

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: 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 is closed 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 May 9, 2002, from 8 a.m. to 6:30 p.m. and on May 10, 2002, from 8 a.m. to 3 p.m.

Location: Hilton Hotel, DC North-Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Gail Dapolito, Center for Biologics Evaluation and Research (HFM-71) or Rosanna L. Harvey, 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 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 9, 2002, at 8 a.m., the committee will receive updates of research programs in the Division of Therapeutic Proteins and the Division of Monoclonal Antibodies; at 9 a.m., the committee will discuss issues related to ooplasm transfer in assisted reproduction. On May 10, 2002, the committee will discuss issues related to inadvertent germline transmission of gene transfer vectors.

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Procedure: On May 9, 2002, from 8 a.m. to 8:45 a.m. and from 9 a.m. to 6:30 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 May 2, 2002. Oral presentations from the public are scheduled between approximately 3:35 p.m. and 4:05 p.m. on May 9, 2002, and from 11:40 a.m. to 12:10 p.m. on May 10, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 2, 2002, 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 May 9, 2002, from 8:45 a.m. to 9:00 a.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 the review of research programs in the Division of Therapeutic Proteins and Division of Monoclonal Antibodies.

FDA regrets that it was unable to publish this notice 15 days prior to the May 9 and 10, 2002, Biological Response Modifiers Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Biological Response Modifiers Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

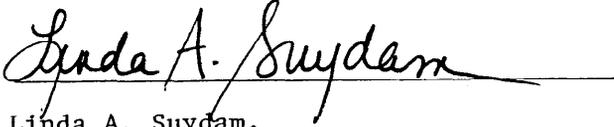
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodation due to a disability, please contact Gail Dapolito or Rosana L. Harvey at least 7 days in advance of the meeting.

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

2).

Dated: 4-23-02

April 23, 2002.



Linda A. Suydam,
Senior Associate Commissioner for
Communications and Constituent Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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