number. Any written comments on the minutes should be directed to Ms. Samara Weinstein, Executive Director of the Working Group, as shown above.

Signed at Washington, DC, this 20th day of April, 1999.

David Gray Ross,

Commissioner, Office of Child Support Enforcement.

[FR Doc. 99–10487 Filed 4–26–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 99F–0994]

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 safe use of phosphorothioic acid, *O,O,O*-triphenyl ester, tert-butyl derivatives, as extreme pressure-antiwear adjuvants for lubricants intended for incidental 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 9B4657) 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 § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) to provide for the safe use of phosphorothioic acid, *O,O,O*-triphenyl ester, *tert*-butyl derivatives, as extreme pressure-antiwear adjuvants for lubricants intended for incidental 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 2, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–10447 Filed 4–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0635]

General Electric Co.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 0B4615) proposing that the food additive regulations be amended to provide for the expanded safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, which may contain up to 1 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer for polypropylene 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: In a notice published in the **Federal Register** of August 5, 1998 (63 FR 41855), FDA announced that a food additive petition (FAP 8B4615) had been filed by General Electric Co., One Lexan Lane, Mt. Vernon IN 47620–9364. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, which may contain up to 1 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer for polypropylene complying with § 177.1520(c), items 1.1, 1.2, or 1.3, intended for use in contact with food. General Electric Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 15, 1999.

Alan M. Rulis,

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

[FR Doc. 99–10445 Filed 4–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dental Products 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: Dental Products 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 May 10, 1999, 10:30 a.m. to 6:30 p.m., and May 11, 1999, 8 a.m. to 3 p.m.

Location: Holiday Inn, Walker-Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Pamela D. Scott, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12518. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 10, 1999, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a total temporomandibular joint (TMJ) prosthesis, which consists of the glenoid fossa prosthesis and the mandibular condyle prosthesis, for reconstruction of the TMJ. On May 11, 1999, the committee will discuss, make recommendations, and vote on a PMA that includes both a total TMJ prosthesis and a glenoid fossa prosthesis that can be used alone without the mandibular condyle prosthesis to reconstruct the TMJ. These PMA's were received in response to the final rule issued in the **Federal Register** of December 30, 1998 (63 FR 71743), requiring the filing of a PMA or a notice of completion of a

product development protocol for the total TMJ prosthesis (21 CFR 872.3940), the glenoid fossa prosthesis (21 CFR 872.3950), the mandibular condyle prosthesis (for permanent reconstruction; 21 CFR 872.3960), and the interarticular disc prosthesis (21 CFR 872.3970) under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)).

Procedure: On May 10, 1999, from 10:30 a.m. to 5:30 p.m., and May 11, 1999, from 8 a.m. to 3 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 May 5, 1999. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 11:45 a.m. on May 10, 1999, and between approximately 8:15 a.m. and 8:45 a.m. on May 11, 1999. Near the end of the committee deliberations on each day, 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 May 5, 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 May 10, 1999, from 5:30 p.m. to 6:30 p.m., the meeting will be closed to permit discussion of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding dental device issues.

FDA regrets that it was unable to publish this notice 15 days prior to the May 10 and 11, 1999, Dental Products Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Dental Products Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: April 20, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–10509 Filed 4–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0972]

Policy on the Disposition of Publications That Constitute Labeling; Draft Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised Compliance Policy Guide (CPG 7153.13) entitled ''Regulatory Policy on the Disposition of Publications that Constitute Labeling.'' We are revising the current CPG to provide clarification and further guidance to our field employees about when publications may constitute labeling for regulated products and to stress our policy with regard to the disposition of these materials when they cause a product to be in violation of the Federal Food, Drug, and Cosmetic Act.

DATES: You may submit written comments on the draft revised CPG by July 26, 1999.

ADDRESSES: You may submit written requests for single copies of the draft revised CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420. Please send two self-addressed adhesive labels to assist us in processing your requests, or you may fax your request to 301–827–0482. Please see the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft revised CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane rm., 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JoAnne C. Marrone, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1242.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has had a longstanding policy related to the seizure of books that constitute labeling for a product. We articulated this policy in a Compliance Policy Guide (CPG 7153.13) in December 1982, which we revised on August 31, 1989. In recent years, questions have arisen concerning when published materials may constitute labeling for regulated products, as well as our position and policy on the disposition of these materials. We intend this draft revised CPG to clarify these issues and to improve guidance to our field employees.

This draft Level 1 guidance document is being issued consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the disposition of publications that constitute labeling for a product that renders a product violative. 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 requirements of the applicable statute, regulations, or both.

II. Request for Comments

You may submit to the Dockets Management Branch (address above) written comments on the draft revised CPG entitled ''Regulatory Policy on the Disposition of Publications that Constitute Labeling.'' You must submit two copies of any comments, except that you may submit one copy if you are an individual. You must identify your comments with the docket number found in brackets in the heading of this document. The agency will review all comments, but in issuing a final CPG, need not specifically address every comment. We will make changes to the CPG in response to comments, as appropriate. You may see a copy of the draft revised CPG and comments received in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

You also may download copies of the draft revised CPG to a personal computer with access to the World Wide Web (WWW). The Office of Regulatory Affairs' (ORA) home page entitled ''compliance references'' includes this draft revised CPG, and you may access it at ''http//www.fda.gov/ora/compliance_ref/default.htm''.