

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cellular, Tissue and Gene Therapies Advisory Committee (formerly Biological Response Modifiers 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, via teleconference, on July 29, 2005, from 12:30 p.m. to 2:30 p.m.

Location: National Institutes of Health, Bldg. 29B, conference room C, 8800 Rockville Pike, Rockville, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the previously mentioned location. A speakerphone will be provided at the specified location for public participation in the meeting.

Contact Person: Gail Dapolito, 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.

Agenda: In open session, the committee will hear brief opening remarks and allow time for public participation and comments related to individual FDA research programs during the open public hearing. The committee will not hear presentations or discuss individual research programs in the open session (see *Closed Committee Deliberations* below).

Procedure: On July 29, 2005, from 12:30 p.m. to 1:30 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 by July 21, 2005. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 21, 2005, 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.

Closed Committee Deliberations: On July 29, 2005, from approximately 1:30 p.m. to 2:30 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 a review of individual FDA research programs.

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

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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: June 23, 2005.

Sheila Dearybury Walcott,

Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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