

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 (Catalog of Federal Domestic Assistance No. 93.103)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes to its Office of Orphan Products Development (OPD) grant program for fiscal years (FY) 2004 and 2005. This announcement supercedes the previous announcement of this program, which was published in the **Federal Register** of August 27, 2002 (67 FR 55020).

DATES: For FY 2004, the application receipt date is October 13, 2003. For FY 2005, the application receipt dates are April 7, 2004, and October 6, 2004.

ADDRESSES: Application requests and completed applications should be submitted to Maura Stephanos, Grants Management Officer, Grants and Assistance Agreements, Division of Contracts and Grants Management (HFA-531), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7183, e-mail: mstepha1@oc.fda.gov. Applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.¹ Applications may also be obtained from the OPD on the Internet at <http://www.fda.gov/orphan> or <http://grants.nih.gov/grants/funding/phs398/phs398.html>.²

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management issues of this notice: Maura Stephanos (see **ADDRESSES**).

Regarding the programmatic issues of this notice: Debra Y. Lewis, Director, Orphan Products Grants Program, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6A-55, Rockville, MD 20857, 301-827-3666, e-mail: dlewis@oc.fda.gov.

SUPPLEMENTARY INFORMATION: Except for applications for studies of medical foods that do not need premarket approval, FDA will only award grants to support premarket clinical studies to determine whether the products are safe and effective for approval under section 301 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*) or under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act. FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

Applicants for Public Health Service (PHS) clinical research grants are encouraged to include minorities and women in study populations so research findings can be of benefit to all people at risk of the disease or condition under study. It is recommended that applicants place special emphasis on including minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy applies to research subjects of all ages. If women or minorities are excluded or poorly represented in clinical research, the applicant should provide a clear and compelling rationale that shows inclusion is inappropriate.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace 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.

FDA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the "Healthy People 2010" objectives, vols. I and II, for \$70 (\$87.50 foreign) S/N 017-000-00550-9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Telephone orders can be placed to 202-512-2250. The document is also available in CD-ROM format, S/N 017-001-00549-5 for \$19 (\$23.50 foreign) as well as on the Internet at <http://www.healthypeople.gov/>. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) Internet viewers should proceed to "Publications."

I. Program Research Goals

The OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and foods for medical purposes that are indicated for a rare disease or condition (that is, one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostic tests and vaccines will qualify only if the U.S. population of intended use is fewer than 200,000 people a year.

The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the product will improve the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include in the application's "Background and Significance" section an explanation of how the proposed study will either help gain product approval or provide essential data needed for product development. All funded studies are subject to the requirements of the act and regulations issued under it.

II. Mechanism of Support

A. Award Instrument

Support will be in the form of a grant. All awards will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. The NIH modular grant program does not apply to this FDA grant program. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the act (21 U.S.C. 355, 360b, and 360e), section 351 of the PHS Act (42 U.S.C. 262), and regulations issued under any of these sections.

B. Award Amount

Of the estimated FY 2004 funding (\$13.2 million), approximately \$9.2 million will fund noncompeting continuation awards, and approximately \$4 million will fund 10 to 12 new awards. The expected start date for the FY 2004 awards will be April 1, 2004. The estimated FY 2005 funding is anticipated to be the same as FY 2004. The expected start date for the FY 2005 awards will begin January 1, 2005.

All applications received for the October 13, 2003, due date that are

¹ Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

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