

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMS

Display Date	3/19/01
Publication Date	3/20/01
Certifier	[Signature]

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: 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 April 5, 2001, from 9 a.m. to 6 p.m. and on April 6, 2001, from 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Gail M. Dapolito (HFM-71), or Rosanna L. Harvey (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 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 April 5 and 6, 2001, the committee will meet to discuss: (1) Responses to the March 6, 2000, FDA gene therapy letter (<http://www.fda.gov/cber/letters.htm>); (2) results of gene therapy clinical site inspections, (3) long-term followup of gene therapy patients, and (4) the FDA proposed rule entitled "Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation" (<http://www.fda.gov/cber/rules.htm>). In addition, the committee will receive

an update on two research programs in the Division of Cellular and Gene Therapies and the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research.

Procedure: On April 5, 2001, from 9 a.m. to 5:15 p.m. and on April 6, 2001, from 8:30 a.m. to 3:30 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 March 26, 2001. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m. on April 5, 2001, and between approximately 11 a.m. to 11:30 a.m. on April 6, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 26, 2001, 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 April 5, 2001, from 5:15 p.m. to 6 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. 5552b(c)(6)). The committee will discuss reports of the review of research programs in the Division of Cellular and Gene Therapies and the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research.

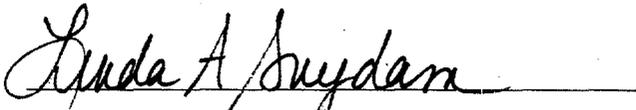
Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

MAR 12 2001

Dated: _____

March 12, 2001



Linda A. Snyder,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

