Specifically, 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 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.**) 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.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–07948 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–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 fifth 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 this 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 Webcast of the Public Workshop: This workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 4 p.m. on May 31, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to

register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after June 4, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview*. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on the topics identified in Section II of this document. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is July 10, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please 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, and will be posted to the docket at *http://www.regulations.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Devices and Radiological Health (CDRH) believes that computer modeling and simulation (M&S) has the potential to substantially augment traditional models used to evaluate medical devices; i.e., animal, bench, and human models, and to accelerate and streamline the total product life cycle of a medical device. The use of computer models to simulate multiple use conditions and to visualize and display complex processes and data can revolutionize the way medical outcomes and medical devices are understood. Nonproprietary computer models could benchmark device performance, yet lack of access to biomedical data to construct the models and rigorous methods to validate the models limit their credibility and use. Before substantial advances in the use of M&S for regulatory decision making can be attained, a strategy and consistent framework to assess the credibility of M&S is needed. Moreover, to foster good science for M&S in the medical device community, CDRH needs to leverage the expertise in industry and academia to develop a strategy to scientifically assess the credibility of M&S and to develop a resource to publicize biomedical data, models and their validation for regulatory use.

II. Topics

Historically, M&S have been used as development and design optimization tools, rather than methods by which performance of final devices can be demonstrated. Further, modeling studies that are submitted to the Agency are supplemental and complement animal, bench and human testing provided in:

- Investigational Device Exemptions (investigational devices),
- 510(k) notifications (class II devices), and
- Pre-Market Approval applications (class III devices).

Some of the challenges with the current uses of M&S are:

- Reports typically lack sufficient details for adequate assessment because there are no reporting standards for computational modeling,
- Lack of sensitivity and uncertainty analyses for crucial input parameters, such as geometry, physical properties, boundary conditions,
- Lack of adequate validation to support the use of the computational model, and
- Lack of complete understanding of physiological loads and variations in patient populations.

Adequate verification and validation (V&V) are necessary in order to foster confidence and wider acceptance of M&S for use in medical device evaluation. Therefore, CDRH, in collaboration with the American Society of Mechanical Engineers, has been drafting a guide on the ''Verification and Validation of Computational Modeling for Medical Devices.'' The strategy is meant to create a framework for determining the risk associated with using a computational model in a specific context of use (COU) to inform decision making and for determining ''how much'' V&V is necessary to support the model for its COU. The two main components of this strategy are the Risk Assessment Matrix and the Credibility Assessment Matrix. Both of these tools will be presented and discussed at the workshop. Note that these tools are still in DRAFT format.

The workshop will also describe and discuss FDA's efforts to create a resource or Library of biomedical data and models that can be used in regulatory applications. Key features and questions related to development of the Library and curation of data and models for the Library will be discussed. The goal of the FDA/NIH/NSF Workshop on Computer Modeling and Validation for Medical Devices is to discuss and receive input on these tools to enhance their utility in the community.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07923 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Highly Potent and Selective Deubiquitinating Enzyme Inhibitor

Description of Technology: Available for licensing are inhibitors that target the USP1/UAF1 deubiquitnating enzyme (DUB) complex. The FDA approval and commercial success of