between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site.

Matters To Be Discussed: Agenda items include updates from the National Institute for Occupational Safety and Health on the progress of current studies; an update on the status of chemical screening and radionuclide screening and a presentation on document search from the Radiological Assessments Corporation; and subcommittee deliberations.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Arthur J. Robinson, Jr., or Sharona Woodley, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: May 4, 1998.

Julia M. Fuller,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 98–12354 Filed 5–8–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 98F–0292]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp., has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of 2-methyl-4,6-bis-[(octylthio)methyl]phenol as a stabilizer for rubber-modified polystyrene intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4594) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591–9005. The petition proposes to amend the food additive regulations to provide for the expanded safe use of 2-methyl-4,6-bis-[(octylthio)methyl]phenol as a stabilizer for rubber-modified polystyrene complying with § 177.1640 *Polystyrene and rubber-modified polystyrene* (21 CFR 177.1640) intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 24, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–12314 Filed 5–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0289]

UBE Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that UBE Industries, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of Nylon 6/12 copolymer resins manufactured using at least 80 weight percent epsilon-caprolactam and no more than 20 weight percent omega-aminododecanoic acid as a component of articles intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by June 10, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3084.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4569) has been filed by UBE Industries, Ltd., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191. The petition proposes to amend the food additive regulations in § 177.1500 *Nylon resins* (21 CFR 177.1500) to provide for the safe use of Nylon 6/12 copolymer resins manufactured using at least 80 weight percent epsilon-caprolactam and no more than 20 weight percent omega-aminododecanoic acid as a component of articles intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before June 10, 1998, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, 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: April 24, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–12313 Filed 5–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0362]

The New 510(k) Paradigm; Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''The New 510(k) Paradigm-Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.'' The New 510(k) Paradigm presents two alternative methods, in addition to the traditional method, of demonstrating substantial equivalence in premarket notifications and is intended to conserve FDA's review resources while facilitating the introduction of safe and effective devices into interstate commerce. The New 510(k) Paradigm addresses the type of information needed in premarket notification submissions, by the Center for Devices and Radiological Health (CDRH), to render substantial equivalence determinations.

DATES: May 11, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of ''The New 510(k) Paradigm-Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Philip J. Phillips, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)), a person who intends to introduce a device into commercial distribution is required to submit a premarket notification, or 510(k), to FDA at least 90 days before commercial distribution is to begin. Section 513(i) of the act (21 U.S.C. 360c(i)) states that FDA may issue an order of substantial equivalence, only upon making a determination that the device to be introduced into commercial distribution is as safe and effective as a legally marketed device. Under 21 CFR 807.87, FDA has codified the content requirements for premarket notifications to be submitted by device manufacturers in support of a substantial equivalence decision. FDA has, however, discretion in the type of information it deems necessary to meet those content requirements.

While the Paradigm maintains the traditional method of demonstrating substantial equivalence under section 510(k) of the act, it also presents two alternatives. The first alternative, the ''Special 510(k): Device Modification,'' utilizes certain aspects of the Quality System regulation, while the second alternative, the ''Abbreviated 510(k),'' relies on the use of FDA guidance documents, special controls and FDA recognized consensus standards to facilitate 510(k) review.

In the **Federal Register** of September 19, 1997 (62 FR 49247), FDA published a notice of availability of a draft of this guidance document on the Paradigm. FDA received 13 comments on the draft. FDA reviewed these comments and has made revisions to the guidance as appropriate.

This guidance document represents the agency's current thinking on the 510(k) Paradigm. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

II. Electronic Access

In order to receive ''A New 510(k) Paradigm-Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 905 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes: Device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1:FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS Topics Page, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may, at any time, submit to the contact person named above written comments regarding this guidance document. Comments will be considered in determining whether to revise or revoke the guidance.

Dated: May 1, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–12311 Filed 5–8–98; 8:45 am]

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