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.
Specifi cally, 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, personnel training, prototype development, and post-marketing needs.

C. Eligibility Information

The grants are available to any domestic, public or private, nonprofit entity (including State and local units of government). Federal agencies that are not part of HHS may apply. Agencies that are part of HHS may not apply. 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

The estimated amount of funds available for support of four to five consortia awarded as a result of this announcement is $3 million for fiscal year 2013. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although PDC financial plans include support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

B. Length of Support

Grants will be awarded on a competitive basis up to $750,000 in total (direct plus indirect) costs per year for up to 5 years, contingent upon favorable annual review and an additional mid-cycle review after 2½ years of funding.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at http://grants.nih.gov/grants/ guide/ or http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm. (FDA has verifi ed 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.) Persons interested in applying for a grant may obtain an application at http://grants.nih.gov/grants/forms.htm. For all paper application submissions, the following steps are required:

• Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
• Step 2: Register With System for Award Management.

Steps 1 and 2, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. After you have followed these steps, submit paper applications to: Vieda Hubbard, Grants Management Specialist, Office of Acquisitions & Grant Services, 5630 Fishers Lane, Rm. 2034, Rockville, MD 20857, phone: 301–827–7177.


Leslie Kux,
Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0345]

Food and Drug Administration/National Institutes of Health/National Science Foundation Public Workshop on Computer Methods for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing its fi fth public workshop on Computer Methods for Medical Devices entitled “FDA/NIH/NSF Workshop on Computer Models and Validation for Medical Devices.” The purpose of the workshop is to present, discuss, and receive input on an FDA library of models and data relevant to medical devices (day 1) and present, discuss, and receive input on a strategy to assess the credibility of computer models used to evaluate medical devices (day 2). Dates: Dates and Times: The workshop will be held on June 11 and 12, 2013, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting 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 Persons: Donna Lochner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3220, Silver Spring, MD 20993, 301–796–6309.

Donna.Lochner@fda.hhs.gov; or Tina M. Morrison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1272, Silver Spring, MD 20993, 301–796–6310.

Tina.Morrison@fda.hhs.gov.

Registration: Registration is free and will be on a first-come, first-served basis. Persons interested in attending the public workshop must register online by 4 p.m. on May 31, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

To register for the public workshop, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. Select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Susan Monahan to register (301–796–5661 or Susan.Monahan@fda.hhs.gov).

Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (Susan.Monahan@fda.hhs.gov or 301–796–5661) no later than May 28, 2013.

Streaming Webcam of the Public Workshop: This workshop will also be available via Webcam. Persons interested in viewing the Webcam must register online by 4 p.m. on May 31, 2013. Early registration is recommended because Webcam connections are limited. Organizations are requested to