samples of asbestos-containing materials will be selected from a repostitory of actual construction materials. Nonasbestos-containing materials will be selected from commonly used construction materials, e.g., fiberglass. These materials are inspected for uniformity and integrity by macroscopic and microscopic examination. Reference characterization for each material will be established by internal and external analysis. The reference values will serve as the standards upon which program participants will be evaluated.

The EPA program will accredit laboratories based on their correct classification of the bulk materials as either asbestos-containing or nonasbestors-containing. To be accredited by EPA, laboratories must correctly classify the samples. It is EPA's intent that in order for a laboratory to be considered capable of analyzing bulk samples for asbestos, a laboratory must demonstrate the ability to correctly analyze four samples on the simple basis of classifying the individual samples as asbestos-containing or nonasbestos-containing. Laboratories will be requested to identify the types of asbestos (identification) and to quantify the amount of asbestos in the sample (quantification) for each asbestos-containing sample. The identification and quantification results will be used to further evaluate the performance of the laboratories meeting the minimal classification criterion. The listing of accredited laboratories will be ranked based on performance in the identification and quantification analyses.

Laboratories which do not correctly classify each of the four samples as asbestos-containing or nonasbestos-containing will be notified of their performance. These laboratories will not be included in the laboratory listing. Laboratories which did not meet the performance criteria of the program may re-enroll in March 1988 to participate in the April 1988 round of samples. Prior to formal enrollment in the program, laboratories must return to Research Triangle Institute a signed statement that the laboratory accepts the conditions of the program for accreditation and understands that failure to classify the samples as asbestos-containing or nonasbestos-containing will prohibit them from receiving accreditation in the program until the subsequent round.

IV. Method of Analysis

Laboratories must employ the EPA *Interim Method for the Determination of Asbestos in Bulk Insulation Samples,* (EPA–600/M4–82–020) for analysis of the samples. (See also 47 FR 38535, September 1, 1982.) The interim method requires the use of a polarizing light microscope (PLM). Copies of this method may be obtained by calling 1–800–334–8571.

Dated: August 27, 1987.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 87–20416 Filed 9–2–87; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–798–DR]

Amendment to Notice of Major-Disaster Declaration; Illinois

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Illinois (FEMA–798–DR), dated August 21, 1987, and related determinations.

DATED: August 28, 1987.

FOR FURTHER INFORMATION CONTACT: Neva E. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, D.C. 20472, (202) 646–3614.

NOTICE: The notice of a major disaster for the State of Illinois, dated August 21, 1987, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 21, 1987:

Elk Grove, Leyden, Maine and Schaumburg Townships in Cook County; and Addison, Bloomingdale, and York Townships in DuPage County for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Joe D. Winkle,

Acting Deputy Associate Director State and Local Programs, and Support, Federal Emergency Management Agency.

[FR Doc. 87–20271 Filed 9–2–87; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–798–DR]

Amendment to Notice of Major-Disaster Declaration; Illinois

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Illinois (FEMA–798–DR), dated August 21, 1987, and related determinations.

DATED: August 27, 1987.

FOR FURTHER INFORMATION CONTACT: Sewall H.E. Johnson, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, D.C. 20472, (202) 646–3616.

NOTICE: The notice of a major disaster for the State of Illinois, dated August 21, 1987, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 21, 1987:

Barrington, Berwyn, Cicero, Evanston, Jefferson, Lake View, New Trier, Niles, Northfield, Oak Park, and Rogers Park Townships, and that portion of the City of Chicago north of Roosevelt Road, in Cook County; and all areas of DuPage County for Individual Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Joseph A. Moreland,

Acting Deputy Associate Director, State and Local Programs, and Support, Federal Emergency Management Agency.

[FR Doc. 87–20272 Filed 9–2–87; 8:45 am]

BILLING CODE 6718–02–M

Senior Performance Review Board Members

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Listing names of the members of the Senior Executive Service Performance Review Board.

DATE: August 5, 1987.

FOR FURTHER INFORMATION CONTACT: Mary J. Stafford, Chief, Staffing Division, Office of Personnel, 500 C Street, SW., Washington, DC 20472, 202–646–4010.

The names of the members of the FEMA Senior Executive Service Performance Review Board established pursuant to 5 U.S.C. 4314(c) are:

Members: Frank H. Thomas, William K. Chipman, John D. Hwang, Edward W. Kernan, Joe D. Winkle, George H. Orrell, John R. Curran, Sr.

Spence W. Perry,

General Counsel.

[FR Doc. 87–20273 Filed 9–2–87; 8:45 am]

BILLING CODE 6817–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 87F-0257]

Filing of Food Additive Petition; Ferro Corp.

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ferro Corp. has filed a petition proposing that the food additive regulations be amended to provide for the additional safe use of 2,4-di-*tert*-butylphenyl 3,5-di-*tert*-butyl-4-hydroxybenzoate as a light stabilizer for olefin copolymers in contact with food.

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

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 7B4011) has been filed by Ferro Corp., 7050 Krick Rd., Bedford, OH 44146, proposing that § 728.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the additional safe use of 2,-di-*tert*=butylphenyl 3, 5-di-*tert*-butyl-4-hydroxybenzoate as a light stabilizer for olefin copolymers complying with § 177.152(c)3.1 and 3.2.

The potential environmental impact of this action is being reviewed. If the agency finds that an evironmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting the finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: August 26, 1987.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-20267 Filed 9-2-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87N-0295]

Drug Export; Rimantadine Hydrochloride (Bulk)

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Hoffmann-LaRoche Inc. has filed an application requesting approval for the export of the human drug Rimantadine Hydrochloride (Bulk) to France and to Switzerland solely for the purpose of further export to France.

ADDRESS: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Rudolf Apodaca, Center for Drugs and Biologics (HFN-310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8063.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the act. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Hoffmann-LaRoche Inc., 340 Kingsland Street, Nutley, New Jersey 07110, has filed an application requesting approval for the export of the drug Rimantadine Hydrochloride (Bulk) to France and to Switzerland solely for the purpose of further export to France. Rimantadine Hydrochloride (Bulk) is indicated for use as an antiviral agent that is active mainly against influenza type A virus. The application was received and filed in the Center for Drugs and Biologics on August 20, 1987, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 14, 1987, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802, Pub. L. 99-660 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drugs and Biologics (21 CFR 5.44).

Dated: August 25, 1987.

Sammie R. Young

Office of Compliance, Center for Drugs and Biologics.

[FR Doc. 87-20266 Filed 9-2-87; 8:45 am]

BILLING CODE 4160-01-M

[FDA 225-75-3003]

Memorandum of Understanding Between the Department of Defense and the Food and Drug Administration

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Department of Defense (DOD) and FDA which replaces the previous MOU on this subject signed in 1974. The MOU establishes the procedures to be followed by DOD regarding the investigational use of drugs, including antibiotics and biologics, and medical devices.

DATE: The agreement became effective May 21, 1987.

FOR FURTHER INFORMATION CONTACT: Walter J. Kustka Intergovernmental and Industry Affairs Staff (HFC-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1583..

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing this memorandum of understanding.

Dated: August 27, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

Memorandum of Understanding Between the Food and Drug Administration and the Department of Defense, Concerning Investigational Use of Drugs, Antibiotics, Biologics, and Medical Devices by the Department of Defense

I. Purpose

This agreement between the Department of Defense (DoD) and the Food and Drug Administration (FDA) establishes the procedures to be followed regarding the investigational use of drugs, including antibiotics and biologics, and medical devices by DoD. This Memorandum of Understanding (MOU), when signed by the representatives of the agencies, replaces the previous MOU on this subject signed in 1974.

II. Backgroung

Sections 505(a) and 507 of the Federal Food, Drug, and Cosmetic Act ("the Act") establish procedures for the approval required before a new drug or antibiotic can be introduced into interstate commerce. Sections 505(i) and 507(d) of the Act (21 U.S.C. 355(i), 357(d)) provide authoirty for the Secretary to exempt from the drug approval procedures new drugs and antibiotics which will be used for investigational purposes. Section 520(g) of the Act (21 U.S.C. 360(g)) provides authority for the Secretary to exempt from the device approval procedures devices which will be used for investigational purposes. Section 351 of the Public Health Service Act establishes procedures for the approval required before a biological product can be introduced into interstate commerce.

Regulations governing investigational new drugs, investigational antibiotics, and investigational biologics are published at 21 CFR Part 312; for investigational medical devices at 21 CFR Parts 812 and 813; for protection of human subjects at 21 CFR Part 50; and for institutional review boards at 21 CFR Part 56. These regulations establish the procedure and prescribe the necessary forms to be filed in order to exempt drugs and devices to be used for investigational purposes from, inter alia, the approval procedures of the Federal Food, Drug, and Cosmetic Act and the biologic licensing provisions of the Public Health Service Act.

Pursuant to Title 5, Section 301, of the United States Code, DoD regulations on protection of human subjects in DoD-supported research in 32 CFR Part 219 and DoD Directive 3216.2 generally adopt the system of Institutional Review Boards (IRBs) established under 21 CFR Part 56. However, the functions of research protocol review and approval are separate in the Department of Defense. The function of protocol review remains with the IRB which recommends approval. The function of approval is held by the commander to whom the review committee reports. In addition, the Surgeon General of each Service may require that the final review and approval for use of investigational drugs, biologics, or medical devices, remain within his or her office. The Surgeons General have the authority to delegate this final review and approval authority to a "Headquarters Review Board" (HRB), or the medical department component holding the IND or IDE. In no case can an approving authority or HRB give final approval to a protocol which has been disapproved by a local IRB, nor can an approving authority or HRB reduce safeguards or special conditions imposed by the local IRB.

A Memorandum of Understanding (MOU) on this subject was first executed by the Departments of Defense and Health, Education, and Welfare in 1964. It was revised in 1974 to state the procedures that would be followed to ensure that the requirements of the Federal Food, Drug, and Cosmetic Act and its implementing regulations are fully met without jeopardizing or impeding the requirements of national security. Experience in operating under these MOUs from 1964 to 1987 indicates that the DoD and FDA have a record of cooperation; that human subject concerns have been adequately addressed in DoD-sponsored studies; that the DoD has been able to carry out effectively its responsibilities for national security without compromising the intent of the above-cited statutes and regulations; and that certain exemptions, relieving the DoD from the need to meet the ordinary requirements of the Investigation New Drug (IND) and Investigational Device Exemption (IDE) regulations are no longer necessary. Accordingly, the DoD and the FDA agree to the following new procedures concerning investigational use of drugs and devices by the DoD.

III. Substance of Agreement

The FDA and the DoD agree that:

A. Clinical testing of investigational drugs, biologics, or medical devices under programs sponsored by the DoD and conducted either by the DoD within its own research facilities, or for the DoD by a contractor or grantee will folllow the provisions of 21 CFR Part 312 or 21 CFR Part 812 governing the investigational use of new drugs and medical devices in human beings, and FDA's informed consent and Institutional Review Board regulations (21 CFR Part 50 and 21 CFR Part 56).

B. They will continue to cooperate in meeting the requirements of the Federal Food, Drug, and Cosmetic Act and its implementing regulations without jeopardizing the mission of the DoD. To accomplish this goal, they agree that an expeditious review of special DoD requirements to meet national defense considerations will be carried out by FDA. This review would consist of an FDA review of available data on a drug, biological, or device under IND or IDE to detemine if stockpiling for future use, or use in an expanded military population is appropriate. When necessary, special reporting requirements would also be established by FDA.

C. It is the general policy of the DoD not to classify medical research and development. However, should it become necessary to classify for reasons of national security the clinical testing of a drug, biologic, or medical device that would normally fall under the provisions of 21 CFR Parts 312 or 812, these studies will be handled under the special provisions of this MOU. The DoD will be solely responsible for determining the security classification of such research projects. If classified studies are required DoD will submit a classified IND or IDE application to be reviewed by appropriate FDA personnel who hold the required security clearances. It will be the responsibility of the FDA to maintain an appropriate cadre of personnel who have security clearances. In the event that a request is made under the Freedom of Information Act for records concerning the research DoD has classified, FDA will refer such requests to DoD for processing and response under DoD regulations.

IV. Name and Address of Participating Agencies

A. Department of Defense, Washington, DC 20301

B. Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857

V. Liaison Officers

A. Senior Program Specialist for Medical Research Office of the Assistant Secretary of Defense (Health Affairs), Washington, DC 20301, Telephone: (202) 695–6800

B. Military Assistant for Medical and Life Sciences Office of Under Secretary of Defense (Acquisition),

Washington, DC 20301, Telephone: (202) 697–8535

C. Associate Commissioner for Health Affairs, HFY–1 (Currently Stuart L. Nightingale, M.D.), Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–6143.

VI. Period of Agreement

This agreement becomes effective upon acceptance by both parties, and will remain in effect indefinitely. It may be amended by mutual written consent or terminated by either party upon a 30-day advance written notice.

Approved and Accepted for the Department of Defense:

William Mayer,

Assistant Secretary of Defense (Health Affairs).

Date: May 21, 1987.

Approved and Accepted for the Food and Drug Administration:

Frank E. Young,

Commissioner, Food and Drug Administration.

Date: May 1, 1987.

[FR Doc. 87–20265 Filed 9–2–87; 8:45 am]

BILLING CODE 4160–01–M

National Institutes of Health

National Cancer Institute; Meetings

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Cancer Advisory Board, National Cancer Institute, September 28–30, 1987, Building 31C, Conference Room 6, 6th Floor, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. Meetings of the Subcommittees of the Board will be held at the times and places listed below. Portions of the Board meeting and its Subcommittees will be open to the public to discuss issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

Portions of the meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Pub. L. 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred J. Lumsden, Committee Management Officer, Division of Extramural Activities, National Cancer Institute, 9000 Rockville Pike, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20892 (301/496–5708), will provide a summary of the minutes and rosters of the Board members upon request.

Name of Committee: Subcommittee on Cancer Centers
Executive Secretary: Ms. Judith Whalen, Building 31, Room 11A19 Bethesda, MD 20892 (301/496–5515)
Date of Meeting: September 27
Place of Meeting: Building 31C, Conference Room 7
Open: 6 p.m. to adjournment
Agenda: Discussion of programmatic issues regarding the Cancer Centers.

Name of Committee: Subcommittee on Organ Systems Program
Executive Secretary: Dr. Andrew Chiarodo, Blair Building, Room 722A Bethesda, MD 20892 (301/427–8818)
Date of Meeting: September 27
Place of Meeting: Building 31C, Conference Room 8
Open: 7:30 p.m. to adjournment
Agenda: Discussion of programmatic issues of the Organ Systems Program.

Name of Committee: Subcommittee on Planning and Budget
Executive Secretary: Ms. Judith Whalen, Building 31, Room 11A19 Bethesda, MD 20892 (301/496–5515)
Date of Meeting: September 28
Place of Meeting: Building 31C, Conference Room 7
Open: Following adjournment of NCAB meeting.
Agenda: Discussion of plans for NCAB portion of the 1988 biennial budget report.

Name of Committee: Subcommittee on Cancer Control for the Year 2000
Executive Secretary: Dr. Peter Greenwald, Building 31, Room 10A52 Bethesda, MD 20892 (301/496–6616)
Date of Meeting: September 28
Place of Meeting: Building 31C, Conference Room 4
Open: 7:30 p.m. to adjournment
Agenda: To discuss NCAB participation and other issues of cancer control.

Name of Committee: Subcommittee on Special Actions for Grants
Executive Secretary: Mrs. Barbara S. Bynum, Building 31, Room 10A03 Bethesda, MD 20892 (301/496–5147)
Date of Meeting: September 29
Place of Meeting: Building 31C, Conference Room 6
Open: 8:30 a.m. to adjournment
Agenda: Review and discussion of individual grant applications.

Name of Committee: Review of Contracts and Budget for the Office of the Director, National Cancer Institute
Executive Secretary: Mr. James Prather, Building 31, Room 11A29 Bethesda, MD 20892 (301/496–5801)
Date of Meeting: September 29
Place of Meeting: Building 31C, Conference Room 7
Open: Following adjournment of the Subcommittee on Special Actions for Grants.
Agenda: Review of contracts and budget for the Office of the Director, National Cancer Institute.

Name of Committee: AIDS Subcommittee
Executive Secretary: Dr. Maryann Roper, Building 31, Room 11A19 Bethesda, MD 20892 (301/496–3505)
Date of Meeting: September 29
Place of Meeting: Building 31C, Conference Room 7
Open: 7:30 p.m. to adjournment
Agenda: The Subcommittee will discuss the National Cancer Institute's involvement in AIDS research.

Name of Committee: National Cancer Advisory Board
Executive Secretary: Mrs. Barbara S. Bynum, Building 31, Room 10A03 Bethesda, MD 20892 (301/496–5147)
Date of Meeting: September 28 and 30, 1987
Place of Meeting: Building 31C, Conference Room 6
Open: September 28, 8:30 a.m. to recess September 30, 8 a.m. to adjournment
Agenda: Reports on activities of the President's Cancer Panel and the Director's Report on the National Cancer Institute; Subcommittee Reports and New Business.

(Catalog of Federal Domestic Assistant Program Nos. 13.392, Project grants in cancer construction; 13.393, Project grants in cancer cause and prevention; 13.394, Project grants in cancer detection and diagnosis; 13.395, Project grants in cancer treatment; 13.396, Project grants in cancer biology; 13.397, Project grants in cancer centers support; 13.398, Project grants in cancer research manpower and 13.399; Project grants and contracts in cancer control.)

Dated: August 19, 1987.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 87–20345 Filed 9–2–87; 8:45 am]

BILLING CODE 4140–01–M