

NDA No.	Drug	Applicant
11-419	Sterisol Mouthwash and Gargle.	Warner-Lambert Co., 170 Tabor Rd., Morris Plains, NJ 07950.
12-542	Oxalid (oxyphenbutazone) Tablets.	Novartis Pharmaceuticals Corp.
13-273	Nitrofurantoin Tablets.	Albran, Inc., 68-43 Juno St., Forest Hills, NY 11375.
16-000	Sulla (sulfameter) Tablets	Berlex Laboratories, Inc.
17-071	Benzedrine (amphetamine sulfate) Spansule Capsules.	Smith Kline & French Laboratories, 1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101.
17-098	Selenomethionine Se-75 Injection.	Mallinckrodt, Inc., 675 McDonnell Blvd., P.O. Box 5840, St. Louis, MO 63134.
17-109	Prednisone Tablets USP, 20 milligrams (mg).	Roxane Laboratories, Inc., P.O. 16532, Columbus, OH 43216-6532.
17-282	Technetium Tc-99m Sulfur Colloid Kit.	E. I. duPont de Nemours & Co., Inc., 331 Treble Cove Rd., North Billerica, MA 01862.
17-454	Osteoscan (Technetium Tc-99m Etidronate Kit).	Mallinckrodt, Inc.
17-518	Ytterbium Yb-169 DTPA.	3M Health Care Group, 3M Center, St. Paul, MN 55144-1000.
17-678	Technetium Tc-99m Pyrophosphate Kit.	Syncor International Corp., 12847 Arroyo St., Sylmar, CA 91342.
17-704	Dantrium Oral Suspension.	Norwich Easton Pharmaceuticals, Inc., P.O. Box 191, Norwich, NY 13815-00191.
18-102	Medrol (methylprednisolone acetate) Enpak Kit.	The Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199.
18-121	Catarase Ophthalmic Solution.	Novartis Pharmaceuticals Corp.
18-236	ZOMAX (zomepirac sodium) Tablets.	The R. W. Johnson Pharmaceutical Research Institute, Welsh and McKean Rds., Spring House, PA 19477-0776.
18-297	Allopurinol Tablets USP, 100 and 300 mg.	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
19-421	Exidine Solution.	Xttrium Laboratories, Inc., 415 West Pershing Rd., Chicago, IL 60609.
50-043	Keflin (cephalothin sodium) Injection.	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
50-219	Kafocin.	Do.
50-469	Keflin, Frozen Neutral.	Do.
50-501	Velosef Injection.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-6837.
50-540	Mandol Injection.	Lilly Research Laboratories.

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 5.82), 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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective May 29, 2002.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 (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.

*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: April 23, 2002.

**Linda A. Suydam,**

*Senior Associate Commissioner for Communications and Constituent Relations.*  
[FR 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 final rule classifying endolymphatic shunt tubes with valve into class II (special controls).

**DATES:** Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** 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 301-443-8818. 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 to 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-