4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0012]

Clinical Studies of Safety and Effectiveness of Orphan Products Research Project Grant (R01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of FDA's Office of Orphan Products Development grant program. The goal of FDA's Orphan Products Development (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 proposed product will be superior to 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 documentation to support the assertion that the product to be studied meets the statutory criteria to qualify for the grant and an explanation of how the proposed study will either help support product approval or provide essential data needed for product development.

DATES: Important dates are as follows:

1. The application due dates are February 4, 2015; February 3, 2016; February 1, 2017; and February 7, 2018.

The resubmission due dates are October 15, 2015; October 14, 2016; October 16, 2017; and October 15, 2018.

2. The anticipated start dates are November 2015; November 2016; November 2017; and November 2018.

3. The opening date is December 4, 2014.

4. The expiration dates are February 8, 2018, and October 16, 2018, (resubmission).

ADDRESSES: Submit electronic applications to: http://www.grants.gov. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT: Katherine Needleman, Director, Orphan Products Grants Program, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5295, Silver Spring, MD 20993-0002, 301-796-8660, katherine.needleman@fda.hhs.gov; or Vieda Hubbard, Grants Management Specialist, Division of Acquisition Support and Grants, Office of Acquisitions & Grant Services, 5630 Fishers Lane, Rockville, MD 20857, 240-402-7588, vieda.hubbard@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at http://grants.nih.gov/grants/guide (select the "Request for Applications" link), http://www.grants.gov (see "For Applicants" section), and http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/WhomtoContactaboutOrphanProductDevelopment/ucm134580.htm.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-15-001

93.103

A. Background

The OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and medical foods that are indicated for a rare disease or condition. The term “rare disease or condition” is defined in section 528 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ee). FDA generally considers drugs, devices, and medical foods potentially eligible for grants under the OPD grant program if they are indicated for a disease or condition that has a prevalence, not incidence, of fewer than 200,000 people in the United States. Diagnostics and vaccines are considered potentially eligible for such grants only if the U.S. population to whom they will be administered is fewer than 200,000 people in the United States per year.

B. Research Objectives

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 proposed product will be superior to 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 documentation to support the assertion that the product to be studied meets the statutory criteria to qualify for the grant and an explanation of how the proposed study will either help support product approval or provide essential data needed for product development.

C. Eligibility Information

The grants are available to any foreign or domestic, public or private, for-profit or nonprofit entity (including State and local units of government). Federal Agencies that are not

part of the Department of Health and Human Services (HHS) may apply. Agencies that are part of HHS may not apply. For-profit entities must commit to excluding fees or profit in their request for support to receive grant awards. Organizations that engage in lobbying activities, as described in section 501(c)(4) of the Internal Revenue Code of 1968, are not eligible to receive grant awards.

II. Award Information/Funds Available

A. Award Amount

Of the estimated Fiscal Year (FY) 2016 funding ($14.1 million), approximately $10 million will fund noncompeting continuation awards, and approximately $4.1 million will fund 5 to 10 new awards, subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2017, FY 2018, and FY 2019 will be similar to FY 2016. Phase 1 studies are eligible for grants of up to $250,000 per year for up to 3 years. Phase 2 and 3 studies are eligible for grants of up to $500,000 per year for up to 4 years. Please note that the dollar limitation will apply to total costs (direct plus indirect). Budgets for each year of requested support may not exceed the $250,000 or $500,000 total cost limit, whichever is applicable.

B. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of more than 1 year, a second, third, or fourth year of noncompetitive continuation of support will depend on the following factors: (1) Performance during the preceding year, (2) compliance with regulatory requirements of investigational new drug/investigational device exemption, and (3) availability of Federal funds.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at http://grants.nih.gov/grants/guide. (FDA has verified the Web site addresses throughout this document but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM) (formerly Central Contractor Registration (CCR))
- Step 3: Obtain Username & Password on Grants.gov
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. After you have followed these steps, submit electronic applications to: http://www.grants.gov.

Dated: August 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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