a copy to the home district, which includes the following language:

''While this inspection found deficiencies concerning (insert 'premarket notification (510(k)),' 'labeling,' or both as appropriate] that would warrant a warning letter if uncorrected, your written response has satisfied us that you either have taken or are taking appropriate corrective actions. At this time, FDA does not intend to take further action based on these inspectional findings. The agency is relying on your commitment regarding corrective actions and, should we later observe that these deficiencies have not been remedied, future regulatory action (e.g. seizure, injunction and civil penalties) may be taken without further notice.''

When a CDRH decision is made not to send a warning letter due to a satisfactory written response from the firm, the district should classify the inspection as VAI and the profile as acceptable for the labeling or 510(k) issues.

When no warning letter is issued, as described previously, and the next inspection of the firm discloses significant 510(k) and/or labeling deficiencies, then FDA personnel should proceed as if a warning letter had been issued for the previous inspection and consider appropriate enforcement action.

C. Administrative

Copies of all warning letters will be forwarded to the Division of Compliance Management and Operations (DCMO), Office of Enforcement (OE)(HFC–210). When Warning Letters are not issued for 510(k) or labeling deficiencies under this pilot, copies of the postinspectional notification letters issued for inspections that are initiated between (insert initiation date) and (insert date that is 18 months after the initiation date) should be sent to Jeffrey B. Governale, Division of Compliance Policy (DCP)/OE, HFC–230.

CDRH's OC will monitor the warning and postinspectional notification letters and evaluate the pilot 1 year after it begins. Any questions about this pilot should be directed to Chester T. Reynolds, OC/CDRH, HFZ–300.

II. Request for Comments

Interested persons may, on or before October 13, 1998, submit to the Dockets Management Branch (address above) written comments on the draft pilot. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The agency will review all comments, but in issuing a final pilot program need not specifically address every comment. The agency will make changes to the draft pilot in response to comments, as appropriate. Copies of the draft pilot and received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

A copy of the draft pilot may also be downloaded to a personal computer with access to the World Wide Web (WWW). The Office of Regulatory Affairs (ORA) and the CDRH home pages include the draft pilot and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cdrh'', respectively. The draft pilot will be available on the compliance references or compliance information pages for ORA and CDRH, respectively.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23027 Filed 8–26–98; 8:45 am]

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 with representation from the Anti-Infective Drugs and Reproductive Health Drugs Advisory Committees.

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 September 11, 1998, 8:30 a.m. to 5 p.m.

Location: Holiday Inn-Bethesda, 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: The committee with representation from the Anti-Infective and Reproductive Health Drugs Advisory Committees 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 and 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 educational brochure. Single copies of the guidance document can be obtained by contacting the Drug Information Branch, Division of Communications Management (HFD–210), 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573 or the Internet ''http://www.fda.gov/cder/guidance/index.htm''.

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 September 4, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 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: August 20, 1998.

Sharon Smith-Holston,

Acting Commissioner of Food and Drugs.

[FR Doc. 98–23025 Filed 8–26–98; 8:45 am]

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