed in § 70.19 of this chapter, unless there is an advance deposit to be used for prepayment of such fees.

NOTE: The provisions of § 80.35 with respect only to diluents for use in cosmetic color additive mixtures were stayed, until a regulation is effected listing safe diluents for cosmetic use, including cosmetics which color the human body, 29 F.R. 18495, Dec. 29, 1964.

§ 80.37 Treatment of batch pending certification.

Immediately after the sample that is to accompany a request for certification of a batch of color additive is taken, the batch shall be:

(a) Stored in containers of such kind as to prevent change in composition.

(b) Held under the control of the person requesting certification until certified.

(c) Marked, by labeling or otherwise, in a manner such that there can be no question as to the identity of the batch and no question that it is not to be used until the requested certificate has been issued.

§ 80.38 Treatment of batch after certification.

(a) Immediately upon notification that a batch of color additive has been certified, the person requesting certification thereof shall identify such batch, by labeling, with the certified lot number.

(b) The person requesting certification shall maintain storage in such manner as to prevent change in composition until such batch has been packaged and labeled as required by §§ 70.20 and 70.25 of this chapter, except that the person requesting certification may use such color additive for the purpose of coloring a food, drug, or cosmetic.

§ 80.39 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

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

Sec.

81.1 Provisional lists of color additives.
81.10 Termination of provisional listings of color additives.
81.25 Temporary tolerances.
81.27 Conditions of provisional listings of additives.
81.30 Cancellation of certificates.
81.32 Limitation of certificates.

AUTHORITY: The provisions of this Part 81 are issued under Title II of Public Law 86-618, sec. 203(c), (d), 74 Stat. 405 (21 U.S.C. 376, note), unless otherwise noted.

§ 81.1 Provisional lists of color additives.

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), 74 Stat. 405 (21 U.S.C. 376 note)). Except for color additives for which petitions have been filed, progress reports are required by January 1, 1968, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in the respective designated sections. The listing of color additives in this section is not to be construed as a listing for surgical suture use unless color additive petitions have been submitted for such use or the Commissioner has been notified of studies underway to establish the safety of the color additive for suc huse. The color additives listed in paragraphs (a), (b), and (c) of this section may not be used in products which are intended to be used in the area of the eye. The color additives listed in paragraphs (a), (b), (c), (f), and (g) of this section are provisionally listed until the closing dates set forth therein, conditioned on compliance with the applicable requirements of paragraphs (a), (b), (c), and (d) of § 81.27.

(a) *Color additives previously and presently subject to certification and provisionally listed for food, drug, and cosmetic use.*

	Closing date		Restrictions
	Food use	Drug and cosmetic use	
FD&C Green No. 3 (sec. 82.203 of this chapter)	Jan. 31, 1981	Jan. 31, 1981	
FD&C Yellow No. 5 (sec. 74.705 of this chapter)	do.[1]	do.	
FD&C Yellow No. 6 (sec. 82.706 of this chapter)	do.	do.	
FD&C Red No. 3 (sec. 74.303 of this chapter)	do.[1]	do.	
FD&C Blue No. 1 (sec. 74.101 of this chapter)	do.[1]	do.	
FD&C Blue No. 2 (sec. 74.1102 of this chapter)	do.	do.	Food and ingested drugs.
Lakes (FD&C) (sec. 82.51 of this chapter)			

[1] Lakes only.

(b) *Color additives previously and presently subject to certification and provisionally listed for drug and cosmetic use.*

	Closing date	Restrictions
D&C Green No. 5 (sec. 74.1205 of this chapter)	Jan. 31, 1981	
D&C Green No. 6 (sec. 74.1206 (a) and (b) of this chapter)	do.	
D&C Yellow No. 10 (sec. 82.1710 of this chapter)	do.	
D&C Red No. 6 (sec. 82.1306 of this chapter)	do.	
D&C Red No. 7 (sec. 82.1307 of this chapter)	do.	
D&C Red No. 8 (sec. 82.1308 of this chapter)	do.	Sec. 81.25.
D&C Red No. 9 (sec. 82.1309 of this chapter)	do.	Do.
D&C Red No. 10 (sec. 82.1310 of this chapter)	do.	Do.
D&C Red No. 11 (sec. 82.1311 of this chapter)	do.	Do.
D&C Red No. 12 (sec. 82.1312 of this c apter)	do.	Do.
D&C Red No. 13 (sec. 82.1313 of this chapter)	do.	Do.
D&C Red No. 19 (sec. 82.1319 of this chapter)	do.	Do.
D&C Red No. 21 (sec. 82.1321 of this chapter)	do.	
D&C Red No. 22 (sec. 82.1322 of this chapter)	do.	
D&C Red o. 27 (sec. 82.1327 of this chapter)	do.	
D&C Red No. 28 (sec. 82.1328 of this chapter)	do.	
D&C Red No. 30 (sec. 82.1330 of this chapter)	do.	
D&C Red No. 33 (sec. 82.1333 of this chapter)	do.	Sec. 81.25.
D&C Red No. 34 (sec. 82.1334 of this chapter)	July 1, 1977	External use only.
D&C Red No. 36 (sec. 82.1336 of this chapter)	Jan. 31, 1981	Sec. 81.25.
D&C Red No. 37 (sec. 82.1337 of this chapter)	do.	Do.
D&C Orange No. 4 (sec. 82.1254 of this chapter)	Oct. 31, 1977	External use only.
D&C Orange No. 5 (sec. 82.1255 of this chapter)	Jan. 31, 1981	Sec. 81.25
D&C Orange No. 10 (sec. 82.1260 of this chapter)	do.	
D&C Orange No. 11 (sec. 82.1261 of this chapter)	do.	
D&C Orange No. 17 (sec. 82.1267 of this chapter)	do.	Do.
D&C Blue No. 6 (sec. 82.1106 of this chapter)	do.	
Lakes (D&C) (sec. 82.1051 of this chapter)		

(c) *Color additives previously and presently subject to certification and provisionally listed for use in externally applied drugs and cosmetics.*

	Closing date	Restrictions
Ext. D&C Yellow No. 1 (sec. 82.2701a of this chapter)	Oct. 31, 1977	
Ext. D&C Green No. 1 (sec. 82.2201 of this chapter)	do	
Lakes (ext. D&C) (sec. 82.2051 of this chapter)		

(d) [Reserved]

(e) [Reserved]

(f) *Color additives provisionally listed for drug use on the basis of prior commercial sale but which have not been nor are now subject to certification.* The color additives listed in this paragraph are listed only for the uses and purposes commercially employed prior to July 12, 1960. Thus, a color additive used only in drugs for external application is not provisionally listed for internal drug use.

	Closing date	Restrictions
Logwood	Oct. 31, 1977	Surgical suture use only.

(g) *Color additives provisionally listed for cosmetic use on the basis of prior commercial sale but which have not been nor are now subject to certification.* The color additives provisionally listed in this paragraph are so listed only for the uses and purposes commercially employed prior to July 12, 1960. Thus, a color additive previously used for coloring cosmetics to be applied to portions of the body other than the eye area (as defined in § 70.3(s)) of this chapter is not provisionally listed for eye-area use.

Color additive	Closing date	Restrictions
Aluminum powder	July 1, 1977	None.
Annatto	do	Do.
Bismuth citrate	Oct. 31, 1977	For use as a color component in hair dye.
Bismuth oxychloride	do	None.
Bronze powder	July 1, 1977	Do.
Caramel	Jan. 31, 1981	Do.
Carmine	July 1, 1977	Do.
Carotene	do	Do.
Chromium hydroxide green	do	Do.
Chromium oxide greens	do	Do.
Copper, metallic powder	do	Do.
Ferric ferrocyanide (iron blue)	do	Do.
Graphite	Oct. 31, 1977	Do.
Guanine (pearl essence)	July 1, 1977	Do.
Lead acetate	Oct. 31, 1977	For use as a color component in hair dye.
Mica	July 1, 1977	None
Zinc oxide	do	Do.

(Sec. 203(a)(2), (d)(1)(E), Public Law 86-618, 74 Stat. 404-405; 21 U.S.C. 376, note)

§ 81.10 Termination of provisional listings of color additives.

(a) *Ext. D&C Yellow Nos. 9 and 10.* These colors cannot be produced with any assurance that they do not contain β-naphthylamine as an impurity. While it has been asserted that the two colors can be produced without the impurity named, no method of analysis has been suggested to establish the fact. β-Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in products to be used in contact with the skin. The Commissioner of Food and Drugs, having concluded that such action is necessary to protect the public health, hereby terminates the provisional listing of Ext. D&C Yellow No. 9 and Ext. D&C Yellow No. 10.

(b)(1) *D&C Red Nos. 8, 9, 10, 19, 33, 37; D&C Orange Nos. 3, 4, 5, and 17.* Subacute studies have established that these colors are toxic substances, unsafe for unrestricted use in drugs and cosmetics.

(2) *D&C Red Nos. 11, 12, and 13.* These colors are chemically related to D&C Red No. 10, being the calcium, barium, and strontium salts of the same dye, and are chemically indistinguishable from D&C Red No. 10 in the analysis of a product in which such colors have been used. They therefore must be subject to the same restrictions imposed on D&C Red No. 10.

The Commissioner of Food and Drugs, having concluded that such action is necessary for the protection of the public health, hereby terminates the provisional listing for the colors named in this section for unrestricted use in drugs and cosmetics. These colors are now listed in Part 82 of this chapter as follows:

D&C Red No. 8 (§ 82.1308 of this chapter).
D&C Red. No. 9 (§ 82.1309 of this chapter).
D&C Red No. 10 (§ 82.1310 of this chapter).
D&C Red No. 11 (§ 82.1311 of this chapter).
D&C Red No. 12 (§ 82.1312 of this chapter).
D&C Red No. 13 (§ 82.1313 of this chapter).
D&C Red No. 19 (§ 82.1319 of this chapter).
D&C Red No. 33 (§ 82.1333 of this chapter).
D&C Red No. 37 (§ 82.1337 of this chapter).
D&C Orange No. 4 (§ 82.1254 of this chapter).
D&C Orange No. 5 (§ 82.1255 of this chapter).
D&C Orange No. 17 (§ 82.1267 of this chapter).

(c) *FD&C Red No. 1.* Results of recent feeding tests of this color additive have demonstrated it to be toxic upon ingestion:

(1) Groups of 50 rats are being fed diets containing FD&C Red No. 1 at levels of 5 percent, 2 percent, 1 percent, 0.5 percent, and 0 percent. At this stage of the tests, which have now been in progress for from 15 months to 18 months, 116 animals from the 250 being fed FD&C Red No. 1 at various levels and 27 of the 100 controls have died. Of these, 11 being fed at the 5 percent level, 16 being fed at the 2 percent level, 11 being fed at the 1 percent level, and 2 being fed at the 0.5 percent level, have shown liver damage. None of the controls that have died have shown liver damage.

(2) Groups of 100 mice are being fed diets containing 2 percent, 1 percent, 0.5 percent, and 0.1 percent FD&C Red No. 1, with 400 mice as controls. All mice on dosage levels of 2 percent and 1 percent died before the seventieth week. Gross liver damage has been observed in all groups fed at the 0.5 percent diet and above.

(3) Groups of 4 dogs are being fed diets containing 2 percent, 1 percent, 0.25 percent, and 0 percent FD&C Red No. 1. Three of the dogs on the 2 percent dosage level died before 32 weeks; the other is living. Three of the dogs on the 1 percent dosage level died or were sacrificed within 13 months. All deceased or sacrificed dogs have shown liver damage grossly and/or microscopically. Deceased dogs on the 1 percent and 2 percent dosage level showed poor physical condition.

The Commissioner of Food and Drugs having concluded that ingestion of this color additive over a long period of time would be unsafe, and in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 1 for use in foods, drugs, and cosmetics.

(d) *FD&C Red No. 4.* Feeding tests of this color additive have been conducted with three species:

(1) Rats of the Osborne-Mendel and Sprague-Dawley strains were fed FD&C Red No. 4 for 2 years at levels of 5 percent, 2 percent, 1 percent, and 0.5 percent of the diet. No effect was found.

(2) Mice of the C3Hf and C57BL strains were fed FD&C Red No. 4 for 2 years at levels of 2 percent and 1 percent of the diet. No effect was found.

(3) Dogs were fed FD&C Red No. 4 at levels of 2 percent and 1 percent of the diet. Adverse effects were found at both levels in the urinary bladder and in the adrenals. Three dogs of five fed on the 2-percent level died after 6 months, 9 months, and 5½ years on the test. Two of the dogs on the 2-percent level and all five of the dogs on the 1-percent level survived to the completion of the 7 year study.

The Commissioner of Food and Drugs has concluded that available data do not permit the establishment of a safe level of use of this color additive in food, in-

gested drugs and ingested cosmetics. In order to protect the public health, the Commissioner hereby terminates the provisional listing of FD&C Red No. 4 for use in food and ingested drugs. The Commissioner has previously terminated the provisional listing of FD&C Red No. 4 for use in ingested cosmetics. FD&C Red No. 4 is listed for use in externally applied drugs and cosmetics by §§ 74.1304 and 74.2304 of this chapter, respectively. Section 82.304 of this chapter is retained in Part 82 of this chapter to permit the use of lakes of FD&C Red No. 4 in externally applied drugs and cosmetics.

(e) *FD&C Violet No. 1.* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of FD&C Violet No. 1 for use in foods, drugs, and cosmetics.

(f) *FD&C Red No. 2.* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 2 for use in food, drugs, and cosmetics.

(g) *Carbon black (prepared by the "impingement" or "channel" process).* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of carbon black (prepared by the "impingement" or "channel" process) for use in food, drugs, and cosmetics.

§ 81.25 Temporary tolerances.

Two-year chronic rat feeding studies, including histopathology, of D&C Red No. 9 and D&C Red No. 10 have been completed. A final determination of the status of these colors for ingestion must await chronic feeding studies with a nonrodent species. However, pharmacologists of the Food and Drug Administration have concluded, on the basis of chronic feeding studies with the rat, that a no-effect level of feeding of 100 parts per million will be accepted pending chronic feeding studies with a nonrodent species. Since the subacute toxicity of the two colors is of the same order of subacute toxicity as the other nine colors listed in § 81.10(b)(1), it can be assumed for the purpose of temporary tolerances that the same no-effect level of feeding for the nine colors is also 100 parts per million. Data have been submitted which indicate that the maximum amount of the color additives listed in paragraph (a) of this section likely to be ingested daily from lipstick will correspond to about 0.1 part per million in the daily diet. On this basis, it is not inconsistent with the protection of the public health to allow, during this transitional period, continued use of these products in lipstick and in other products that may be ingested in the amounts specified in this section.

(a) Pursuant, therefore, to the authority in section 203(d)(1)(C) of the Color Additive Amendments of 1960, temporary tolerances are established for the following color additives:

Color additive	*Percent*
D&C Orange No. 5 (§ 82.1255 of this chapter)	6
D&C Orange No. 17 (§ 82.1267 of this chapter)	6
D&C Red No. 8 (§ 82.1308 of this chapter)	6
D&C Red No. 9 (§ 82.1309 of this chapter)	6
D&C Red No. 10 (§ 82.1310 of this chapter)	6
D&C Red No. 11 (§ 82.1311 of this chapter)	6
D&C Red No. 12 (§ 82.1312 of this chapter)	6
D&C Red No. 13 (§ 82.1313 of this chapter)	6
D&C Red No. 19 (§ 82.1319 of this chapter)	6
D&C Red No. 33 (§ 82.1333 of this chapter)	6
D&C Red No. 36 (§ 82.1336 of this chapter)	6

These color additives are therefore retained on the provisional list for use in lipstick with the indicated temporary tolerances which are expressed as percent pure dye by weight of each lipstick. These color additives may be used in combinations provided the individual tolerance is not exceeded and the total percent of all colors used does not exceed 6 percent pure dye by weight of the lipstick. These color additives and D&C Red No. 37 are retained without tolerance restrictions for externally applied drugs and cosmetics.

(b)(1) The colors named in this paragraph may safely be used, during the transitional period, in drug products and in such other preparations subject to ingestion as mouthwashes and dentifrices, where total usage reasonably to be expected to be ingested does not contribute more than 1 part per million of any such color additive or combination of color additives to the human diet. Therefore, to meet this limitation the following colors are retained on the provisional list of color additives for use in drug products for internal use, mouthwashes, dentifrices, and proprietary products, under a temporary tolerance, provided that in no instance shall such color additives contribute more than 0.75 milligram of the color additive, expressed as pure dye, to the amount of the product reasonably expected to be ingested in 1 day.

D&C Orange No. 5 (§ 82.1255 of this chapter).
D&C Red No. 8 (§ 82.1308 of this chapter).
D&C Red No. 12 (§ 82.1312 of this chapter).
D&C Red No. 19 (§ 82.1319 of this chapter).
D&C Red No. 33 (§ 82.1333 of this chapter).
D&C Red No. 37 (§ 82.1337 of this chapter).

(2) D&C Red No. 36 (§ 82.1336 of this chapter) is retained on the provisional list of color additives for use in drug products for internal use, mouthwashes, dentifrices, and proprietary products, under a temporary tolerance, provided that in no instance shall it contribute more than 1.7 milligrams of the color additive, expressed as pure dye, to the amount of the product reasonably expected to be ingested in 1 day.

§ 81.27 Conditions of provisional listing.

The closing dates for the use of the color additives provisionally listed in § 81.1 are postponed until the dates established in that section conditioned on compliance with the requirements of paragraphs (a), (b), (c), and (d) of this section, where applicable. The closing dates will not be postponed beyond the dates in § 81.1 unless extraordinary circumstances are shown. Requests for further postponement based on extraordinary circumstances shall be submitted in writing and state in detail the basis for the request. If the requirements of paragraphs (a), (b), (c), and (d) of this section are not complied with, the provisional listing for the color additive(s) involved will be terminated immediately.

(a) The closing date for the following 14 color additives is postponed until July 1, 1977, while 4-week eye area studies in the rabbit are conducted and evaluated, and subject to compliance with the requirements of this paragraph: Aluminum powder, annatto, bismuth oxychloride, bronze powder, caramel, carmine, carotene, chromium hydroxide green, chromium oxide greens, copper (metallic powder), ferric ferrocyanide, guanine (pearl essence), mica, and zinc oxide.

(1) At least one petitioner for each of the 14 color additives listed in paragraph (a) of this section shall agree in writing by March 7, 1977 to undertake the eye area studies.

(2) A full written report of the results of the studies shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, by March 21, 1977.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additive to cause adverse effects.

(b) The closing date for bismuth citrate, bismuth oxychloride, caramel, and lead acetate is postponed until October 31, 1977, while short-term studies are conducted and evaluated, and subject to compliance with the requirements of this paragraph.

(1) At least one petitioner for each of of the four color additives listed in paragraph (b) of this section shall agree in writing by March 7, 1977 to undertake the short-term studies on the color additives.

(2) A full written report on the absorption studies for bismuth citrate and lead acetate and a full written report on the subchronic studies for bismuth citrate, bismuth oxychloride, and caramel shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, by August 3, 1977.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additive to cause adverse effects.

(c) The closing date for the following nine color additives is postponed until October 31, 1977, while chemistry data and analytical methods to establish specifications for them are developed and evaluated and subject to compliance with the requirements of this paragraph: D&C Yellow No. 10, D&C Red No. 6, D&C Red No. 7, D&C Red No. 30, D&C Orange No. 4, D&C Blue No. 6, Ext. D&C Yellow No. 1, Ext. D&C Green No. 1, and graphite.

(1) At least one petitioner for each of the nine color additives listed in paragraph (c) of this section shall agree in writing by March 3, 1977 to undertake to develop the necessary chemistry data and analytical methods for the color additives.

(2) The required chemistry data and analytical methods shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, by August 3, 1977.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additive to cause adverse effects.

(d) The closing date for the following 32 color additives is postponed until January 31, 1981, while chronic toxicity feeding studies and in the case of caramel, a lifetime mouse skin painting study, are conducted and evaluated, and subject to compliance with the requirements of this paragraph: FD&C Yellow No. 5, FD&C Yellow No. 6, D&C Yellow No. 10, FD&C Red No. 3, D&C Red No. 6, D&C Red No. 7, D&C Red No. 8, D&C Red No. 9, D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, D&C Red No. 13, D&C Red No. 19, D&C Red No. 21, D&C Red No. 22, D&C Red No. 27, D&C Red No. 28, D&C Red No. 30, D&C Red No. 33, D&C Red No. 36, D&C Red No. 37, FD&C Green No. 3, D&C Green No. 5, D&C Green No. 6, FD&C Blue No. 1, FD&C Blue No. 2, D&C Blue No. 6, D&C Orange No. 5, D&C Orange No. 10, D&C Orange No. 11, D&C Orange No. 17, and caramel.

(1) At least one petitioner for each of the 32 color additives listed in paragraph (d) of this section shall agree in writing by March 7, 1977 to undertake the required studies on the color additives.

(2) The petitioners undertaking the studies shall submit a protocol for the conduct of the studies to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, for review, and acceptance or rejection, by April 5, 1977.

(3) An initial progress report of the studies on the color additives shall be submitted to the Division of Food and Color Additives by December 31, 1977. Further progress reports shall be submitted at 6-month intervals thereafter. A full report of the studies conducted on the color additives shall be submitted to the Division of Food and Color Additives by August 4, 1980.

(4) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate potential for the color additive to cause adverse effects.

§ 81.30 Cancellation of certificates.

(a) Certificates issued heretofore for colors being removed from the provisional list (§ 81.10(a)) are cancelled and of no effect after December 1, 1960, and use of such color additives in drugs or cosmetics after that date will result in adulteration.

(b) (1) Certificates issued heretofore for the color additive designated FD&C Red No. 1 are cancelled as of the date of the publication of this Order, and use of this color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him, taking into account that the additive is not an acute toxic substance and that it is only used in small amounts in foods, drugs, and cosmetics.

(c) Certificates issued for FD&C Red No. 4 and all mixtures containing this color additive are cancelled and have no effect after September 23, 1976 insofar as food, ingested drugs, and ingested cosmetics are concerned, and use of this color additive in the manufacture of food, ingested drugs, and ingested cosmetics after this date will result in adulteration. The certificates shall continue in effect for the use of FD&C Red No. 4 in externally applied drugs and cosmetics. The Commissioner finds, on the basis of the scientific evidence before him that no action has to be taken to remove from the market food, ingested drugs and ingested cosmetics containing the color additive.

(d) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after October 4, 1966, and use of such color additives in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration:

FD&C Green No. 1.
FD&C Green No. 2.
D&C Green No. 7.
D&C Red No. 5.
D&C Red No. 14.
D&C Red No. 18.
D&C Red No. 24.
D&C Red No. 29.
D&C Red No. 35.
D&C Red No. 38.
D&C Orange No. 3.
D&C Orange No. 8.
D&C Orange No. 14.
D&C Orange No. 15.
D&C Orange No. 16.
D&C Blue No. 7.
D&C Black No. 1.
Ext. D&C Yellow No. 5.
Ext. D&C Yellow No. 6.
Ext. D&C Red No. 1.
Ext. D&C Red No. 2.
Ext. D&C Red No. 3.
Ext. D&C Red No. 10.
Ext. D&C Red No. 11.
Ext. D&C Red No. 13.
Ext. D&C Red No. 14.
Ext. D&C Red No. 15.
Ext. D&C Blue No. 1.
Ext. D&C Blue No. 4.
Ext. D&C Orange No. 1.
Ext. D&C Orange No. 4.

(e) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after July 1, 1968, and use of such color additives in the manufacture of drugs or cosmetics after that date will result in adulteration:

Ext. D&C Yellow No. 3.
Ext. D&C Red No. 8.
Ext. D&C Orange No. 3.

(f) Certificates issued for D&C Yellow No. 11 and all mixtures containing this color additive are canceled and have no effect after April 30, 1968, insofar as ingested use is concerned. Use of this color additive in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(g) Certificates issued for D&C Red No. 17, D&C Red No. 31, D&C Red No. 34, D&C Orange No. 4, and D&C Violet No. 2, and all mixtures containing these color additives, are canceled and have no effect after December 31, 1968, insofar as ingested use is concerned. Use of these color additives in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(h) (1) Certificates issued for FD&C Violet No. 1 and all mixtures containing this color additive are canceled and have no effect after April 10, 1973, and use of such color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him.

(i) Certificates issued prior to July 1, 1968, for D&C Brown No. 1 and Ext. D&C Violet No. 2 and all mixtures containing these colors are canceled and have no effect. This cancellation does not apply to certificates issued after March 15, 1973, for D&C Brown No. 1 and Ext. D&C Violet No. 2, which are provisionally listed in § 81.1 (b) and (c) respectively for coloring externally applied cosmetics.

(j) (1) Certificates issued for FD&C Red No. 2 and all mixtures containing this color additive are cancelled and have no effect after January 28, 1976, and use of this color additive in the manufacture of food, drugs, or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market food, drugs, and cosmetics containing the color additive.

§ 81.32 Limitation of certificates.

(a) *Certain color additives.* Certificates issued heretofore for color additives being retained on the provisional list in § 81.25, but under tolerance and usage restrictions, are hereby limited to those uses and under those conditions imposed by that section. Use of such color additives in any other manner after December 1, 1960, in drugs or cosmetics will result in adulteration. Any color additive certified under such tolerance and usage restrictions after Oc-

tober 12, 1960, shall bear a label statement of the name of the color additive and of the tolerance and use limitations applicable to it.

(b) [Reserved]

(c) *D&C Red No. 36.* Certificates issued heretofore for D&C Red No. 36 and all mixtures containing this color additive are limited effective October 31, 1970, to the conditions imposed by § 81.25 (a) and (b) (2)). Use of D&C Red No. 36 in any other manner after October 31, 1970, in drugs or cosmetics will result in adulteration. Any D&C Red No. 36 distributed after October 31, 1970, shall bear a label statement of the tolerance applicable to it.

(Sec. 203(a)(2), 74 Stat. 404; 21 U.S.C. 376, note)

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

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82.1309 D&C Red No. 9.
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82.1331 D&C Red No. 31.
82.1333 D&C Red No. 33.
82.1334 D&C Red No. 34.
82.1336 D&C Red No. 36.
82.1337 D&C Red No. 37.
82.1602 D&C Red Violet No. 2.
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82.2201 Ext. D&C Green No. 1.
82.2701a Ext. D&C Yellow No. 1.
82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: Secs. 406, 504, 604, 701, 702, 706, 52 Stat. 1049 as amended, 1055–1056 as amended, 1058 as amended (21 U.S.C. 346, 354, 364, 371, 372, 376), unless otherwise noted.

Subpart A—General Provisions

§ 82.3 Definitions.

For the purposes of this part:

(a)–(f) [Reserved]

(g) The term "alumina" means a suspension in water of precipitated aluminum hydroxide.

(h) The term "blanc fixe" means a suspension in water of precipitated barium sulfate.

(i) The term "gloss white" means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term "mixed oxides" means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)–(m) [Reserved]

(n) The term "externally applied drugs and cosmetics" means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o) and (p) [Reserved]

(q) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in this part.

§ 82.5 General specifications for straight colors.

No batch of a straight color listed in Subpart B, C, or D shall be certified under this part unless:

(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in Subpart B:

(i) Lead (as Pb), not more than 0.001 percent.

(ii) Arsenic (as As_2O_3), not more than 0.00014 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in Subpart C or D:

(i) Lead (as Pb), not more than 0.002 percent.

(ii) Arsenic (as As_2O_3), not more than 0.0002 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in Subpart C or D—soluble barium (in dilute HCl) (as $BaCl_2$), not more than 0.05 percent.

§ 82.6 Certifiable Mixtures.

(a) A batch of a mixture which contains no straight color listed in Subpart C or D may be certified for use in food, drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) Each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, pectin and, in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than 1/10 of 1 percent) in such mixture is a nonnutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with § 80.21 of this chapter, and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in Subpart D, or which contains a diluent not permitted by paragraph (a)(3) of this section, may be certified in accordance with the provisions of this part, for use only in drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

(c) A batch of a mixture which contains a straight color listed in Subpart D may be certified in accordance with the provisions of this part, for use only in externally applied drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

Subpart B—Foods, Drugs, and Cosmetics

§ 82.50 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of the regulations in this part, for use in food, drugs, and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications in this subpart set forth for such color.

§ 82.51 Lakes (FD&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, a

salt prepared from one of the certified water-soluble straight colors hereinbefore listed in this subpart by combining such color with the basic radical aluminum or calcium.

(2) *Specifications.*

Prepared from previously certified colors listed in this subpart.

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.

Inorganic matter, insoluble HCl, not more than 0.5 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word "Lake".

(For example, the name of a lake prepared by extending the aluminum salt prepared from FD&C Blue No. 1 upon the substratum would be FD&C Blue No. 1—Aluminum Lake.)

§ 82.101 FD&C Blue No. 1.

The color additive FD&C Blue No. 1 shall conform in identity and specifications to the requirements of § 74.101 (a) (1) and (b) of this chapter.

§ 82.102 FD&C Blue No. 2.

The color additive FD&C Blue No. 2 shall conform in identity and specifications to the requirements of § 74.1102(a) and (b) of this chapter.

§ 82.203 FD&C Gren No. 3.

Disodium salt of 4-{[4-(*N*-ethyl-*p*-sulfobenzylamino) - phenyl] - (4-hydroxy-2-sulfoniumphenyl) -methylene} - [1 - (*N* - ethyl - *N* - *p* - sulfobenzyl) -$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

§ 82.303 FD&C Red No. 3.

The color additive FD&C Red No. 3 shall conform in identity and specifications to the requirements of § 74.303(a) (1) and (b) of this chapter.

§ 82.304 FD&C Red No. 4.

The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a) (1) and (b) of this chapter. FD&C Red No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.705 FD&C Yellow No. 5.

The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705(a) (1) and (b) of this chapter.

§ 82.706 FD&C Yellow No. 6.

Disodium salt of 1-*p*-sulfophenylazo-2-naphthol-6-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Subpart C—Drugs and Cosmetics

§ 82.1050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use only in drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.1051 Lakes (D&C).

(a) (1) *General.* Any lake, other than those listed in Subpart B, made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of two or more of these, (i) one of the straight colors (except lakes) listed in Subpart B or hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium; or (ii) a salt prepared from one of the straight colors (except lakes) listed in Subpart B, or hereinbefore listed in this subpart, by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared, except that if such name contains the symbol "FD&C" such symbol shall be changed to "D&C";

(2) The name of the basic radical combined in such color; and

(3) The word "Lake."

(For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is "D&C Red No. 9—Barium Lake", and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is "D&C Green No. 1—Aluminum Lake".)

§ 82.1104 D&C Blue No. 4.

The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a) (1) and (b) of this chapter. D&C Blue No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.1106 D&C Blue No. 6.

Indigotin.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 2.0 percent.

Matter insoluble in dichlorhydrin, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

§ 82.1205 D&C Green No. 5.

The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205 (a) and (b) of this chapter.

§ 82.1206 D&C Green No. 6.

The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b) of this chapter.

§ 82.1254 D&C Orange No. 4.

Monosodium salt of 1-*p*-sulfophenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

β-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

§ 82.1255 D&C Orange No. 5.

4,5-Dibromo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 31.0–35.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

§ 82.1260 D&C Orange No. 10.

4,5-Diiodo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 41.5–45.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

§ 82.1261 D&C Orange No. 11.

Disodium salt of 9-*o*-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 38.5–42.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

§ 82.1267 D&C Orange No. 17.

1-(2,4-Dinitrophenylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in toluene, not more than 1.5 percent.

2,4-Dinitroaniline, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

§ 82.1306 D&C Red No. 6.

Monosodium salt of 4-(*o*-sulfo-*p*-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

§ 82.1307 D&C Red No. 7.

Calcium salt of 4-(*o*-sulfo-*p*-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 8.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

§ 82.1308 D&C Red No. 8.

Monosodium salt of 1-(4-chloro-*o*-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

§ 82.1309 D&C Red No. 9.

Barium salt of 1-(4-chloro-*o*-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C), not more than 5.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 87.0 percent.

§ 82.1310 D&C Red No. 10.

Monosodium salt of 2-(2-hydroxy-1-naphthylazo) - 1 - naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

§ 82.1311 D&C Red No. 11.

Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalensulfonic acid.

Volatile matter at (135° C.), not more than 5.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

§ 82.1312 D&C Red No. 12.

Barium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

§ 82.1313 D&C Red No. 13.

Strontium salt of 2-(2-hydroxy-1-naphthylazo) - 1 - naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

§ 82.1317 D&C Red No. 17.

The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317 (a)(1) and (b) of this chapter. D&C Red No. 17 is restricted to use in externally applied drugs and cosmetics.

§ 82.1319 D&C Red No. 19.

3-Ethochloride of 9-*o*-carboxyphenyl-6 - diethylamino-3-ethylimino-3-isoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts (from acid solution), not more than 0.5 percent.

Diethyl-*m*-aminophenol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

§ 82.1321 D&C Red No. 21.

2,4,5,7-Tetrabromo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 47.5–51.5 percent.

Pure dye (as determined gravimetrically), not less than 93.0 percent.

§ 82.1322 D&C Red No. 22.

Disodium salt of 2,4,5,7-tetrabromo-9-o-carboxyphenyl-6-hydroxy - 3 - isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 44.5–48.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

§ 82.1327 D&C Red No. 27.

2,4,5,7-Tetrabromo - 12,13,14,15-tetrachloro-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 38.5–42.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0–19.0 percent.

Pure dye (as determined gravimetrically, not less than 90.0 percent.

§ 82.1328 D&C Red No. 28.

Disodium salt of 2,4,5,7-tetrabromo-9-(3,4,5,6 - tetrachloro-o-carboxyphenyl) - 6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye 36.5–40.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0–18.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

§ 82.1330 D&C Red No. 30.

5,5'-Dichloro-3,3' - dimethyl - thioindigo.

Volatile matter (at 135° C.), not more than 5.0 percent.

Matter insoluble in xylene, not more than 1.0 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

§ 82.1331 D&C Red No. 31.

The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331 (a) (1) and (b) of this chapter. D&C Red No. 31 is restricted to use in externally applied drugs and cosmetics.

§ 82.1333 D&C Red No. 33.

Disodium salt of 8-amino-2-phenylazo-1-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 6.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

§ 82.1334 D&C Red No. 34.

Calcium salt of 3-hydroxy-4-[(1-sulfo-2 - naphthalenyl)azol - 2-naphthalenecarboxylic acid.

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

2-Amino-1-naphthalensulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.

Subsidiary colors, not more than 4 percent.

Total color not less than 85 percent.

§ 82.1336 D&C Red No. 36.

1 - (o - Chloro - p - nitrophenylazo - 2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in toluene, not more than 1.0 percent.

o-Chloro-p-nitroaniline, not more than 0.2 percent.

β-Naphthol, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

§ 82.1337 D&C Red No. 37.

3-Ethostearate of 9-o-carboxyphenyl-6 - diethylamino-3-ethylimino-3-isoxanthene.

Volatile matter (at 80° C.), not more than 2.0 percent.

Sulfated ash, not more than 3.0 percent.

Matter insoluble in benzene, not more than 0.5 percent.

Diethyl-m-aminophenol, not more than 0.2 percent.

Stearic acid (not part of the dye), not more than 50.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 50.0 percent.

§ 82.1602 D&C Violet No. 2.

The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602 (a) (1) and (b) of this chapter.

§ 82.1707 D&C Yellow No. 7.

The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a) (1) and (b) of this chapter. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

§ 82.1708 D&C Yellow No. 8

The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1707 (a) (1) and (b) of this chapter. D&C Yellow No. 8 is restricted to use in externally applied drugs and cosmetics.

§ 82.1710 D&C Yellow No. 10.

Disodium salt of disulfonic acid of 2-(2-quinolyl) -1,3-indandione.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Quinaldine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 82.0 percent.

Subpart D—Externally Applied Drugs and Cosmetics

§ 82.2050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.2051 Lakes (Ext. D&C).

(a) (1) *General.* Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or on any combination of two or more of these (i) one of the straight colors hereinbefore listed in this subpart, which color is a salt in which is combined the basic radi-

cal sodium, potassium, barium, or calcium; or (ii) a salt prepared from one of the straight colors hereinbefore listed in this subpart by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word "Lake."

(For example, the name of a lake prepared by extending the color Ext. D&C Yellow No. 2 upon a substratum is "Ext. D&C Yellow No. 2—Calcium Lake," and a lake prepared by extending the barium salt prepared from Ext. D&C Red No. 2 upon the substratum is "Ext. D&C Red No. 2—Barium Lake.")

§ 82.2201 Ext. D&C Green No. 1.

Ferric salt of 6-sodiumsulfo-1-isonitroso-1,2-naphthoquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.5 percent.

Water-insoluble matter, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

§ 82.2701a Ext. D&C Yellow No. 1.

Monosodium salt of 4-*m*-sulfophenylazo-diphenylamine.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 1.0 percent.

Chloroform-soluble matter, not more than 0.5 percent.

Diphenylamine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 7.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

§ 82.2707a Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity with specifications to the requirements of § 74.1707a (a)(1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

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[Docket No. 77N-0032]

RECODIFICATION EDITORIAL AMENDMENTS

The Food and Drug Administration is in the process of recodifying all of Chapter I of Title 21 of the Code of Federal Regulations, for the purposes of providing orderly development of such regulations, furnishing ample room for expansion in the years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand.

The 17th and final document in a series of recodification documents, which reorganizes and recodifies existing Parts 1 through 9 and transfers § 200.18 from Subchapter C to reorganized Subchapter A, Parts 1 through 99, is published elsewhere in this issue of the FEDERAL REGISTER.

To provide uniformity and continuity during the recodification, the Commissioner concludes that the references to the recodified material should be amended at this time.

Due to the complexity and volume of cross-references involved in the recodification of these regulations, if necessary, supplemental documents will be issued at a later date.

Therefore, Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

PART 101—FOOD LABELING

§ 101.2 [Amended]

1. Section 101.2 is amended as follows:

a. In paragraph (c)(4)(ii)(a) by changing the reference "§ 1.1c(a)(5)(ii)" to read "§ 1.24(a)(5)(ii) of this chapter".

b. In paragraph (c)(4)(ii)(b)(2) by changing the reference "§ 1.1c(a)(5)(ii)" to read "§ 1.24(a)(5)(ii) of this chapter".

c. In paragraph (f) by changing the reference "Part 2" to read "Part 10".

§ 101.103 [Amended]

2. Section 101.103 is amended by changing the reference "Part 2" to read "Part 10".

§ 101.105 [Amended]

3. Section 101.105(s) is amended by changing the reference "§ 1.1c(a) (10) and (11)" to read "§ 1.24(a) (10) and (11) of this chapter".

PART 102—COMMON OR USUAL NAMES FOR NONSTANDARDIZED FOODS

§ 102.19 [Amended]

4. Section 102.19 is amended as follows:

a. In paragraph (a) by changing the reference "Part 2" to read "Part 10".

b. In paragraph (b) by changing the reference "Part 2" to read "Part 10".

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

§ 103.5 [Amended]

5. Section 103.5(e) is amended by changing the reference "Part 2" to read "Part 10".

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

§ 104.19 [Amended]

6. Section 104.19 is amended by changing the reference "Part 2" to read "Part 10".

PART 105—FOOD FOR SPECIAL DIETARY USE

§ 105.85 [Amended]

7. Section 105.85(a)(5) is amended by changing the reference "Part 2" to read "Part 10".

PART 108—EMERGENCY PERMIT CONTROL

§ 108.19 [Amended]

8. Section 108.19(a) is amended by changing the reference "Part 2" to read "Part 10".

§ 108.35 [Amended]

9. Section 108.35(1) is amended by changing the references "§ 4.81" and "§ 4.61" to read "§ 20.81" and "§ 20.61," respectively.

PART 130—FOOD STANDARDS: GENERAL

§ 130.5 [Amended]

10. Section 130.5(a) is amended by changing the reference "Part 2" to read "Part 10".

§ 130.17 [Amended]

11. Section 130.17(k) is amended by changing the reference "Part 4" to read "Part 20".

PART 158—FROZEN VEGETABLES

§ 158.170 [Amended]

12. Section 158.170(a)(1) is amended by changing the reference "§ 1.1(b)" to read "§ 1.20".

PART 170—FOOD ADDITIVES

§ 170.15 [Amended]

13. Section 170.15(b) is amended by changing the reference "Part 2" to read "Part 10".

§ 170.35 [Amended]

14. Section 170.35(c)(1) is amended by changing the reference "Part 2" to read "Part 10".

§ 170.38 [Amended]

15. Section 170.38(b)(1) is amended by changing the reference "Part 2" to read "Part 10".

PART 171—FOOD ADDITIVE PETITIONS

§ 171.1 [Amended]

16. Section 171.1 is amended as follows:

a. In paragraph (c), Form, item H. by changing the reference "§ 6.1" to read "§ 25.1".

b. In paragraph (h)(1)(ii) by changing the reference "§ 4.61" to read "§ 20.61".

c. In paragraph (h)(1)(iv) by changing the reference "§ 4.61" to read "§ 20.61".

d. In paragraph (h)(1)(v) by changing the reference "§ 4.61" to read "§ 20.61".

e. In paragraph (h)(2) by changing the references "§ 4.81" and "§ 4.61" to read "§ 20.81" and "§ 20.61," respectively.

f. In paragraph (h)(3) by changing the reference "Part 4" to read "Part 20".

§ 171.6 [Amended]

17. Section 171.6 is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 171.110 [Amended]

18. Section 171.110 is amended by changing the reference "Part 2" to read "Part 12".

§ 171.130 [Amended]

19. Section 171.130(a) is amended by changing the reference "Part 2" to read "Part 10".

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

§ 175.125 [Amended]

20. Section 175.125(a)(3) is amended by changing the reference "Part 8" to read "Parts 73 and 74".

PART 180—INTERIM FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

§ 180.1 [Amended]

21. Section 180.1(c) is amended by changing the reference "Part 2" to read "Part 10".

SUBCHAPTER C—DRUGS: GENERAL

PART 201—LABELING

§ 201.100 [Amended]

22. Section 201.100(b)(5)(ii) is amended by changing the reference "Part 8" to read "Subchapter A".

§ 201.105 [Amended]

23. Section 201.105(b)(5)(ii) is amended by changing the reference "Part 8" to read "Subchapter A".

PART 202—PRESCRIPTION DRUG ADVERTISING

§ 202.1 [Amended]

24. Section 202.1(j)(5) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 310—NEW DRUGS

§ 310.101 [Amended]

25. Section 310.101(a) is amended by changing the references "§ 8.502(d)", "§ 8.501(a)", "§ 8.510(c)" and "§ 8.503" to read "§ 81.10(d)", "§ 81.1(a)", "§ 81.30(c)" and "§ 81.25," respectively.

§ 310.200 [Amended]

26. Section 310.200(b) is amended by changing the reference "Part 2" to read "Part 10".

§ 310.303 [Amended]

27. Section 310.303(b) is amended by changing the reference "Part 2" to read "Part 10".

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

§ 312.1 [Amended]

28. Section 312.1 is amended as follows:

a. In paragraph (a)(2), Form FD-1571, item 15, by changing the reference "§ 6.1" to read "§ 25.1".

b. In paragraph (c)(1) by changing the reference "Subpart F of Part 2" to read "Part 16".

c. In paragraph (c)(4) by changing the reference "Subpart F of Part 2" to read "Part 16".

d. In paragraph (d)(11) by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 312.9 [Amended]

29. Section 312.9(c)(2) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

PART 314—NEW DRUG APPLICATIONS

§ 314.1 [Amended]

30. Section 314.1 is amended as follows:

a. In paragraph (c)(2), Form FD-356H, item 15, by changing the reference "§ 6.1" to read "§ 25.1".

b. In paragraph (f)(6) by changing the reference "§ 6.1" to read "§ 25.1".

§ 314.8 [Amended]

31. Section 314.8(a)(1) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 314.11 [Amended]

32. Section 314.11(b) is amended by changing the reference "Part 4" to read "Part 20".

§ 314.14 [Amended]

33. Section 314.14 is amended as follows:

a. In paragraph (e)(1) by changing the reference "§ 4.81" to read "§ 20.81".

b. In paragraph (e)(3) by changing the reference "§ 4.61" to read "§ 20.61".

c. In paragraph (e)(5) by changing the reference "§ 4.81" to read "§ 20.81".

d. In paragraph (e)(6) by changing the reference "§ 4.61" to read "§ 20.61".

e. In paragraph (e)(7) by changing the reference "Part 4" to read "Part 20".

f. In paragraph (g) by changing the reference "§ 4.81" and "§ 4.61" to read "§ 20.81" and "§ 20.61," respectively.

g. In paragraph (h) by changing the reference "§ 4.117" to read "§ 20.117".

§ 314.110 [Amended]

34. Section 314.110(a)(8) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 314.111 [Amended]

35. Section 314.111(a)(7) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 314.201 [Amended]

36. Section 314.201 is amended by changing the reference "Part 2" to read "Parts 10 through 16".

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENT

§ 320.51 [Amended]

37. Section 320.51(b) is amended by changing the references "§§ 2.5 and 2.7" to read "§§ 10.20 and 10.30".

§ 320.59 [Amended]

38. Section 320.59 is amended as follows:

a. In paragraph (a) by changing the reference "§ 4.61" to read "§ 20.61".

b. In paragraph (c) by changing the reference "§ 4.61" to read "§ 20.61".

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

§ 330.1 [Amended]

39. Section 330.1(e) is amended by changing the reference "Parts 8 and 9" to read "Subchapter A".

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

§ 361.1 [Amended]

40. Section 361.1(c)(3) is amended by changing the reference "21 CFR 4.61" and "§ 4.61" to read "21 CFR 20.61" and "§ 20.61," respectively.

PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

§ 429.50 [Amended]

41. Section 429.50 is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

PART 430—ANTIBIOTIC DRUGS: GENERAL

§ 430.20 [Amended]

42. Section 430.20 is amended as follows:

a. In paragraph (a) by changing the reference "Part 2" to read "Part 10".

b. In paragraph (b)(2) by changing the reference "§§ 2.10(e) and 2.110(c)(2)" to read "§§ 10.40(e) and 12.5(c)(2)".

c. In paragraph (b)(8)(v) by changing the reference "Part 2" to read "Part 12".

d. In paragraph (c) by changing the reference "Part 2" in both places to read "Part 10".

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

§ 431.17 [Amended]

43. Section 431.17(i) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 431.52 [Amended]

44. Section 431.52 is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 431.71 [Amended]

45. Section 431.71 is amended as follows:

a. In paragraph (e)(2) by changing the reference "§ 4.61" to read "§ 20.61".

b. In paragraph (e)(4) by changing the reference "§ 4.81" to read "§ 20.81".

c. In paragraph (e)(5) by changing the reference "§ 4.61" to read "§ 20.61".

d. In paragraph (e)(6) by changing the reference "Part 4" to read "Part 20".

e. In paragraph (f) by changing the reference "§ 4.81" and "§ 4.61" to read "§ 20.81" and "§ 20.61," respectively.

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

§ 433.2 [Amended]

46. Section 433.2(d) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 433.12 [Amended]

47. Section 433.12(b)(5) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 433.13 [Amended]

48. Section 433.13(b)(3) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 433.14 [Amended]

49. Section 433.14(b)(2) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 433.15 [Amended]

50. Section 433.15(b)(3) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 433.16 [Amended]

51. Section 433.16(b)(3) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 501—ANIMAL FOOD LABELING

§ 501.2 [Amended]

52. Section 501.2(f) is amended by changing the reference "Part 2" to read "Part 10".

§ 501.22 [Amended]

53. Section 501.22(a)(4) is amended by changing the reference "§ 8.1(f)" to read "§ 70.3(f)".

§ 501.103 [Amended]

54. Section 501.103 is amended by changing the reference "Part 2" to read "Part 10".

PART 503—COMMON OR USUAL NAMES FOR NONSTANDARDIZED ANIMAL FOODS

§ 503.22 [Amended]

55. Section 503.22 is amended as follows:

a. In paragraph (a) by changing the reference "Part 2" to read "Part 10".

b. In paragraph (b) by changing the reference "Part 2" to read "Part 10".

PART 508—EMERGENCY PERMIT CONTROL

§ 508.19 [Amended]

56. Section 508.19(a) is amended by changing the reference "Part 2" to read "Part 10".

§ 508.35 [Amended]

57. Section 508.35(1) is amended by changing the references "§ 4.81" and "§ 4.61" to read "§ 20.81" and "§ 20.61", respectively.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

§ 511.1 [Amended]

58. Section 511.1 is amended as follows:

a. In paragraph (b)(5) by changing the reference "Subpart F of Part 2" to read "Part 16".

b. In paragraph (b)(10) by changing the reference "§ 6.1" to read "§ 25.1".

c. In paragraph (c)(1) by changing the reference "Subpart F of Part 2" to read "Part 16".

d. In paragraph (c)(4) by changing the reference "Subpart F of Part 2" to read "Part 16".

e. In paragraph (d)(2) by changing the reference "Subpart F of Part 2" to read "Part 16".

PART 514—NEW ANIMAL DRUG APPLICATIONS

§ 514.1 [Amended]

59. Section 514.1(b)(14) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 514.8 [Amended]

60. Section 514.8(a)(1) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 514.9 [Amended]

61. Section 514.9(d) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 514.11 [Amended]

62. Section 514.11 is amended as follows:

a. In paragraph (e)(1) by changing the reference "§ 4.81" to read "§ 20.81".

b. In paragraph (e)(3) by changing the reference "§ 4.61" to read "§ 20.61".

c. In paragraph (e)(5) by changing the reference "§ 4.81" to read "§ 20.81".

d. In paragraph (e)(6) by changing the reference "§ 4.61" to read "§ 20.61".

e. In paragraph (e)(7) by changing the reference "Part 4" to read "Part 20".

f. In paragraph (g) by changing the references "§ 4.81" and "§ 4.61" to read "§ 20.81" and "§ 20.61," respectively.

§ 514.111 [Amended]

63. Section 514.111(a)(9) is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 514.201 [Amended]

64. Section 514.201 is amended by changing the reference "Part 2" to read "Part 12".

§ 514.210 [Amended]

65. Section 514.210 is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

PART 564—DEFINITIONS AND STANDARDS FOR ANIMAL FOOD

§ 564.5 [Amended]

66. Section 564.5 is amended by changing the reference "Part 2" to read "Part 10".

§ 564.17 [Amended]

67. Section 564.17(1) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

PART 570—FOOD ADDITIVES

§ 570.15 [Amended]

68. Section 570.15(b) is amended by changing the reference "Part 2" to read "Part 10".

§ 570.35 [Amended]

69. Section 570.35(c)(1) is amended by changing the reference "Part 2" to read "Part 10".

§ 570.38 [Amended]

70. Section 570.38(b)(1) is amended by changing the reference "Part 2" to read "Part 10".

§ 571.1 [Amended]

71. Section 571.1 is amended as follows:

a. In paragraph (h)(1)(ii) by changing the reference "§ 4.61" to read "§ 20.61".

b. In paragraph (h)(1)(iv) by changing the reference "§ 4.61" to read "§ 20.61".

c. In paragraph (h)(1)(v) by changing the reference "§ 4.61" to read "§ 20.61".

d. In paragraph (h)(2) by changing the references "§ 4.81" and § 4.61" to read "§ 20.81" and § 20.61," respectively.

e. In paragraph (h)(3) by changing the reference "Part 4" to read "Part 20".

§ 571.6 [Amended]

72. Section 571.6 is amended by changing the reference "§ 6.1" to read "§ 25.1".

§ 571.110 [Amended]

73. Section 571.110 is amended by changing the reference "Part 2" to read "Part 12".

§ 571.130 [Amended]

74. Section 571.130(a) is amended by changing the reference "Part 2" to read "Part 10".

SUBCHAPTER F—BIOLOGICS

PART 601—LICENSING

§ 601.4 [Amended]

75. Section 601.4(b) is amended by changing the reference "§ 2.111(b)" to read "§ 12.20(b)".

§ 601.5 [Amended]

76. Section 601.5(b) is amended by changing the reference "§ 2.111(b)" to read "§ 12.20(b)".

§ 601.7 [Amended]

77. Section 601.7 is amended as follows:

a. In paragraph (a) by changing the reference "§ 2.111(b)" to read "§ 12.20(b)".

b. In paragraph (b) by changing the reference "Part 2" to read "Part 12".

§ 601.51 [Amended]

78. Section 601.51 is amended as follows:

a. In paragraph (e)(2) by changing the reference "§ 4.61" to read "§ 20.61".

b. In paragraph (e)(4) by changing the reference "§ 4.81" to read "§ 20.81".

c. In paragraph (e)(5) by changing the reference "§ 4.61" to read "§ 20.61".

d. In paragraph (e)(6) by changing the reference "Part 4" to read "Part 20".

e. In paragraph (e)(7) by changing the reference "§ 4.61" to read "§ 20.61".

f. In paragraph (f) by changing the references "§ 4.81" and "§ 4.61" to read "§ 20.81" and "§ 20.61," respectively.

SUBCHAPTER G—COSMETICS

PART 701—COSMETIC LABELING

§ 701.3 [Amended]

79. Section 701.3 is amended as follows:

a. In paragraph (b) the reference to "Part 2" is changed to read "Part 10".

b. In paragraph (e) the reference to "Part 2" is changed to read "Part 10".

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT AND COSMETIC RAW MATERIAL COMPOSITION STATEMENTS

§ 720.5 [Amended]

80. Section 720.5(c)(4) is amended by changing the reference "Part 8" to read "Subchapter A".

§ 720.8 [Amended]

81. Section 720.8 is amended as follows:

a. In paragraph (a) by changing the references "Part 4", "§ 4.44", "§ 4.111", "Subpart D of Part 4", and "Subpart E of Part 4" to read "Part 20", "§ 20.44", "§ 20.111", "Subpart D of Part 20", and "Subpart E of Part 20", respectively.

b. In paragraph (b) by changing the references "§ 4.44" and "§ 4.61" to read "§ 20.44" and "§ 20.61," respectively.

PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

§ 730.7 [Amended]

82. Section 730.7 is amended by changing the references "Part 4", "§ 4.111", "Subpart D of Part 4" and "Subpart E of Part 4" to read "Part 20", "§ 20.111", "Subpart D of Part 20" and "Subpart E of Part 20," respectively.

PART 740—COSMETIC PRODUCT WARNING STATEMENTS

§ 740.1 [Amended]

83. Section 740.1(b) is amended by changing the reference "Part 2" to read "Part 10".

§ 740.2 [Amended]

84. Section 740.2(b) is amended by changing the reference "Part 2" to read "Part 10".

SUBCHAPTER H—MEDICAL DEVICES

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

§ 809.4 [Amended]

85. Section 809.4(a) is amended by changing the reference "Part 4" to read "Part 20".

§ 809.30 [Amended]

86. Section 809.30(a) is amended by changing the reference "Part 2" to read "Part 10".

SUBCHAPTER J—RADIOLOGICAL HEALTH

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

§ 1003.11 [Amended]

87. Section 1003.11(a) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

§ 1003.31 [Amended]

88. Section 1003.31(d) is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

§ 1004.6 [Amended]

89. Section 1004.6 is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

PART 1210—REGULATIONS UNDER THE FEDERAL IMPORT MILK ACT

§ 1210.30 [Amended]

90. Section 1210.30 is amended by changing the reference "Subpart F of Part 2" to read "Part 16".

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation.

Effective date. These amendments shall be effective March 22, 1977.

Dated: March 14, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-7952 Filed 3-21-77;8:45 am]

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