

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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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). At least one portion of the meeting will be closed 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 by teleconference on February 5, 2008, from 12 noon to approximately 3:15 p.m. Eastern Time.

Location: National Institutes of Health, Building 29B, Conference Room C, 9000 Rockville Pike, Bethesda, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the specified location. A speakerphone will be provided at the specified location for public participation in the meeting, on site. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at <http://www.nih.gov/about/visitor/index.htm>. Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and

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park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at <http://www.nih.gov/about/visitorssecurity.htm>. Because of the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Gail Dapolito or Danielle Cubbage, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512389. 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 February 5, 2008, the committee will meet in open session to hear updates of research programs in the Division of Therapeutic Proteins and the Division of Monoclonal Antibodies, Office of Biotechnology Products, Center for Drug Evaluation and Research, FDA.

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 will be available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: On February 5, 2008, from 12 noon to approximately 2:30 p.m., the meeting is open to the public. 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 January 29, 2008. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those desiring to make 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 January 21, 2008. 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 person regarding their request to speak by January 22, 2008.

Closed Committee Deliberations: On February 5, 2008, from approximately 2:30 p.m. to 3:15p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and issues related to personnel progress and promotion.

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/oc/advisory/default.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: 12/18/07
December 18, 2007.



Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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