funds. No new grants are expected to be made in 1988 since current grantees are coordinating activities in all political jurisdictions in the United States. Funding estimates outlined above may vary and are subject to change.

Amendments

Public Law 100–177 mandates the following changes in the previously published program announcement (Project Grants for Preventive Health Services-Immunization; Program Announcement; Program Guidelines, 52 FR 16451, May 5, 1987). On page 16455, column two, "Use of Grant Funds", letters B. and C. should be deleted and replaced with the following:

"B. No charge may be made to patients for the cost of vaccines provided through project grant funds, whether administered in public clinics or by private physicians. If an administration fee is charged, information must be prominently displayed which indicates that no one receiving an immunization in public clinics may be denied vaccine provided through project grant funds for failure to pay the administration fee or failure to make a donation to the provider."

C. Grant funds may be used for maintaining patient record systems, purchasing equipment (including data processing equipment), or providing vaccination facilities and services, only after complete justification has been included in the application and fund provided accordingly.

D. Grant funds may be used to supplement (not substitute for) existing immunization operations and services."

Information

Applications are subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs. Application forms, information on review procedures, deadlines, the consequences of late submission, and copies of the program announcement and regulations may be obtained from the appropriate Department of Health and Human Services Regional Office as set forth below.

Dated: May 19, 1988.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

Department of Health and Human Services (HHS)—Regional Offices

Regional Health Administrator, PHS, HHS Region I, John Fitzgerald Kennedy Building, Boston, Massachusetts 02203, (617) 223–6827

Regional Health Administrator, PHS, HHS Region II, Federal Building, 26 Federal Plaza, Room 3337, New York, New York 10278, (212) 264–2561

Regional Health Administrator, PHS, HHS Region III, Gateway Building #1, 3521–35 Market Street, Mailing Address: P.O. Box 13716, Philadelphia, Pennsylvania 19101, (215) 596–6637

Regional Health Administrator, PHS, HHS Region IV, 101 Marietta Tower, Suite 1007, Atlanta, Georgia 30323, (404) 331–2316

Regional Health Administrator, PHS, HHS Region V, 300 South Wacker Drive, 33rd Floor, Chicago, Illinois 60606, (312) 353–1385

Regional Health Administrator, PHS, HHS Region VI, 1200 Main Tower Building, Room 1835, Dallas, Texas 75202, (214) 767–3879

Regional Health Administrator, PHS, HHS Region VII, 601 East 12th Street, Room 501, Kansas City, Missouri 64106, (816) 426–3291

Regional Health Administrator, PHS, HHS Region VIII, 1185 Federal Building, 1961 Stout Street, Denver, Colorado 80294, (303) 844–6163

Regional Health Administrator, PHS, HHS Region IX, 50 United Nations Plaza, San Francisco, California 94102, (415) 556–5810

Regional Health Administrator, PHS, HHS Region X, 2901 Third Avenue, M.S. 402, Seattle, Washington 98121, (206) 442–0430

[FR Doc. 88–11789 Filed 5–25–88; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 88F–0167]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of *N,N'*-1,4-phenylenebis[4-[(2,5-dichlorophenyl)azo]-3-hydroxy-2-naphthalenecarboxamide] as a colorant for food-contact polymers.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, 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 8B4080) has been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.3297 *Colorants for polymers* (21 CFR 178.3297) be amended to provide for the safe use of *N,N'*-1,4-phenylenebis[4-[(2,5-dichlorophenyl)azo]-3-hydroxy-2-naphthalenecarboxamide] as colorant for food-contact polymers.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Dated: May 18, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–11791 Filed 5–25–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88F–0118]

Diversey Wyandotte Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Diversey Wyandotte Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of hydrogen peroxide, peroxyacetic acid, acetic acid, sulfuric acid, and 2,6-pyridinedicarboxylic acid as components of a sanitizing solution for use on food-processing equipment and utensils.

FOR FURTHER INFORMATION CONTACT: Gillian Robert-Baldo, 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 8H4076) has been filed by Diversey Wyandotte Corp., 1532 Biddle Ave., Wyandotte, MI 48192, proposing that § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) be amended to provide for the safe use of hydrogen peroxide, peroxyacetic acid, acetic acid, sulfuric acid, and 2,6-pyridinedicarboxylic acid as components of a sanitizing solution for use on food-processing equipment and utensils.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental 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 that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: May 18, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-11792 Filed 5-25-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0151]

Pfizer Central Research, Pfizer, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Pfizer Central Research, Pfizer, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polydextrose in fruit spreads.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-5487.

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 Pfizer Central Research, Pfizer, Inc., 235 East 42d Street, New York, NY 10017, has filed a petition (FAP 8A4068), proposing that the food additive regulations be amended to provide for the safe use of polydextrose in fruit spreads.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental 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 that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: May 18, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-11793 Filed 5-25-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0111]

Union Camp Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a food additive petition has been filed by the Union Camp Corp. proposing that the food additive regulations be amended to provide for the safe use of poly(oxypropylene)diamine as a component of adhesives in food-packaging applications.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, 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 8B4056) has been filed by the Union Camp Corp., P.O. Box 2668, Savannah, GA 31402, proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of poly(oxypropylene)diamine as a component of adhesives in food-packaging applications.

The potential environmental impact of this section is being reviewed. If the agency finds that an environmental 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 that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: May 18, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-11794 Filed 5-25-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0113]

West Agro, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that West Agro, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium-*N*-cyclohexyl-*N*-palmitoyl taurate; acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1*H*-imidazole-1-ethanol and sodium hydroxide; dodecylbenzene sulfonic acid; phosphoric acid; isopropyl alcohol; iodine/hydroiodic acid; and calcium chloride as components of a santizing solution to be used on food-contact surfaces.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, 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 7B4010) has been filed by West Agro, Inc., 11100 North Congress Ave., Kansas City, MO 64153, proposing

that § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) be amended to provide for the safe use of sodium-*N*-cyclohexyl-*N*-palmitoyl taurate; acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1*H*-imidazole-1-ethanol and sodium hydroxide; dodecylbenzene sulfonic acid; phosphoric acid; isopropyl alcohol; iodine/hydroiodic acid; and calcium chloride as components of a sanitizing solution to be used on food-contact surfaces.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental 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 that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: May 18, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-11795 Filed 5-25-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88M-0095]

Resonex, Inc.; Premarket Approval of Resonex Rx-4000™ Magnetic Resonance Imaging System

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Resonex, Inc., Sunnyvale, CA, for premarket approval, under the Medical Device Amendments of 1976, of the Resonex Rx-4000™ Magnetic Resonance Imaging System. After reviewing the application and determining that the data in the application met the safety and effectiveness approval criteria for magnetic resonance imaging devices established by the Radiological Devices Panel (an FDA advisory committee), FDA's Center for Devices and Radiological Health (CDRH) notified the applicant by letter of February 29, 1988, of the approval of the application.

DATE: Petitions for administrative review by June 27, 1988.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Adrianne Galdi, Center for Devices and Radiological Health (HFZ-430), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7514.

SUPPLEMENTARY INFORMATION: On August 26, 1987, Resonex, Inc., Sunnyvale, CA 94008-3626, submitted to CDRH an application for premarket approval (PMA) of the Resonex Rx-4000™ Magnetic Resonance Imaging System, a magnetic resonance imaging device with multislice operation and a resistive magnet operating at 0.38 tesla. Magnetic resonance imaging, as performed by the Resonex Rx-4000™ Magnetic Resonance Imaging System, is a diagnostic imaging procedure used to generate a picture of the internal structure of the body, including the head. Images reflecting the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance can be produced in four planes: transverse (axial), sagittal, coronal, and oblique. Image appearance is a function of proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and fluid flow. Magnetic resonance imaging provides useful diagnostic information when interpreted by a properly trained physician. All other uses of the Resonex Rx-4000™ Magnetic Resonance Imaging System remain investigational.

The Radiological Device Panel is deemed to have recommended approval of the device. Panel guidelines for magnetic resonance imaging devices were established at the July 27, 1987, public meeting. The guidelines set forth approval criteria for safety and effectiveness, predicated on uniform device design and labeling (the transcript of the July 27, 1987, meeting is available at the Docket Management Branch). Since CDRH determined that the Panel guidelines were satisfied by the PMA, the Resonex Rx-4000™ Magnetic Resonance Imaging System was approved by a February 29, 1988, letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Adrianne Galdi (HFZ-430), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 27, 1988, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: May 18, 1988.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 88-11800 Filed 5-25-88; 8:45 am]

BILLING CODE 4160-01-M