

requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**FDA Safety Alert/Public Health Advisory Readership Survey (OMB No. 0910-0341B—Extension)**

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The FDA Safety Alert and (2) the Public Health Advisory. Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of previous alerts included spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

FDA estimates the burden of this collection of information as follows:

**TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>**

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	1.7	157

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: November 19, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 99-30728 Filed 11-24-99; 8:45 am]

**BILLING CODE 4160-01-F**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 99F-5012]**

**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 expand the safe use of oxidized bis(hydrogenated tallow alkyl) amines as a process stabilizer for certain olefin polymers intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:**

Andrew J. Zajac, Center for Food Safety and Applied Nutrition, (HFS-215), Food

and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3095.

**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 0B4700) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., P.O. Box 2005, Tarrytown, NY 10591-9005. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to expand the safe use of oxidized bis(hydrogenated tallow alkyl) amines as a process stabilizer for certain olefin polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a 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: November 3, 1999.

**Alan M. Rulis,**

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

[FR Doc. 99-30729 Filed 11-24-99; 8:45 am]

**BILLING CODE 4160-01-F**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

**Name of Committee:** Immunology Devices Panel of the Medical Devices Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on December 13, 1999, 9:30 a.m. to 5:30 p.m.

**Location:** Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

**Contact Person:** Louise E. Magruder, Center for Devices and Radiological Health (HFZ-440), Food and Drug

Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The committee will discuss, make recommendations, and vote on a premarket approval application for an enzyme immunoassay to be used as an aid in the diagnosis of patients with transitional cell carcinoma of the urinary tract.

**Procedure:** On December 13, 1999, from 10 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 1999. On December 13, 1999, oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:15 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

**Closed Committee Deliberations:** On December 13, 1999, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 1999.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 99-30704 Filed 11-24-99; 8:45 am]

**BILLING CODE 4160-01-F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Radiological Devices Panel of the Medical Devices Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on December 16, 1999, 8:30 a.m. to 5 p.m.

**Location:** DoubleTree Hotel, Plaza Ballroom, 1750 Rockville Pike, Rockville, MD.

**Contact Person:** Robert J. Doyle, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd. Rockville, MD 20850, 301-594-1212, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The committee will discuss, make recommendations, and vote on a premarket approval application for a digital mammography device.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 8, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of the committee deliberations, a 30 minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 1999.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 99-30705 Filed 11-24-99; 8:45 am]

**BILLING CODE 4160-01-F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-4577]

#### Draft "Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma;" Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a draft guidance document entitled "Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma." The purpose of the draft guidance document is to seek public comment on FDA's approach to regulating nucleic acid testing for infectious agents when intended for use in blood donor screening and/or manufacturing of blood products. FDA is issuing the draft guidance document in response to requests from manufacturers for guidance in the development of nucleic acid testing of plasma pools for infectious agents.

**DATES:** Written comments may be submitted at any time, however, comments should be submitted by January 25, 2000, to ensure their adequate consideration in preparation of the final document.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma" to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at