4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0012]

Pediatric Device Consortia Grant Program

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 the Office of Orphan Products Development (OOPD) Pediatric Device Consortia (PDC) Grant Program. The goal of the PDC Grant Program is to facilitate the development, production, and distribution of pediatric medical devices. The PDC will provide grants to nonprofit consortia which provide expert advising and support services to innovators of pediatric devices. These services should include business and regulatory consulting as well as device testing capabilities. This program is intended to further the development of multiple pediatric devices; thus, grants are not awarded to support the development of a single device project.

Although administered by the OOPD, this grant program is intended to encompass devices that could be used in all pediatric conditions and diseases, not just rare diseases. The pediatric population (neonates, infants, children, and adolescents) includes patients who are 21 years of age or younger at the time of diagnosis or treatment.

DATES: Important dates are as follows:

1. The application due date is June 1, 2013.

2. The anticipated start date is September, 2013.

3. The opening date is May 1, 2013.

4. The expiration date is June 2, 2013.

ADDRESSES: Submit the paper application to: Vieda Hubbard, Grants Management (HFA-500), 5630 Fishers Lane, rm. 2034, Rockville, MD 20857. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT:

Linda C. Ulrich,

Director, Pediatric Device Consortia Grants Program,

Food and Drug Administration,

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10903 New Hampshire Ave.,

Silver Spring, MD 20993-0002,

301-796-8660; or

Vieda Hubbard,

Grants Management Specialist,

Office of Acquisitions & Grant Services,

Food and Drug Administration,

5630 Fishers Lane, rm. 2034,

Rockville, MD 20857,

301-827-7177.

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/ or http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-13-010

93.103

A. Background

The development of pediatric medical devices currently lags behind the development of devices for adults. Pediatric patients often differ from adults in terms of their size, growth, development, body chemistry, and disease propensity, adding to the challenges of pediatric device development. There currently exists a great need for pediatric medical devices, including devices designed originally for pediatric patients as well as existing adult devices adapted for pediatric use. Recent passage of the Food and Drug Administration Safety and Improvement Act (FDASIA) (Public Law 112-144) reauthorized support of section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110-85), which requires HHS to provide demonstration grants to nonprofit consortia to promote pediatric device development. While the consortia themselves are nonprofit entities, their contacts and membership can include for-profit partners.

B. Research Objectives

The Pediatric Device Consortia Grant Program aims to fund networks of pediatric medical device advisors who are able to provide a platform of experienced regulatory, business planning, and device development services (such as intellectual property advising; prototyping; engineering; laboratory and animal testing; grant writing; and clinical trial design) to help foster and guide the advancement of medical devices for pediatric patients. A successful PDC brings together individuals and institutions that can support pediatric medical device progression

through all stages of development--concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialization. The consortia are expected to support a mix of projects at all stages of development, particularly the later stages of clinical, manufacturing, and marketing.

Specifically, the consortia will facilitate the development, production, and distribution of pediatric medical devices by: (1) Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers; (2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing; (3) connecting innovators and physicians to existing Federal and non-Federal resources; (4) assessing the scientific and medical merit of proposed pediatric device projects; and (5) providing assistance and advice as needed on business development, personnel training, prototype development, and post-marketing needs.

C. Eligibility Information

The grants are available to any domestic, public or private, nonprofit entity (including State and local units of government). Federal agencies that are not part of HHS may apply. Agencies that are part of HHS may not apply. 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

The estimated amount of funds available for support of four to five consortia awarded as a result of this announcement is $3 million for fiscal year 2013. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and

duration of each award will also vary. Although PDC financial plans include support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

B. Length of Support

Grants will be awarded on a competitive basis up to $750,000 in total (direct plus indirect) costs per year for up to 5 years, contingent upon favorable annual review and an additional mid-cycle review after 2 1/2 years of funding.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at http://grants.nih.gov/grants/guide/ or http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm. (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.) Persons interested in applying for a grant may obtain an application at http://grants.nih.gov/grants/forms.htm. For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management

Steps 1 and 2, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. After you have followed these steps, submit paper applications to: Vieda Hubbard, Grants Management Specialist, Office of Acquisitions & Grant Services, 5630 Fishers Lane, rm. 2034, Rockville, MD 20857, phone: 301-827-7177.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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