

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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Certifier R. LEDESMA

**Biological Response Modifiers Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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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:* Biological Response Modifiers 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 March 18, 2004, from approximately 8:30 a.m. and 5 p.m.; and on March 19, 2004, from approximately 8:30 a.m. to 3 p.m.

*Location:* Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD.

*Contact Person:* Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3014, e-mail [dapolito@cber.fda.gov](mailto:dapolito@cber.fda.gov), 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:* On March 18 and 19, 2004, the committee will discuss issues related to the design of early phase clinical trials of cellular therapies for the treatment of cardiac diseases.

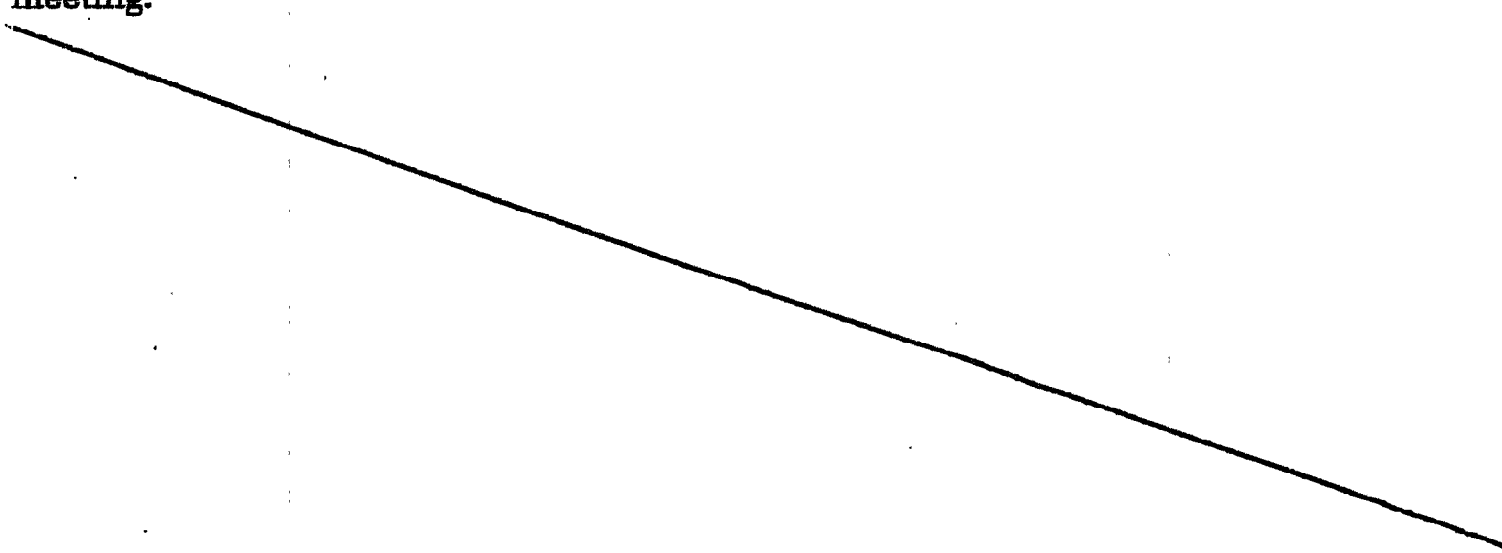
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*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 11, 2004. Oral presentations from the public will be scheduled on March 18, 2004, between approximately 4:30 p.m. and 5 p.m.; and on March 19, 2004, between approximately 9:50 a.m. and 10:20 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 11, 2004, 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.


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: 12/22/03  
December 22, 2003.

  
Peter W. Pitts,  
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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