

Dated: April 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0012]

Analgesic Clinical Trials Innovation, Opportunities, and Networks (ACTION) Initiative

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 Analgesic Clinical Trials Innovation, Opportunities, and Networks (ACTION) Initiative. The goal of the ACTION Initiative is to streamline the discovery and development process for new analgesic drug products for the benefit of public health. The ACTION Initiative is being developed, in large part, through the establishment of a cooperative agreement with one or more organizations. The ACTION Initiative will address major gaps in scientific information, which can slow down analgesic clinical trials and analgesic drug development. FDA will support the ACTION Initiative under the authority of the Federal Food, Drug, and Cosmetic Act.

DATES: Important dates are as follows:

1. The application due date is June 8, 2011.
2. The anticipated start date is July 14, 2011.
3. The opening date is April 22, 2011.
4. The expiration date is June 9, 2011.

FOR FURTHER INFORMATION AND

ADDITIONAL REQUIREMENTS CONTACT: Igor Cerny, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3124, Silver Spring, MD 20993-0002, 301-796-4273, e-mail: Igor.Cerny@fda.hhs.gov; Vieda Hubbard, Office of Acquisitions and Grant Services, Food and Drug Administration, 5630 Fishers Lane (HFA-500), Rockville, MD 20857, 301-827-7177, e-mail: 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/or <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm231130.htm>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-11-006

93.103

A. Background

Despite the enormous advances in drug development over the past 2 or 3 decades (e.g., drugs that cure cancer and biologic drug products that halt the progression of rheumatoid arthritis), the development of novel analgesic drug products has lagged behind. Indeed, to this day, the only analgesic drug products that are used widely and successfully are opioids, acetaminophen, and nonsteroidal anti-inflammatory agents, all of which have serious, potentially life-threatening toxicities, even when used properly. While there has been exploration at the earliest stages of drug development, there has been widespread reluctance on the part of the pharmaceutical industry to take novel products further into development. This is in no small part due to the often daunting task of demonstrating the efficacy of analgesics in clinical trials. Many experts in analgesic drug development believe that it is the design of the clinical trials that is at fault in this situation and that better trial designs will yield more successful results. This hypothesis is certainly supported by the frequent failures of clinical efficacy trials of opioid drug products, considering the well established effectiveness of these products from literally thousands of years of clinical experience. For these reasons, additional studies are needed to assess the confounding nature of analgesic clinical trials and analgesic drug development.

B. Research Objectives

Based on collaboration with FDA, key stakeholder input, best Government, academic, and industry practices, and knowledge gained through workshops, the Grantee will be responsible for developing, defining, and recommending projects as described in this section. Applicants should, at a minimum, address the following three overarching research domains in this section. The overall study design processes within each of these domains should be aligned with established strategic goals and provide results and

recommendations in alignment with the objectives of the ACTION Initiative.

1. Data analysis of primarily group analgesic clinical trials data (databases) for relationships between assay sensitivity and metrics including, but not limited to, specific research designs and methodological features so as to inform the future design of analgesic clinical trials.

2. Scientific assessment of FDA's clinical trial databases and development of novel and alternative means of analyzing various pain scores in a manner that effectively considers variables, such as bias and interindividual variance.

3. Development of methodologies for the execution and transformation of pooled trial data from multiple relevant analgesic trials.

C. Eligibility Information

The following organizations/institutions are eligible to apply:

- Higher education institutions as defined in section 101 of the Higher Education Act of 1965 (or a consortium of such institutions).

The following types of higher education institutions are always encouraged to apply for National Institutes of Health support as public or private institutions of higher education:

- Hispanic serving institutions.
- Historically Black colleges and universities.
- Tribally controlled colleges and universities.
- Alaska Native and Native Hawaiian serving institutions.

Nonprofits other than institutions of higher education.

- A nonprofit organization described in section 501(c)(3) of the Internal Revenue Code of 1986, which is exempt from tax under section 501(a) of that code.

An eligible organization that wishes to enter into a collaborative agreement must provide an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by FDA unless the entity provides assurances in its agreement with FDA that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

II. Award Information/Funds Available

A. Award Amount

It is anticipated that no more than \$1 million will be allocated to this cooperative agreement. It is anticipated that a single award will be made.

B. Length of Support

The scope of the proposed project will determine the project period. The maximum period is 5 years.

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/> (select the "Request for Applications" link), <http://www.grants.gov/> (see "For Applicants" section) and <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm166082.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**.) 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>.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 29, 2011, from 8 a.m. to 5 p.m.

Location: Crowne Plaza Hotel, 8777 Georgia Ave., Silver Spring, MD 20910.

Contact Person: Gail Dapolito or Sheryl Clark, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On June 29, 2011, the committee will discuss cellular and gene therapy products for the treatment of retinal disorders. Topics to be considered include the following: (1) Efficacy endpoints in pediatric and adult populations, (2) potential safety issues related to repeat administration or second eye administration, and (3) evaluation of product delivery into target site.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at [http://www.fda.gov/AdvisoryCommittees/Calendar/](http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm)

[default.htm](http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm). Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 22, 2011. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 14, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 15, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

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