

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DmS

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Certifier A. Corbin

Biological Response Modifiers Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Biological Response Modifiers Advisory Committee. This meeting was originally announced in the **Federal Register** of September 27, 2002 (67 FR 61142). The amendment is being made to reflect a change in the *Date and Time, Agenda, Procedure, Location, and Closed Committee Deliberations* portions of the meeting. The meeting was originally scheduled as a teleconference on October 10, 2002, from 5:30 p.m. to 7:30 p.m. at the National Institutes of Health, Bldg. 29C, 29 Lincoln Dr., Bethesda, MD. FDA added a discussion topic related to retrovirus vectors in gene therapies for the treatment of patients with severe combined immune deficiency disease to the meeting and the meeting will be held on October 10 at the Hilton DC North—Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD from 8 a.m. to 5 p.m.

**FOR FURTHER INFORMATION CONTACT:** Gail Dapolito 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 call the 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.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 27, 2002 (67 FR 61142), FDA announced that a meeting of the Biological Response Modifiers Advisory Committee would be held on October 10, 2002. This amendment is to update information provided earlier pertaining to the meeting. On page 61142, beginning in the last column, the *Date and Time*, *Location*, *Agenda*, *Procedure*, and *Closed Committee Deliberations* portions of the meeting are amended to read as follows:

*Date and Time:* The meeting will be held on October 10, 2002, from 8 a.m. to approximately 5:30 p.m.

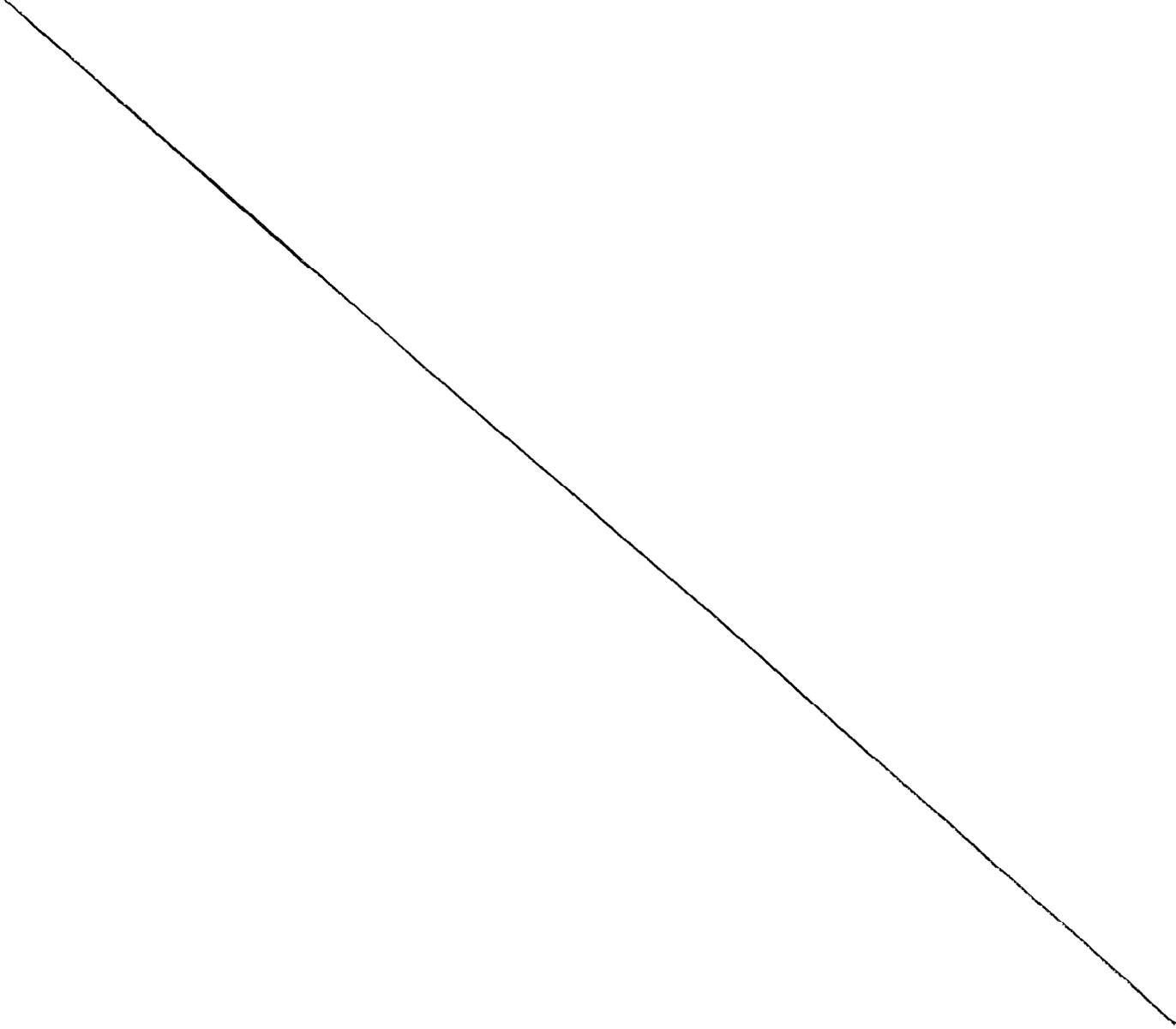
*Location:* Hilton DC North—Gaithersburg, Grand Ballrooms A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

*Agenda:* On October 10, 2002, the committee will discuss safety issues recently identified related to retrovirus vectors in gene therapies for the treatment of patients with severe combined immune deficiency disease and receive updates on individual research programs in the Division of Cell and Gene Therapies and the Division of Therapeutic Proteins.

*Procedure:* On October 10, 2002, from 8 a.m. to 5 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 October 9. Oral presentations from the public will be scheduled between approximately 11:30 a.m. to 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 9, 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 October 10, 2002, between approximately 5 p.m. and 5:30 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 reports of individual research programs in the Center for Biologics Evaluation and Research.



This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: Oct 2, 2002  
October 2, 2002.

  
Linda Arey Skladany,  
Senior Associate Commissioner for  
External Relations.

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

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