

Time and date: 10 a.m.–3 p.m., September 16, 1998.

Location: NIOSH, CDC, Room 1046, 1095 Willowdale Road, Morgantown, West Virginia 26505.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: Participants will provide NIOSH with their individual advice and comments regarding the technical and scientific aspects of the study protocol, Assessment of Workers' Postural Stability and Cardiovascular Reactivity While Working in a Restricted and Elevated Space, being conducted at NIOSH. Participants on the peer review panel will review the study protocol and provide individual advice on the conduct of the study. Viewpoints and suggestions from industry, labor, academia, other governmental agencies, and the public are invited.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Brian Dotson, M.S., NIOSH, CDC, M/S P119, 1095 Willowdale Road, Morgantown, West Virginia 26505, telephone 304/285-6142.

Dated: July 28, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-20857 Filed 8-4-98; 8:45 am]

BILLING CODE 4160-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0635]

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 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-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 8B4615) has been filed by General Electric Co., One Lexan Lane, Mt. Vernon, IN 47620-9364. 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 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.

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: July 24, 1998.

Laura M. Tarantino,

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

[FR Doc. 98-20824 Filed 8-4-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes to its Orphan Products Development (OPD) grant program for fiscal year (FY) 1999. The previous announcement of this program, which was published in the **Federal Register** of July 9, 1997, is superseded by this announcement. In the future, a new announcement will be published annually.

DATES: The application receipt date is November 2, 1998.

ADDRESSES: Application forms are available from, and completed

applications should be submitted to: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA-522), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301-827-7185. (Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852.)

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: Ronda A. Balham, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, rm. 8-73, Rockville, MD 20857, 301-827-3668.

SUPPLEMENTARY INFORMATION: FDA is announcing the anticipated availability of funds for FY 1999 for awarding grants to support clinical trials on the safety and effectiveness of products for a rare disease or condition (i.e., one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Contingent on availability of FY 1999 funds, it is anticipated that \$11.3 million will be available, of which 8.8 million will be for noncompeting continuation awards. This will leave \$2.5 million for funding approximately 10 new applications. Any phase clinical trial is eligible for up to \$100,000 in direct costs per annum plus applicable indirect costs for up to 3 years. Phase 2 and phase 3 clinical trials are eligible for up to \$200,000 in direct costs per annum plus applicable indirect costs for up to 3 years.

FDA will support the clinical studies covered by this notice under section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free work place and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHS urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, stock No. 017-001-00474-0) through the Superintendent of Documents, Government Printing Office,