SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 24, 2011 (76 FR 4120), FDA published a notice with a 60-day comment period to request comments from stakeholders on strategies to address a document for the NARMS program entitled "NARMS Strategic Plan 2011–2015." The notice expressed FDA's interest in receiving comments on the goals and objectives in the Strategic Plan and whether the goals and objectives meet the recommendations of the subcommittee.

The Agency has received requests for a 60-day extension of the comment period along with request for background material on the development of the "NARMS Strategic Plan 2011–2015." The requests conveyed concern that the current 60-day comment period does not allow respondents sufficient time to address fully the many important issues FDA raised in the notice.

FDA has considered the requests and is extending the comment period for the notice for 60 days, until May 24, 2011. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain documents at either *http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm, http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm062630.htm, http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059135.htm, http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_06_NARMS%20Review%20Update.pdf,* or *http://www.regulations.gov.*

Dated: March 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–7068 Filed 3–24–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0155]

Pediatric Anesthesia Safety Initiative (PASI)

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 Pediatric Anesthesia Safety Initiative (PASI). The goal of PASI is to bridge the scientific and clinical gaps in the field of pediatrics to ensure the safe use of anesthetic and sedative agents in children. FDA seeks under PASI to encourage and facilitate scientific collaboration among multiple stakeholders within a public-private partnership (PPP) framework and to support the conduct of non-clinical and clinical studies to answer unknown questions regarding the effects of anesthetics and sedatives in the pediatric population. The output from PASI will help to inform the work of FDA as part of its public health mission.

DATES: Important dates are as follows:

1. The application due date is April 29, 2011.
2. The anticipated start date is July 14, 2011.
3. The opening date is March 30, 2011.
4. The expiration date is April 30, 2011.

For Further Information and Additional Requirements Contact: ShaAvhree Buckman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4554, Silver Spring, MD 20993, 301–796–1653, *e-mail: ShaAvhreeBuckman@fda.hhs.gov.* Vieda Hubbard, Office of Acquisitions & 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 *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm166082.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–11–005.

93.103.

A. Background

Non-clinical studies in juvenile animal models have shown that exposure to some anesthestics and sedatives is associated with neurodegenerative changes in the central nervous system, as well as memory and learning deficits. Anesthetic agents that have been specifically implicated are *N*-methyl-D-aspartate (NMDA) receptor antagonists, such as ketamine, and gamma aminobutyric acid (GABA) agonists, such as sevoflurane. The anesthesia community and FDA acknowledge that there are insufficient human data to either support or refute the clinical relevance of these findings for pediatric patients. Therefore, numerous non-clinical and clinical studies are needed to assess the effect of anesthetics and sedatives on the developing human brain, including long-term studies in neonates and young children. However, the planning and performance of the numerous studies needed to address the aforementioned issues will involve enormous challenges in terms of design, assurance of validity and reliability of the outcome measures, and ethical considerations. It is unlikely that any one entity will possess the necessary expertise and resources to accomplish all the work needed to address the issues in an expeditious manner.

B. Objectives

PASI aims to bridge the scientific and clinical gaps in the field of pediatrics to ensure the safe use of anesthetic and sedative agents in children. Specific activities to be funded through this announcement include, but are not limited to:

1. Project management of PASI PPP:

• Development, implementation, and management of a scientific and administrative infrastructure to support the creation and execution of a series of projects aligned with PASI.

• Coordination of the overall governance board, to include luminary experts to lead the overall PPP; said governance board to establish necessary

steering committees and working groups to ensure appropriate project implementation, oversight, and management for all projects under the PPP.

• Development of a scientific review panel to evaluate the progress of projects funded under the PPP and development of feasibility plans for additional projects aligned with PASI.

• Coordination with FDA and other partners; the development and publication of scientific articles in support of educational and outreach activities (with data, know-how, and other outcomes from the aforementioned projects supported under the PPP) and to benefit patients and other stakeholders.

• Development of a strategy to identify and establish relationships with key experts in the fields of anesthesia and sedation, including stakeholders from industry, professional organizations, academia, and awardees of the projects under the "research and analysis" section for leveraging and collaborative efforts under PASI.

• Coordination of annual scientific workshops with collaboration by FDA and the aforementioned experts in the fields of anesthesia and sedation, including stakeholders from industry, professional organizations, academia, and Government Agencies.

2. Research projects (which may include, but are not limited to):

• Clinical trials including prospective, randomized, and blinded investigations assessing the immediate and delayed neurodevelopmental effects of regional/caudal anesthesia versus general anesthesia in neonates/infants;

• Observational trials including the comparison of two groups of children, one group exposed to general anesthesia within the first 3 years of life and the other, unexposed. Assessments should utilize neuropsychological tests of attention, memory, motor function, and behavior; and

• Epidemiologic investigations surveying large existing population databases for cognitive developmental effects where exposure to general anesthesia before the age of 3 can be compared to the overall population.

C. Eligibility Information

Higher education institutions:

• Public/state-controlled institutions of higher education

• Private institutions of higher education

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

• Nonprofits with 501(c)(3) Internal Revenue Service (IRS) status (other than institutions of higher education)

• Nonprofits without 501(c)(3) IRS status (other than institutions of higher education)

For-profit organizations:

• Small businesses

• For-profit organizations (other than small businesses)

Other:

• Regional organizations

Non-domestic (non-U.S.) entities (foreign organizations) are not eligible to apply. Foreign (non-U.S.) components of U.S. organizations are not allowed.

II. Award Information/Funds Available

A. Award Amount

FDA intends to fund one or more awards, corresponding to a total of $1 million, for fiscal year 2011, to carry out the project management and research project objectives described in Part I of this document. Future year amounts will depend on annual appropriations. No more than four awards are anticipated under this FOA. The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications.

B. Length of Support

The anticipated length of the individual awards 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 and 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: March 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–7055 Filed 3–24–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel; LOAN REPAYMENT.

Date: April 7, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carol Lambert, PhD, Scientific Review Officer, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Blvd., One Democracy Plaza, Room 1076, MSC 4874, Bethesda, MD 20892–4874, 301–435–0814, *lambert@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing