the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

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 Donald W. Jehn or Denise Royster 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).

Dated: April 2, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–07961 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

2013 Medical Countermeasures Initiative Regulatory Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: 2013 Medical Countermeasures initiative (MCMi) Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of ideas for medical countermeasure development, highlight work on regulatory science as it applies to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

Dates and Times: The symposium will be held on May 29 and May 30, 2013, from 9 a.m. to 5 p.m., and on May 31, 2013, from 9 a.m. to 12 noon. Persons interested in attending the symposium in person or viewing via Webcast must register by May 24, 2013, at 5 p.m. EST.

Location: The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the symposium participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Contact: Rakesh Raghuwanshi, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4283, Silver Spring, MD 20993, 301–796–4769, Fax: 301–847–8615, email: *AskMCMi@fda.hhs.gov*.

Registration: If you wish to attend the symposium or view via Webcast, you must register at *http://www.fda.gov/medicalcountermeasures* by May 24, 2013, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) phone number, and (6) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you need special accommodations due to a disability, please enter pertinent information in the ''Notes'' section of the electronic registration form when you register.

Date: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07893 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Society of Clinical Research Associates-Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The conference on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents, and regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, IRBs, and research sponsors.

DATES: *Date and Time:* The conference will be held on May 15 and 16, 2013, from 8 a.m. to 5 p.m.

Location: The conference will be held at the Renaissance Seattle Hotel, 515 Madison St., Seattle, WA 98104.

Contact Person: Jane Kreis, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739; or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292, FAX: 215–822–8633, email: *SoCRAmail@aol.com,* Web site: *www.socra.org*.

Registration and Meeting Information: See SOCRA Web site, *www.SoCRA.org*. *http://www.socra.org/html/FDA_Conference.htm*. Registrations fees are as follows: $575.00 for SOCRA members; $650.00 for nonmembers (includes membership); $450.00 for Federal Government members; $525.00 for Federal Government nonmembers; FDA employee rate is fee-waived. The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. If you need special accommodations due to a disability, please contact Jane Kreis (see *Contact Person*) at least 10 days in advance.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, institutional review board inspections, electronic record

requirements, and investigator-initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting—Science, Regulation, Error, and Safety; (3) Part 11 Compliance—Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator-Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; and (12) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions.

Extended periods of question and answer and discussion have been included in the program schedule. This program offers 13.3 hours of continuing medical education (CME) and continuing nursing education (CNE) credit. *CME for Physicians:* The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for Nurses:* Society of Clinical Research Associates is an approved provider of continuing nursing education by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission (ANCC) on Accreditation. ANCC/PSNA Provider Reference Number: 205–3–A–09.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government agencies to small businesses.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07894 Filed 4–4–13; 8:45 am]

BILLING CODE 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, Bldg. 32, Rm. 5271, 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) (Pub. L. 112–144) reauthorized support of section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 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.