Washington, DC 20406, telephone 703–305–5745.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95F–0149]

General Electric Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that General Electric Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester as an antioxidant and/or stabilizer in olefin polymers used in articles intended for food-contact applications.

DATES: Written comments on the petitioner's environmental assessment by July 21, 1995.

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

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), 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 5B4463) has been filed by General Electric Co., 501 Avery St., Parkersburg, WV 26102–1868. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester as an antioxidant and/or stabilizer in olefin polymers used in articles intended for food-contact applications.

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 July 21, 1995, 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: June 12, 1995.

Alan M. Rulis,

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

[FR Doc. 95–15085 Filed 6–20–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95G–0102]

Gist-brocades International B.V.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Gist-brocades International B.V., has filed a petition (GRASP 5G0413), proposing that lipase enzyme preparation derived from *Rhizopus oryzae* be affirmed as generally recognized as safe (GRAS) as a direct human food ingredient.

DATES: Written comments by September 5, 1995.

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

FOR FURTHER INFORMATION CONTACT: Vincent E. Zenger, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Gist-brocades International B.V., P.O. Box 241068, Charlotte, NC 28224–1068, has filed a petition (GRASP 5G0413) proposing that a lipase enzyme preparation from *Rhizopus oryzae* be affirmed as GRAS for use in food as a direct human food ingredient.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

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).

Interested persons may, on or before September 5, 1995, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4 (b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 7, 1995.

Alan M. Rulis,

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

[FR Doc. 95–15082 Filed 6–20–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Biological Response Modifiers Advisory Committee

Date, time, and place. July 13 and 14, 1995, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, July 13, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; open public hearing, 6 p.m. to 6:30 p.m., unless public participation does not last that long; open public hearing, July 14, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 10:10 a.m.; closed committee deliberations, 10:10 a.m. to 10:30 a.m.; open committee discussion, 10:30 a.m. to 4:30 p.m.; William Freas or Pearline Muckelvene, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Biological Response Modifiers Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 5, 1995, 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 required to make their comments.

Open committee discussion. On July 13, 1995, the committee will discuss public health concerns in xenotransplantation. On the morning of July 14, 1995, the committee will discuss data in support of the safety of a proposed baboon bone marrow transplant in the treatment of advanced human immunodeficiency virus, type 1, (HIV–1) disease, and a discussion of the safety of clinical transplantation of nonhuman primate tissue into human recipients. In the afternoon, the committee will discuss extracorporeal liver assist devices for treatment of liver failure, followed by a discussion of the utility of polymerase chain reaction in the clinical trials of biologic therapies for hepatitis C.

Closed committee deliberations. On July 14, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications (IND's). This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. July 13 and 14, 1995, 8 a.m., Holiday—Inn Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, July 13, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5 p.m.; closed presentation of data, July 14, 1995, 8 a.m. to 10 a.m.; open public hearing, 10 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 4 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, FAX 301–443–0699, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, 12536.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 7, 1995, 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 required to make their comments.

Open committee discussion. On July 13, 1995, the committee will hear presentations and discuss data submitted regarding the safety and efficacy of alendronate, new drug application (NDA) 20–560 (Fosamax®, Merck), for an osteoporosis indication. On July 14, 1995, the committee will discuss guidance criteria for the development of safe and effective medications for the treatment of obesity.

Closed presentation of data. On July 14, 1995, the committee will hear trade secret and/or confidential commercial information relevant to pending IND's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Joint Meeting of Nonprescription Drugs Advisory Committee With Gastrointestinal Drugs Advisory Committee and With Arthritis Advisory Committee

Date, time, and place. July 13 and 14, 1995, 8:30 a.m., conference rooms D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.