

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Display Date

12-18-07

Publication Date

12-19-07

Certifier

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[Docket No. 2007N-0471]

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 April 10, 2008, from 9 a.m. to approximately 6 p.m. and on April 11, 2008, from 8 a.m. to approximately 12 noon.

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2007N-0471—Scientific Considerations for Safety Testing for Cellular Therapy Products Derived From Human Embryonic Stem Cell" and follow prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on March 26, 2008. All comments received will be posted without change, including any personal information

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provided. Comments received on or before March 26, 2008, will be provided to the committee before or at the meeting.

Location: Hilton DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Gail Dapolito or Danielle Cubbage, Center for Biologics Evaluation and Research (HFM-71), 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 April 10, 2008, the committee will meet to discuss scientific considerations for safety testing for cellular therapy products derived from human embryonic stem cells. On April 11, 2008, the committee will meet to discuss updates on the following topics: (1) Research management related to the September 29, 2005, review of research programs of the Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research; (2) FDA's Somatic Cell Therapy Letter; and (3) recently released FDA guidance documents.

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 2008 and 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 April 3, 2008. Oral presentations from the public will be scheduled on April 10, 2008, between approximately 1:45 p.m. and 2:15 p.m. and on April 11, 2008, between approximately 10:15 a.m. and 10:45 a.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 March 26, 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 persons regarding their request to speak by March 27, 2008.

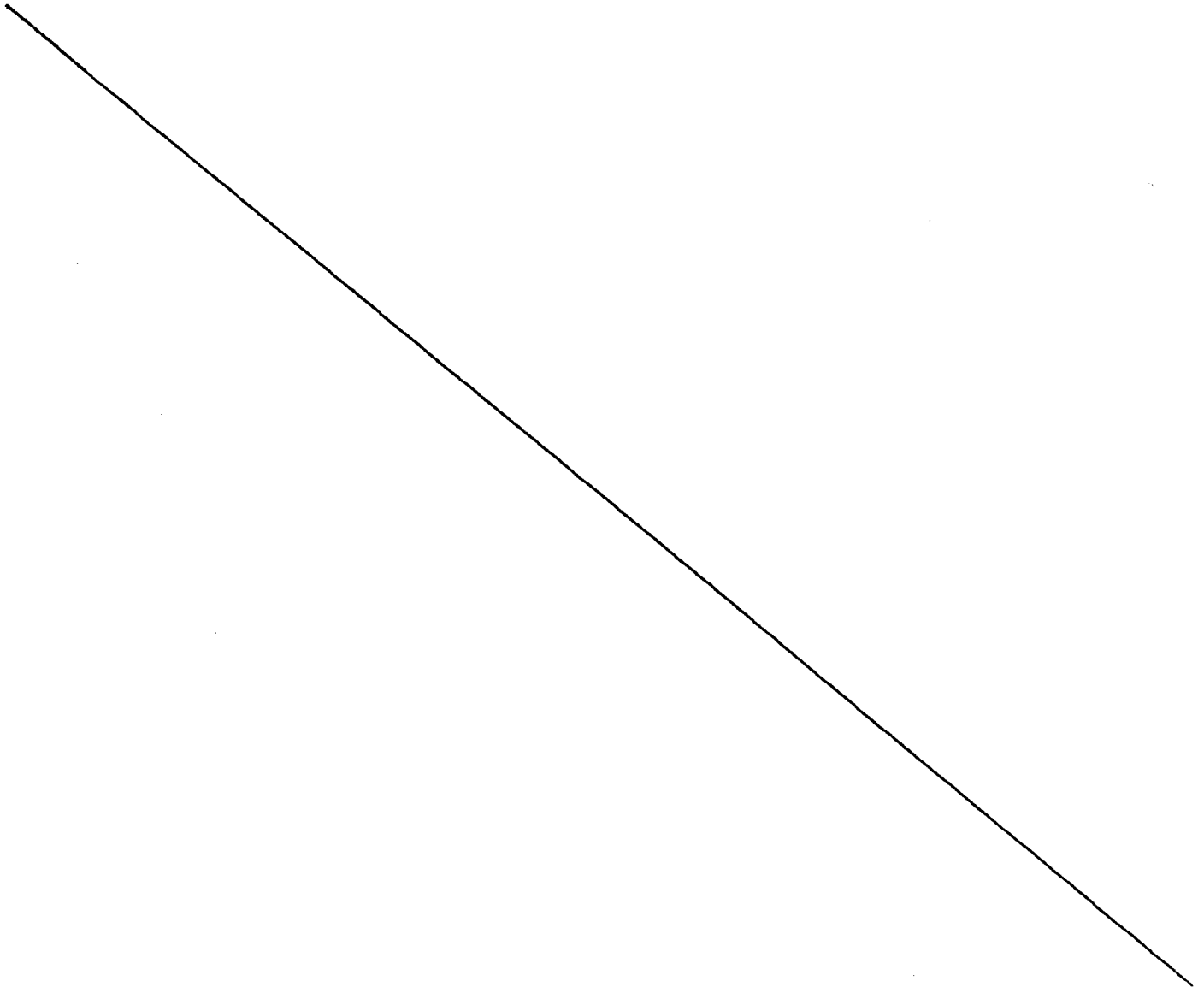
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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.

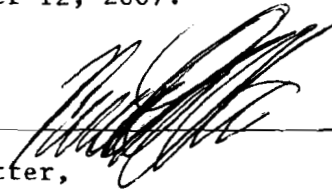
FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

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



Dated: 12/12/07
December 12, 2007.

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Randall W. Lutter,
Deputy Commissioner for Policy.

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

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