

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices 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). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices 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 July 23, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) Premarket approval application (PMA) for a toric intraocular lens for primary implantation for the visual correction of aphakia, and (2) PMA for an excimer laser for the surgical correction of hyperopia, sphere only, using photorefractive keratotomy.

Procedure: 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 July 15, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. An additional 30-minute time period will be given for public comment at the end of committee discussion and prior to voting on each PMA. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 12, 1998, 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 18, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-17075 Filed 6-25-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that published in the **Federal Register** of June 11, 1998 (63 FR 32014). The notice announced a meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee, which is scheduled for June 29 and 30, 1998. The notice published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Anita Prout, Committee Management Office (HFA-306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5503.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 11, 1998 (63 FR 32014), in FR Doc. 98-15602, FDA announced that a meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee would be held on June 29 and 30, 1998. The notice incorrectly published the agenda for June 30, 1998.

Beginning on page 32014, in the 2d column, under the *Agenda* portion of the meeting, the agenda for June 30, 1998, should be corrected to read: "On June 30, 1998, the committee will discuss and make recommendations on clinical issues related to antimicrobial coatings on permanent cardiovascular implants, such as heart valves and vascular grafts."

Dated: June 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-17143 Filed 6-23-98; 5:02 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs 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). The meeting will be open to the public.

Name of Committee: Nonprescription Drugs 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 July 28 and 29, 1998, 8:30 a.m. to 5 p.m.

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

Contact Person: Rhonda W. Stover or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 28, 1998, the committee will discuss class labeling for over-the-counter (OTC) vaginal antifungal drug products. In the **Federal Register** of February 27, 1997 (62 FR 9024), the agency published a proposed rule intended to enable consumers to better read and understand OTC drug product labeling and to better apply this information in the labeling to the safe and effective use of such products. An important element of FDA's proposed rule is a standardized labeling format for OTC drug products. The agency has developed class labeling for OTC vaginal antifungal drug products in accordance with the February 27, 1997, proposed rule. The committee will also discuss the agency's draft guidance document for industry entitled "Class Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)" and other related issues. The draft guidance document is intended to provide guidance for both the carton and the educational brochure. In the next several weeks after publication of this notice, a copy of the draft guidance