

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Board of Scientific Advisors.

Date: June 22–23, 2009.

Time: June 22, 2009, 8 a.m. to 6 p.m.

Agenda: Director's Report; Ongoing and New Business; Reports of Program Review Group(s); and Budget Presentations; Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Time: June 23, 2009, 8:30 a.m. to 12 p.m.

Agenda: Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Paulette S. Gray, PhD, Executive Secretary, Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Rm. 8001, Bethesda, MD 20892, 301-496-5147, grayp@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/bsa.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and

Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 27, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0199]

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 Grant Program (PDCGP). The goal of the PDCGP is to promote pediatric device development by providing grants to nonprofit consortia whose business model and approach to device development will either result in, or substantially contribute to, market approval of medical devices designed specifically for use in children. Although administered by the OOPD, this grant program is intended to encompass devices that could be used in all pediatric conditions or 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 15, 2009.
2. The anticipated start date is September 2009.
3. The opening date is May 1, 2009.
4. The expiration date is June 16, 2009.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Linda C. Ulrich or Debra Y. Lewis, Pediatric Device Consortia 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. Camille Peake, Division of

Acquisition Support and Grants, Office of Acquisitions & Grant Services (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2139, Rockville, MD 20852, 301-827-7175.

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/index.html>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-009-007
Catalog of Federal Domestic Assistance
Number 93.103

A. Background

The development of pediatric medical devices currently lags 5 to 10 years behind the development of devices for adults. Children differ from adults in terms of their size, growth, development, and body chemistry, adding to the challenges of pediatric device development. There currently exists a great need for medical devices designed specifically with children in mind. Such needs include the original development of pediatric medical devices, as well as the specific adaptation of existing adult devices for children. Thus, as part of the 2007 Food and Drug Administration Amendments Act (FDAAA) legislation, Congress passed the Pediatric Medical Device Safety and Improvement Act of 2007. Section 305 of FDAAA requires the Secretary of Health and Human Services to provide demonstration grants or contracts to nonprofit consortia to promote pediatric device development.

B. Research Objectives

The goal of FDA's PDCGP is to promote pediatric device development by providing grants to nonprofit consortia. 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,