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 September 22, 2011, the committee will discuss BLA 125397, Umbilical Cord Blood, New York Blood Center, indicated for hematologic malignancies, bone marrow failure, primary immunodeficiency diseases, beta thalassemia, Hurler syndrome, Krabbe disease, and X-linked adrenoleukodystrophy. On September 23, 2011, the Committee will discuss HDE BH110018, CliniMACS CD34 Selection System, Miltenyi Biotec, for processing allogeneic HLA-matched hematopoietic progenitor cells-apheresis (HPC–C) from a related donor to obtain a $CD34^+$ Cell population intended for hematopoietic reconstitution following a Myeloablative preparative regimen without the need for additional graft-vs-host disease (GVHD) prophylaxis in patients with acute myelogenous leukemia in first or second morphologic complete remission.

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/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 September 15, 2011. Oral presentations from the public will be scheduled on September 22, 2011, between approximately 11 a.m. and 12 noon and on September 23, 2011, 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 September 7, 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 September 8, 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).

Dated: August 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20399 Filed 8–10–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Food and Drug Administration/National Heart, Lung, and Blood Institute/National Science Foundation Public Workshop on Computer Methods for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''FDA/NHLBI/NSF Workshop on Computer Methods for Medical Devices.'' FDA is cosponsoring the conference workshop with the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health and the National Science Foundation (NSF). The purpose of the workshop is to facilitate discussion between FDA and other interested parties on the use of computational modeling in the design, development and evaluation of medical devices.

Dates and Times: The public workshop will be held on September 7, 8, and 9, 2011, from 9 a.m. to 5 p.m. An optional FDA Microstructure Modeling session will be held from 1 to 5 p.m. on September 6, 2011. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Security screening will begin at 8 a.m. Persons interested in attending this public workshop must register by 5 p.m. on August 30, 2011.

Location: The public workshop and optional session will be held at the FDA White Oak Campus, 10903 New Hampshire Ave, Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002.

Contact Persons: Donna R. Lochner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3220, Silver Spring, MD 20993–0002, 301–796–6309, *e-mail: 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 20993–0002, 301–796–6310, *e-mail: tina.morrison@fda.hhs.gov.*

Registration: To register for the public workshop and optional session, please visit the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go to *http://www.fda.gov* and select the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. For those without Internet access, please call the contact person to register. Registration is mandatory as space is limited and onsite registration will not be available. FDA may limit the number of participants from each organization. There is no registration fee for the public workshop.

Registrants requesting to present written materials or to make oral presentations at the public workshop, please call the contact persons by August 23, 2011.

If you need special accommodations because of a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring,

MD 20993–0002, 301–796–5661 at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Why are we holding this public workshop?

The purpose of the public workshop is to facilitate discussion between FDA and other interested parties on the use of computational modeling in medical device design, development and evaluation.

II. What are the topics we intend to address at the public workshop?

We hope to discuss a large number of issues at the public workshop, with our overall theme being the validation of computer models with nonclinical models. Topics include, but are not limited to the following:

- Advancing Computational Modeling Studies—how is computational modeling being used for device design, development, and/or evaluation?
- Best Validation Practices—what validation scheme has worked for computational model systems?
- Lessons Learned—what validation schemes have been unsuccessful for computational model systems?
- Data Resources—where are data for boundary conditions, loading conditions, material properties, etc. obtained for model systems?

III. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, food services, and other relevant information will be posted, as it becomes available, on the Internet at: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go to *http://www.fda.gov* and select the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list).

Dated *August 8, 2011.*

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20446 Filed 8–10–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

The Development and Evaluation of Next-Generation Smallpox Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) and the National Institutes of Health, the National Institute of Allergy and Infectious Diseases are announcing a public workshop entitled ''The Development and Evaluation of Next-Generation Smallpox Vaccines.'' The purpose of the public workshop is to identify and discuss the key issues related to the development and evaluation of next-generation smallpox vaccines. The public workshop will include presentations on the human response to smallpox vaccines and development of animal models for demonstration of effectiveness of next-generation smallpox vaccines.

Date and Time: The public workshop will be held on September 16, 2011, from 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Bernadette Williamson-Taylor, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, *Fax:* 301–827–3079, *e-mail: CBERTraining@fda.hhs.gov* (in the subject line type ''Smallpox Workshop'').

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by August 23, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Bernadette Williamson-Taylor (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Smallpox is a serious, highly contagious, and sometimes fatal infectious disease. Although the World Health Organization declared the disease eradicated in 1980, the threat of smallpox as a biological weapon remains. Vaccination is the only prevention for the disease and there are currently no FDA-approved treatments.

First-generation smallpox vaccines were prepared on the skin of calves or other animals or in chicken eggs. Although these vaccines were not evaluated for efficacy in well-controlled trials, they were highly effective as evidenced by the successful global eradication of smallpox. Manufacturing of these vaccines has ceased and they are no longer licensed in the United States.

In 2007, FDA licensed the first second-generation smallpox vaccine, ACAM2000. This vaccine is based on a single plaque-purified vaccinia virus derivative of Dryvax (a previously licensed first-generation vaccine) and is aseptically propagated using cell culture technology under modern manufacturing practices and standards. Both ACAM2000 and Dryvax are derived from the New York City Board of Health strain and produce a vesicular or pustular lesion (referred to as a ''vaccine take'') that has been shown to correlate with protection. In clinical trials, ACAM2000 elicited vaccinia-neutralizing antibodies and cell-mediated immune responses, with both clinical and immunological outcomes similar to Dryvax.

Because ACAM2000 may cause serious adverse reactions, there is a desire to develop safer vaccines should there be a need to vaccinate the general population due to a threat of an attack with the smallpox virus. Currently, the next-generation smallpox vaccines under development do not produce the characteristic ''vaccine take.'' In addition, it is not ethical or feasible to evaluate the effectiveness of these vaccines in humans as the natural disease has been eradicated. Therefore, the effectiveness of these next-generation smallpox vaccines may be based on animal efficacy data, if scientifically appropriate, and to comparative human immune response data. As for any biologic product, licensure of new smallpox vaccines requires demonstration of safety, purity, and potency.

The public workshop will: (1) Discuss regulatory challenges and approaches related to the licensure of next-generation smallpox vaccines; (2) discuss the strengths and weaknesses of various animal models relative to their ability to mimic human disease that can be used to predict the effectiveness of