

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier N. Hawkins

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 July 26, 2007 from 11 a.m. to approximately 3:15 p.m.

Location: National Institutes of Health, Bldg. 29B, Conference rms. A/B, 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. 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 park on the NIH

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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/visitorsecurity.htm>. Due to 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 July 26, 2007, the committee will meet in open session to hear updates of research programs in: (1) The Division of Therapeutic Proteins and the Division of Monoclonal Antibodies, Office of Biotechnology Products, Center for Drug Evaluation and Research, FDA and (2) the Division of Cellular and Gene Therapies, Office of Cellular, Tissue, and Gene Therapies, Center for Biologics 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 is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: On July 26, 2007, from 11 a.m. to approximately 2 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 July 12, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 July 18, 2007. 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 July 19, 2007.

Closed Committee Deliberations: On July 26, 2007, from approximately 2:15 p.m. to 3:30 p.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 make recommendations regarding personnel staffing decisions.

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.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 6-11-07

June 11, 2007.



Randall W. Lutter,
Associate Commissioner for Policy and Planning.

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

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