Competing Applications—Approximately $200,000 to $300,000 is expected to be awarded to fund one new STD P/T center and funding is expected to be awarded on or about September 1, 1988. It is expected that the grant will be for a 12-month budget period, in a 1–5 year project period.

Review and Evaluation Criteria

Competing Supplemental applications from current STD P/T centers for funds to provide AIDS-related training will be reviewed and evaluated based on the following:

1. The extent to which AIDS-related training are proposed and where they are not proposed, the reasoning behind the decision to demur;
2. The extent to which AIDS-related training proposed is developed with consideration given to the Curriculum Guidelines or includes acceptable reasoning for any departures from the Guidelines;
3. The extent to which AIDS-related training proposed appears to meet documented needs and to be instructionally sound;
4. Evidence suggesting that any AIDS-related training proposed has been coordinated with local/regional recipients of HRSA AIDS ETCs and that disruptive conflict or competition for a limited number of trainees will be avoided;
5. The extent to which the P/T center can assure that it will be able to acquire the additional training facilities needed to provide the AIDS-related training proposed without disrupting or curtailing the current schedule or required compliment of STD clinical training or STD intervention outreach training, where that instruction is also now provided.
6. The extent to which the applicant is willing to arrange for the instructors selected to teach any AIDS-related courses to meet with the project officer and CDC staff to discuss the instructional offerings planned before curricula are finalized.

Competing applications for a new STD P/T center will be reviewed and evaluated based on the following:

1. The ability to meet the objectives of the program;
2. Evidence that the P/T center will be located in a health department clinic that:

a. Is dedicated to the diagnosis and treatment of STD patients;

b. Serves an average of at least 300 patients per 40 weekly service hours;

c. Serves patients of sufficient demographic variety and morbidity; and

d. Is accessible to trainees and patients;

3. Evidence of a satisfactory commitment from the State/local health department administration toward meeting STD 1990 Objectives for the Nation.
4. Evidence that the P/T center corresponds to the needs, plans, and objectives of the State/local STD Program; and that the P/T center activities will be effectively coordinated with both the basic control components of the local STD program and CDC to assure a quality national model;
5. The extent to which long- and short-term objectives address the applicant's expected role in meeting the STD 1990 Objectives for the Nation;
6. The extent to which methods will be evaluated for effectiveness and the long- and short-term objectives will be tracked to measure achievement;
7. Evidence of the capability of complying with the CDC documents entitled "Quality Assurance Guidelines for STD Clinics, 1986" (QAG) and revised STD guidelines published in CDC's *Morbidity and Mortality Weekly Report (MMWR)*.
8. Evidence of the capability of complying with the "Sexually Transmitted Disease Prevention/Training Center Curriculum Guidelines and Performance Standards for STD Clinical Training".
9. Evidence of a commitment from a local university medical school to participate with the applicant in the establishment of a P/T center.
10. Duties and qualifications of individuals performing activities for the training centers and organizational relationship of proposed centers to existing program structure;
11. An itemized budget with accompanying justification, which is clearly and thoroughly explained, reasonable, and consistent with the intended use of grant funds.

Grantee Financial Participation

There are no grantee cost participation requirements for this program.

Application Submission and Deadline

The original and two unbound copies of the application (PHS 5161–1, revised 3/86) must be submitted to Nancy C. Bridger, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305. Supplemental and competing grant applications are due on or before July 1, 1988.

Deadline: Applications shall be considered as meeting the deadline if they are either:

1. Received at the above address on or before the deadline date; or
2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria addressed in 1. or 2. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Other Requirements: Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Recipients must comply with the document titled: Content of Aids-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions in Centers for Disease Control Assistance Programs (January 1988) (53 FR 6034, February 29, 1988).

Where To Obtain Additional Information

A full description of the program, including areas of interest, program requirements, criteria for review of applications, application forms (PHS 5161–1), and other materials may be obtained from Marsha Driggans, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305, (404) 842–6575 or FTS 236–6575.

Technical assistance may be obtained from Yvonne Green, Division of Sexually Transmitted Diseases, Center for Prevention Services, Centers for Disease Control, (E02) Atlanta, GA 30333, (404) 639–2775 or FTS 236–2775.

Dated: June 3, 1988.

Robert L. Foster,

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

[FR Doc. 88–12953 Filed 6–8–88; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 88D-0017]

Conditions Under Which Homeopathic Drugs May Be Marketed; Availability of Compliance Policy Guide

AGENCY: Food and Drug Administration; MMS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Compliance Policy Guide 7132.15 entitled "Conditions Under Which Homeopathic Drugs May Be Marketed"—May 31, 1988, that prescribes conditions under which homeopathic drugs may be marketed. FDA developed the compliance policy guide in response to the significant increase in the importation and domestic marketing of homeopathic drug products that are being offered for use (or promoted) significantly beyond recognized or customary practice.

ADDRESS: Written requests for single copies of FDA Compliance Policy Guide 7132.15 may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. (Send two self-addressed adhesive labels to assist the Branch in processing your requests.).

FOR FURTHER INFORMATION CONTACT: Joel Davis, Center for Drug Evaluation and Research (HFD-335), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8104.

SUPPLEMENTARY INFORMATION: Until recently, homeopathic drugs have been marketed on a limited scale by a few manufacturers who have been in business for many years an have predominantly served the needs of a limited number of licensed practitioners. Today, the homeopathic drug market has grown into a multimillion dollar industry in the United States based in part on a significant increase in the importation and domestic marketing of over-the-counter (OTC) homeopathic drug products. FDA has prepared Compliance Policy Guide 7132.15 entitled "Conditions Under Which Homeopathic Drugs May Be Marketed"—May 31, 1988, to provide guidance on the regulation of OTC and prescription homeopathic drugs and to delineate conditions under which homeopathic drugs may be marketed.

Compliance Policy Guide 7132.5 is available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Requests for single copies of Compliance Policy Guide 7132.5 should refer to the docket number found in brackets in the heading of this document and should be submitted to the Dockets Management Branch.

This notice is issued under 21 CFR 10.85.

Dated: May 31, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-12949 Filed 6-8-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0176]

AKZO Chemie America; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that AKZO Chemie America has filed a petition proposing that the food additive regulations be amended to provide for the safe use of dimethyl(2-ethylhexyl) hydrogenated tallow ammonium chloride as a decolorizing agent in the clarification of refinery sugar liquors.

FOR FURTHER INFORMATION CONTACT: Geraldine E. Harris, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

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 7A3992) has been filed on behalf of AKZO Chemie Amreica, McCook, IL 60525, proposing that Part 172 (21 CFR Part 172) be amended to provide for the safe use of a dimethyl(2-ethylhexyl) hydrogenated tallow ammonium chloride as a decolorizing agent in the clarification of refinery sugar liquors.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement s 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 27, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-12938 Filed 6-8-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0139]

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 tris(2,4-di-*tert*-butylphenyl)phosphite as an antioxidant and thermal stabilizer in poly-1-butene resins and butene/ethylene copolymers intended for use in contact with food.

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

SUPPLEMENTARY INFORMATION: 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 8B4077) has been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of tris(2,4-di-*tert*-butylphenyl)phosphite as an antioxidant and thermal stabilizer in poly-1-butene resins and butene/ethylene copolymers intended for use in contact with food.

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 27, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-12939 Filed 6-8-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0175]

Mitsui Petrochemical Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Mitsui Petrochemical Industries,

Ltd., has filed a petition proposing that the food additive regulations be amended to provide for an increase in the weight-percent of butene-1 in propylene/butene-1 copolymers for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: 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 8B4081) has been filed by Mitsui Petrochemical Industries, Ltd., Kasumigaseki Bldg., P.O. Box 90, 2–5 Kasumigaseki 3-Chome, Chiyoda-KU, Tokyo 100, Japan. proposing that § 177.1520 *Olefin polymers* (21 CFR 177.1520) be amended to provide for an increase in the weight-percent of butene-1 in propylene/butene-1 copolymers for use in contact with food.

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 27, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–12940 Filed 6–8–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 87F–0389]

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

AGENCY: Food and Drug Administration.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the document that announced that Pfizer Central Research, Pfizer, Inc., had filed a food additive petition proposing that the food additive regulations be amended to provide for the use of polydextrose in peanut butter spread (53 FR 2093; January 26, 1988). The food product to which polydextrose would be added was inadvertently described as peanut butter spread, rather than peanut spread, in accordance with 21 CFR 102.23. This notice removes the word "butter" from the last line under the heading "**SUMMARY**" and the last line of the first paragraph under the heading "**SUPPLEMENTARY INFORMATION**" of the January 26, 1988, notice.

DATE: June 9, 1988.

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

SUPPLEMENTARY INFORMATION: In FR Doc. 88–1457, appearing on page 2093, third column, in the issue of Tuesday, January 26, 1988, under the heading "**SUMMARY**" in the last line, and under the heading "**SUPPLEMENTARY INFORMATION**" in the last line of the first paragraph, the word "butter" is removed to make it clear that the proposed use of polydextrose is in peanut spread in accordance with 21 CFR 102.23.

Dated: May 27, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–12937 Filed 6–8–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88M–0187]

Cook Pacemaker Corp.; Premarket Approval of Sensor® Model Kelvin® 500 Pulse Generator, Model K Unipolar Temperature Sensing Lead, Model 5000 Transceiver, and Model 50 Lead Tester

AGENCY: Food and Drug Administration; HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Cook Pacemaker Corp., Leechburg, PA, for premarket appoval, under the Medical Device Amendments of 1976, of the Sensor® Model Kelvin® 500 Unipolar Cardiac Pulse Generator, Model K Unipolar Temperature Sensing Lead, Model 5000 Transceiver, and Model 50 Lead Tester. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant by letter of April 29, 1988, of the approval of the application.

DATE: Petitions for administrative review by July 11, 1988.

ADDRESS: Written request 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: Donald F. Dahms, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–3171.

SUPPLEMENTARY INFORMATION: On December 18, 1987, Cook Pacemaker Corp., Leechburg, PA 15656, submitted to FDA an application for premarket approval of Sensor® Model Kelvin® 500 Unipolar Pulse Generator, Model K Unipolar Temperature Sensing Lead, Model 5000 Transceiver, and Model 50 Lead Tester. The device is indicated for use as a cardiac pacing system. FDA filed the application on December 28, 1987.

On March 11, 1988, the Circulatory System Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On April 29, 1988, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, DCRH.

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 DCRH—Contact Donald F. Dahms (HFZ–450), 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 DCRH'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