Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 3.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective May 29, 2002.

Dated: March 21, 2002.

Janet Woodcock,
Director, Center for Drug Evaluation and Research.

[FR Doc. 02–10425 Filed 4–26–02; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 Institute, Welsh and McKean Rds., Spring House, PA 19477–0776.

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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.

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)). 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).

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

[SFR Doc. 02–10508 Filed 4–24–02; 3:29 pm]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 01D–0311]

Medical Devices: Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Final Guidance for Industry Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA.” This document describes a means by which the endolymphatic shunt tube with valve may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the Federal Register, FDA is publishing a rule classifying endolymphatic shunt tubes with valve into class II (special controls).

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESS: Submit written requests for single copies on a 3.5” diskette of the guidance document entitled “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301–443–8018. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Eric Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 15, 2001 (66 FR 42809), FDA published a proposed rule to reclassify the endolymphatic shunt tube with valve from class III (premarket approval) into class II (special controls) based on new information regarding this device. E. Benson Hood Laboratories, Inc. (Hood Laboratories), submitted the new information in a reclassification petition. FDA also identified the document “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Draft Guidance for Industry and FDA” as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the draft guidance by November 13, 2001. FDA received one comment. The comment, from the petitioner, Hood Laboratories, strongly supported the draft guidance as the proposed special control.

FDA has since revised the draft guidance to provide manufacturers the option of submitting an abbreviated 510(k) to further reduce regulatory burden.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive the document “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA” via your fax machine, call the CDRH Facts-On-Demand system at 800–