should be labeled: ''Response to RFA–FDA–OP–96–1.''

The grants are funded under the legislative authority of section 301 of the Public Health Service Act (PHS act)(42 U.S.C. 241). All awards will be subject to all policies and requirements that govern the research grant programs of PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and regulations promulgated thereunder. The regulations promulgated under Executive Order 12372 do not apply to this program.

All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 507, 512, 515, and 520 of the act (21 U.S.C. 355, 357, 360b, 360e, and 360j), section 351 of the PHS act (42 U.S.C. 262), and regulations promulgated under any of these sections.

Dated: June 19, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–15350 Filed 6–21–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94D–0397]

Powered Wheelchair Labeling; Letter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a letter concerning the labeling of powered wheelchairs. This letter, which was sent to all powered wheelchair, scooter, and accessory and component manufacturers, describes the agency's increasing concern about electromagnetic interference (EMI) with powered wheelchairs and motorized scooters (hereinafter collectively called powered wheelchairs). FDA believes that electromagnetic (EM) energy is causing these devices to move unintentionally. This letter is intended to establish certain necessary steps that powered wheelchair manufacturers should follow in order to help minimize the risks associated with the unintended movement of powered wheelchairs caused by EMI. FDA is publishing this notice because it believes that the letter may not have reached all interested persons.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the letter to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 or 1–800–638–2041. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the letter to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The letter and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Marie A. Schroeder, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.

SUPPLEMENTARY INFORMATION: On May 26, 1994, FDA issued a letter to all powered wheelchair, scooter, accessory, and component manufacturers explaining FDA's increasing concern about the effects of EMI on the safe use of powered wheelchairs. FDA has received many reports of erratic and unintentional powered wheelchair movement. The agency believes that EM energy is causing these devices to move unintentionally. As a result of these concerns, FDA established the following steps in order to provide information to protect powered wheelchair users from the potential hazards of EMI.

I. Minimum Recommended Immunity Level

FDA recommends that all marketed powered wheelchairs have a minimum immunity level of 20 volts per meter (V/m). This immunity level was proposed by wheelchair manufacturers at the American National Standards Institute/Association for the Advancement of Rehabilitation Technology meeting in June 1993, and it reflects the present technological capability that can be immediately implemented.

II. Product Labeling

The labeling described in FDA's letter is intended to inform powered wheelchair users about the risks from EMI associated with the use of powered wheelchairs and how to avoid these risks. This labeling should be on or attached to the powered wheelchair and provide the following information:

1. An explanation of what EMI is, what causes EMI, and the risks associated with EMI;

2. An explanation of how the user can avoid risks associated with EMI, including warnings to use caution around sources of EMI;

3. A Warning that the addition of accessories or components, or modifications to a powered wheelchair may make it more susceptible to EMI, and that there is no easy way to evaluate their effect on the overall immunity of the powered wheelchair;

4. A statement that, as of May 1994, 20 V/m is a generally achievable and useful immunity level; and

5. A statement of the EMI immunity level of the powered wheelchair, or a statement that the EMI immunity level is not known.

FDA believes that this information will help minimize the risks associated with unintended movement of powered wheelchairs caused by EMI. Omission of the labeling information requested above will result in a failure of the powered wheelchair labeling to include facts relevant to the powered wheelchair's use and in a failure to provide adequate warnings, as required by section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352). Accordingly, products shipped without the required labeling may be considered misbranded under section 502 of the act.

III. Recommended Educational Program

FDA recommends that manufacturers implement an educational program to warn users of the potential hazards of EMI and to provide information about the risks and how to avoid them.

Additionally, FDA will continue to solicit reports of EMI problems and to monitor the problems in order to evaluate the full scope of the problem.

Interested persons may, at any time, submit to the Docket Management Branch (address above) written comments on the powered wheelchair labeling letter. 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. The letter and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether future action should be taken to address concerns about the effects of EMI on powered wheelchairs.

Dated: June 12, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–15347 Filed 6–21–95; 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:

Gastrointestinal Drugs Advisory Committee

Date, time, and place. July 12, 1995, 9 a.m., Holiday Inn—Bethesda, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211, or Valerie M. Mealy, Advisors and Consultants Staff (HFD–9), 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Gastrointestinal Drugs Advisory Committee, code 12538.

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 gastrointestinal 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 June 30, 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. The committee will discuss new drug application (NDA) 20–458, Lemmon Co., zinc acetate to be indicated for use in Wilson's disease. The advisory committee will also consider draft ''Points to Consider'' from the Division of Anti-Infective Drug Products on *Helicobacter pylori* studies to prevent peptic ulcer recurrence.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. July 18 and 19, 1995, 9 a.m., Hyatt Regency—Bethesda, Cabinet-Judiciary Suite, One Bethesda Metro Center, Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–657–1234 and reference the FDA Committee meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, July 18, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open subcommittee discussions, 10 a.m. to 5 p.m.; open subcommittee discussions, July 19, 1995, 9 a.m. to 2 p.m.; open committee discussion, 2 p.m. to 5 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

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 11, 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 19, 1995, the committee will discuss the ongoing work of the three subcommittees: Access to Mammography Services, Physicists Availability, and Cost Benefit of Compliance.

Open subcommittee discussions. On July 18 and 19, 1995, the three subcommittees will meet concurrently. The subcommittees will discuss the ongoing work which is necessary to make the determinations and subsequently prepare the reports as mandated in the Mammography Quality Standards Act. Upon completion, the subcommittee reports will be reviewed by the committee prior to submission to the Secretary of Health and Human Services and Congress.

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 20 and 21, 1995, 8:30 a.m., Bethesda Pooks Hill Marriott, Congressional Ballroom, 5151 Pooks Hill Rd., Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–897–9400 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, July 20, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; open public hearing, July 21, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 12 m.; Sara M. Thornton, Center for Devices and Radiological Health