

requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of July 30, 2009 (74 FR 38033), FDA published a notice announcing the availability of a draft guidance entitled "E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions." The notice gave interested persons an opportunity to submit comments by September 28, 2009.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in September 2010.

The guidance provides recommendations on the context, structure, and format of qualification submissions as follows:

- The proposed context of use of a biomarker corresponds to the data supporting its qualification. The context of use of a biomarker in a biomarker

qualification can be narrow or broad—the biomarker(s) might be useful for only a single drug or biotechnology product, for several drug or biotechnology products in a drug class, or even across several drug classes.

- The structure of the submission should be consistent regardless of the context proposed and flexible enough to deal with the specific attributes of each submission. In addition, use of the recommended structure should facilitate submission and review of future biomarker qualification submissions expanding the use of the biomarker to new contexts, as would be the case if, for example, a nonclinical context of use expands to a clinical context of use.

- The format of the data for qualifying a biomarker can vary significantly depending on the context. The format should support an evaluation of the data and can include reports, tabulations, and raw data (if requested by regulatory authorities according to the relevant practices in place).

The application structure described in this guidance is intended for biomarker qualification submissions after sufficient supporting data have been generated. However, this structure can also be considered for submissions intended to obtain scientific advice from regulatory authorities before or during the generation of the biomarker data intended to support qualification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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 the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: August 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 22 and 23, 2011, from 8 a.m. to 5 p.m.

Location: Hilton Hotel, Washington, DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20977, 301-977-8900. For those unable to attend in person, the meeting will also be available by Web cast. On September 22, 2011, the link for the Web cast is available at <http://fda.yorkcast.com/webcast/Viewer/?peid=637f14248dca4236a5f9a3b622e6501e1d>. On September 23, 2011, the link for the Web cast is available at <http://fda.yorkcast.com/webcast/Viewer/?peid=2e8b3eb7638d42ca9652c328a854efb51d>.

Contact Person: Gail Dapolito or Sheryl Clark (HFM-71), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20853, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a

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.

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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,