

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 24, 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 evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 13, 1995.

Alan M. Rulus,

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

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BILLING CODE 4160-01-F

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) 1996. Previously, the \$200,000 grant for phase 2 or 3 trials could only be awarded for a maximum of 2 years. Now all grants, including the \$200,000 grant, may be awarded for a maximum of 3 years. This document is intended to inform eligible applicants of the application receipt dates, the estimated amount of funds available, the estimated number of awards to be made in FY 1996, and any changes in

programmatic requirements, as well as to inform eligible applicants of the new extended length for all grants.

DATES: Application receipt dates are October 1, 1995, and January 15, 1996. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Robert L. Robins, Grants Management Officer, Grants and Agreements Management Branch (HFA-520), Food and Drug Administration, Park Bldg., rm. 3-40, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6170.

Note: Applications hand-carried or commercially delivered should be addressed to the Park Bldg., rm. 3-40, 12420 Parklawn Dr., Rockville, MD 20857. Do not send applications to the Division of Research Grants, National Institutes of Health (NIH).

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: Patricia R. Robuck, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, rm. 8-73, Rockville, MD 20857, 301-443-4903.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 15, 1994 (59 FR 41769), FDA announced that the agency would publish a notice annually in the **Federal Register** that references the August 15, 1994, standing announcement and reminds eligible applicants of: The receipt dates, the estimated amount of funds available, the estimated number of awards to be made during the fiscal year, and any changes in programmatic requirements or criteria. All provisions of the August 1994 standing announcement are applicable to the FY 1996 OPD grant program, except for the changes described below, and applicants should refer to the standing announcement for additional information. The OPD grant program standing announcement changes for FY 1996 are set forth below.

FDA is announcing the anticipated availability of funds for FY 1996 for awarding grants to support clinical trials on safety and effectiveness of products for rare diseases and conditions (i.e., those affecting fewer than 200,000 people in the United States). Contingent on availability of FY 1996 funds, it is anticipated that \$12 million will be available for these grants, of which \$6.2

million will be for noncompeting continuation awards. This will leave \$5.8 million for funding the following: Approximately \$2.9 million for 20 grants (phase 1, 2, or 3 trials) up to \$100,000 each in direct costs per annum plus applicable indirect costs for up to 3 years, and approximately \$2.9 million for 10 grants (phase 2 and 3 trials only) up to \$200,000 each in direct costs per annum plus applicable indirect costs for up to 3 years. Applications exceeding this direct cost limit will be considered nonresponsive and will be returned to the applicant. The current, active investigational new drug (IND) or investigational device exemption (IDE) number for the proposed study must appear on the face page of the application with the title of the project.

In the **Federal Register** of August 15, 1994, under "II. Human Subject Protection and Informed Consent," in section B. Informed Consent, the agency stated that consent and/or assent forms, and any additional information to be given to a subject should accompany the grant application. Under current procedures, consent and/or assent forms, and any additional information to be given to a subject, must be included in the grant application.

In addition, in the **Federal Register** of August 15, 1994, under "V. Review Procedure and Criteria," in section B. Program Review Criteria, paragraph 3, the agency stated that if the sponsor of the IND/IDE is other than the principal investigator listed on the application, a letter from the sponsor verifying access to the IND/IDE is required. Under current procedures, if the sponsor of the IND/IDE is other than the principal investigator listed on the application, documentation must be provided in the grant application verifying that the grant applicant and the proposed protocol are included in the IND/IDE. Applications that do not have an active IND or IDE for the proposed study *at the time of application* will be considered nonresponsive.

In the same section, paragraph 4, the agency stated that the requested budget must be within the limits (either \$100,000 in direct costs for up to 3 years or \$200,000 in direct costs for up to 2 years) as stated in the request for applications. Under current procedures, the requested budget must be within the limits (either \$100,000 in direct costs for any phase study or up to \$200,000 in direct costs for studies in phase 2 or 3) as stated in the request for applications. The maximum study period will be 3 years.

The outside of the mailing package and item 2 of the application face page

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.

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[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.