II. Electronic Access

Persons with access to the Internet may obtain the documents at either *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: July 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19087 Filed 8–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0011]

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 (OPD) grant program. 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.

DATES: Important dates are as follows:

1. The application due dates are February 6, 2013; February 5, 2014. The resubmission due dates are October 15, 2013; October 15, 2014.

2. The anticipated start dates are November 2013; November 2014.

3. The opening date is December 6, 2013.

4. The expiration date is February 6, 2014; October 16, 2014 (resubmission).

For Further Information and Additional Requirements Contact: Katherine Needleman, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993–0002, Phone: 301–796–8660, Email: *katherine.needleman@fda.hhs.gov*; or Vieda Hubbard, Office of Acquisitions & Grant Services, 5630 Fishers Lane, rm. 2034, Rockville, MD 20857, Phone: 301–827–7177, Email: *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–13–001
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 FY 2014 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 2015 will be similar to FY 2014. Phase 1 studies are eligible for grants of up to $200,000 per year for up to 3 years. Phase 2 and 3 studies are eligible for grants of up to $400,000 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 $200,000 or $400,000 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 IND/investigational device exemption (IDE); 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.* For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Obtain Username & Password
- 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: July 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19086 Filed 8–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Early-Stage Innovative Technology Development for Cancer Research (R21).

Date: October 17, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8059, Bethesda, MD 20892–8329, 301–496–7904, *decluej@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.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: July 31, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–19064 Filed 8–3–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Closed: September 5, 2012.

Time: 1 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

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

Contact Person: Paulette S. Gray, Ph.D., 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.*

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ncab/ncab.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: July 31, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–19065 Filed 8–3–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the NCI–Frederick Advisory Committee.

The meeting will be open to the public as indicated below, 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.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9) (B), Title 5 U.S.C., as amended. The premature disclosure of information to be discussed during the meeting would significantly frustrate implementation of a proposed agency action.

Name of Committee: NCI–Frederick Advisory Committee.

Open: September 12, 2012, 9 a.m. to 1 p.m.

Agenda: Ongoing and New Business and Scientific Presentations.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: September 12, 2012, 1 p.m. to 3 p.m.

Agenda: Discussion of Proposed Frederick National Laboratory for Cancer Research Strategic Plan.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.