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Food and Drug Administration
Meetings: Nonprescription Drugs Advisory Committee, << 34902>> -34903

★ First Match

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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 20557, 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-tc-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 The committee will also discuss the agency's draft guidance document for industry entitled ''Class Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)'' and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 The draft guidance document is intended to provide guidance for both the carton and the educational brochure. In the next several weeks after publication of this notice, a copy of the draft guidance

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document for industry will be on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. A copy of the draft guidance document will also be available on the Internet at ``http://www.fda.gov/cder/guidance/index.htm''.

On July 29, 1998, the committee will discuss effectiveness testing for final formulations of health-care antiseptic drug products relative to performance expectations for these OTC drug products. In the Federal Register of June 17, 1994 (59 FR 31402 through 31452), the agency published a proposed rule for OTC health-care antiseptic drug products, i.e., patient preoperative skin preparations, surgical hand scrubs, and health-care personnel and antiseptic handwashes. Included in the proposed rule are key characteristics for each drug product class of health-care antiseptic drug products (i.e., definitions), a requirement for final formulation testing, effectiveness standards, and labeling of each of the drug product categories. In response to the proposed rule, the agency received comments to consider six drug product categories (preoperative skin preparation, surgical hand scrub, health-care personnel handwash, food handler handwash, antimicrobial handwash, and antimicrobial bodywash). Comments also proposed alternate: (1) Testing requirements, (2) key characteristics, and (3) labeling for each of the categories. FDA is seeking the recommendations of the committee and experts on appropriate performance expectations for OTC health-care antiseptic drug products and how these final formulations should be tested.

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 21, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 28 and 29, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 21, 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.
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