Dated: July 31, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–23031 Filed 8–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0645]

Medical Device Warning Letter Draft Pilot; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is planning to initiate a pilot program involving the medical device industry that is a continuation of the ''medical device industry initiatives.'' This draft pilot concerns the issuance of warning letters for quality system, premarket notification submission (510(k)), and labeling violations. This draft pilot is intended to optimize resource utilization, enhance communication between industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. The draft pilot includes eligibility criteria and procedures for the issuance of warning letters and will not be implemented until after the public comment period has expired.

DATES: Written comments on the draft pilot may be submitted by October 13, 1998.

ADDRESSES: Submit written comments on the draft pilot to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft pilot.

FOR FURTHER INFORMATION CONTACT:

Device quality system warning letter draft pilot: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, FAX 301–827–0482.

Premarket notification (510(k)) and labeling warning letter draft pilot: Chester T. Reynolds, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4618, FAX 301–594–4610.

SUPPLEMENTARY INFORMATION:

I. Background

During recent FDA/medical device industry grassroots forums, several issues were discussed concerning FDA's interaction with the medical device industry. After considering these issues, the agency plans to initiate a pilot program that will last for 18 months, and then be formally evaluated. The draft pilot includes procedures for the issuance of warning letters for quality system (21 CFR part 820), 510(k) (part 807, subpart E) (21 CFR part 807, subpart E), and labeling (e.g., 21 CFR part 800, subpart B; part 801, and part 809, subparts B and C) violations. This draft pilot is currently restricted to the medical device industry and is a continuation of the medical device industry initiatives.

FDA currently maintains contracts with the States of California, Colorado, and Texas that will expire on September 30, 1998, to conduct medical device inspections on behalf of FDA. This draft pilot does not include those inspections done under State contract for FDA. However, noncontract medical device inspections done by FDA personnel in these States will be eligible for this draft pilot.

The purpose of this draft pilot is to optimize resource utilization, enhance communication between the medical device industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. Implementation of this draft pilot will not impact on violative situations where enforcement action is necessary to protect the public health.

The medical device warning letter draft pilot is being issued as a guidance document and represents the agency's current thinking on the subject. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This pilot is being issued as a draft level 1 guidance consistent with GGP's.

The draft pilot consists of two parts that are described as follows:

I. Device Quality System Warning Letter Draft Pilot

Dates: (insert initiation and ending dates 18 months apart)

This draft pilot is restricted to the medical device industry and is a continuation of the medical device industry initiatives.

Following a domestic device quality system inspection which finds current good manufacturing practice (CGMP) deficiencies (situation 1, compliance program (CP) 7382.830—part V) that warrant a warning letter, the establishment is to be given 15 working days to respond from the issuance date of the list of inspectional observations (FDA–483). If the firm's written response to the FDA–483 is deemed to be satisfactory by the district office, then a warning letter should not be issued.

This draft pilot does not apply to:

1. Nonquality system inspections such as mammography, radiological health, and bioresearch inspections;

2. Establishments that manufacture devices as well as other FDA regulated products;

3. Establishments that manufacture devices that are regulated by the Center for Biologics Evaluation and Research (CBER);

4. Recidivous establishments as defined in CP 7382.830;

5. An inspection that uncovered CGMP, premarket notification submission (510(k)), or labeling deficiencies that may cause serious adverse health consequences;

6. A compliance followup inspection when the previous inspection resulted in a warning letter or regulatory action for quality system, 510(k), or labeling violations;

7. An inspection that disclosed other significant device violations (e.g., medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action; or

8. A situation where the firm's management failed to make available to FDA personnel all requested information and records required by regulations or laws enforced by FDA.

If the district is essentially satisfied with the written response to the FDA–483 but needs further clarification, it may seek additional information via untitled correspondence, meetings, or telephone.

If the firm fails to respond to the FDA–483, a warning letter should be sent to the establishment once the 15 working day period has expired. If the district receives a response to the FDA–483 within 15 working days, the district has 15 working days from the receipt date to determine whether the response is satisfactory. If it is necessary for the district to consult with the Center for Devices and Radiological Health's Office of Compliance for technical assistance, the latter office has 15 working days to respond to the district and then the district has 15 working days to respond to the establishment. If the written response to the FDA–483 is determined to be unsatisfactory, the district should send a warning letter to the establishment.

When no warning letter is issued by the district office due to the firm's satisfactory written response, the postinspectional notification letter (see attachment 1 of this

document) should be sent to the establishment.

When a decision is made not to send a warning letter due to a satisfactory written response from the firm, the inspection should be classified as voluntary action indicated (VAI) and the profile should be designated as acceptable.

When no warning letter is issued, as described previously, and the next inspection discloses situation 1 CGMP deficiencies, then FDA personnel should proceed as if a warning letter had been issued for the previous inspection and consider appropriate enforcement action. (See the graphic for the device quality system warning letter draft pilot as attachment 2 and table 1 for attachment 3.)

This draft pilot will be evaluated by FDA at the end of the 18-month period.

Copies of all domestic warning letters that include a device CGMP adulteration charge (section 501(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(h))) for inspections that are initiated between (insert initiation date) and (insert date 18 months after start date) should be forwarded to the Division of Compliance Management and Operations (DCMO)/Office of Enforcement (OE) (HFC–210) with a cover page. (See attachment 4 for a copy of this cover page.)

When warning letters are not issued for situation 1 CGMP deficiencies under this draft pilot, copies of the postinspectional notification letters issued for the inspections initiated between the above dates should be sent to Jeffrey B. Governale, Division of Compliance Policy (DCP)/OE (HFC–230).

Any questions concerning this draft pilot should be directed to Jeffrey B. Governale via telephone (301–827–0411), facsimile (301–827–0482), or electronic mail (Jeffrey Governale@OE@FDAORAHQ).

Attachments: As stated

Attachment 1—Model Postinspectional Notification Letter for Device Quality System Warning Letter Draft Pilot

[Name and title of most responsible individual]

[Establishment's name and address]

Dear _____ :

The Food and Drug Administration (FDA) conducted an inspection of your firm's [description] facility at [address] on [date]. The inspection covered the following devices:

[list devices and their profile classes]

At the end of the inspection, the FDA investigator left a list of inspectional observations (FDA–483) at your firm. We have received your firm's written response, dated [date] to that FDA–483. Copies of this response and the FDA–483 are enclosed.

While this inspection found deficiencies of your quality system that would warrant a warning letter if not corrected, 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 the deviations from the quality system regulation have not been remedied, future regulatory action (e.g., seizure, injunction and civil penalties) may be taken without further notice.

Based upon your corrective action, the deficiencies noted during FDA's inspection will not affect applicable pending premarket submissions or export certificates for devices manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other devices and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address the quality system regulation in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits to assure you are continuing to maintain conformance with the quality system regulation.

For further information, please contact the following individual at this office:

[name and telephone number]

Sincerely,

District Director

_____ District Office

Enclosures

bcc:

HFC–230 (Governale)

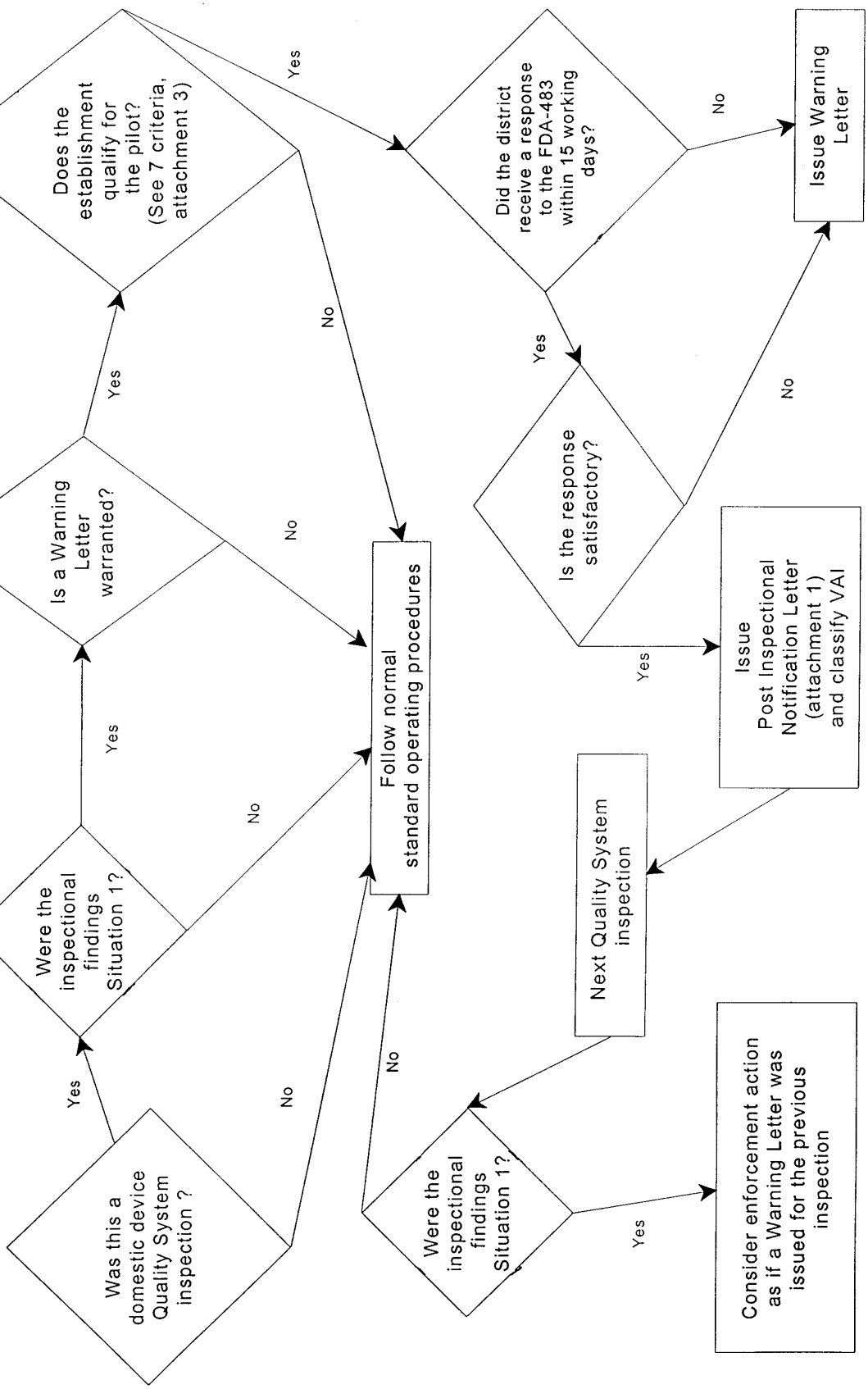
(district office internal distribution)

BILLING CODE 4160–01–F

Attachment 2

Device Quality System Warning Letter Pilot

DRAFT



BILLING CODE 4160–01–C

Attachment 3—Device Quality System Warning Letter Draft Pilot

Important

If one or more of your answers to any of the questions are different than those found in the answer column of this Table, then this pilot does *not* apply to your situation. You should follow FDA's normal standard operating procedures instead.

TABLE 1

Number	Question	Answer
1	In addition to devices, does the establishment manufacture other FDA regulated products?	No
2	Does the establishment manufacture devices that are regulated by CBER?	No
3	Is the establishment a recidivous firm per CP 7382.830?	No
4	Did the inspection uncover CGMP, 510(k), or labeling deficiencies that may cause serious adverse health consequences?	No
5	Was this a compliance followup inspection to a warning letter or regulatory action for quality system, 510(k), or labeling violations?	No
6	Did the inspection disclose other significant device violations in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action?	No
7	Did the firm's management make available to FDA all required information that was requested?	Yes

Attachment 4—Cover Page for the Device Quality System Warning Letter Draft Pilot

To: FDA/ORA/OE/DCMO (HFC–210)
(mailing address: 5600 Fishers Lane, Rockville, MD 20857–001)
From: _____
_____District (HFR–_____)
Establishment's name and address:
Date inspection was initiated:
(This cover page should be attached to each warning letter that includes a device CGMP adulteration charge (under section 501(h) of the act). Please refer to the device quality system warning letter pilot before filling out this cover page.)

The attached warning letter was issued for device CGMP deficiencies for one or more of the following reasons. Please check the appropriate reason(s):

_____ The establishment did not respond to the FDA–483 within 15 working days.

_____ The establishment provided an unsatisfactory response to the FDA–483 within 15 working days.

_____ The establishment manufactures devices as well as other FDA regulated products.

_____ The establishment manufactures devices that are regulated by CBER.

_____ The inspection uncovered CGMP, 510(k), or labeling deficiencies that may cause serious adverse health consequences.

_____ The inspection disclosed other significant device violations (e.g., medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action.

_____ The firm's management failed to make available to FDA personnel all requested information and records required by regulations or laws enforced by FDA.

Please record any comments that the district may have concerning this pilot on the back of this cover page.

II. Premarket Notification (510(k)) and Labeling Warning Letter Draft Pilot

Dates: (insert initiation and ending dates 18 months apart)

A. Background

The impetus for this draft pilot has its origins in FDA grassroots meetings with the medical device industry. During these meetings warning letters, for both premarket notification submission (510(k)) and labeling violations, were identified as topics for discussion. Manufacturers contend that:

1. They are often unaware of the agency's concerns about 510(k) and labeling issues until they receive a warning letter;

2. Information about these concerns is often available at the time of the inspection; and

3. If notified during the inspection manufacturers would have an opportunity to respond, and perhaps resolve, the concerns identified by the investigators.

Consequently, this draft pilot has been developed in response to the device industry's concerns. The purpose of this draft pilot is to determine if notifying firms about 510(k) and labeling issues, in lieu of a warning letter, will result in the efficient resolution of the issues.

B. Draft Pilot Procedures

The 510(k) and labeling warning letter draft pilot does not apply to the following situations:

1. Advertising and promotion issues;

2. Establishments that manufacture devices as well as other FDA regulated products;

3. Establishments that manufacture devices that are regulated by the Center for Biologics Evaluation and Research (CBER);

4. An inspection that uncovered CGMP, 510(k), or labeling deficiencies that may cause serious adverse health consequences;

5. A compliance followup inspection when the previous inspection resulted in a warning letter or regulatory action for quality system, 510(k), or labeling violations;

6. An inspection that disclosed other significant device violations (e.g., medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action;

7. A situation where the firm's management failed to make available to FDA personnel all requested information and records required by regulations or laws enforced by FDA;

8. Devices that were never cleared by FDA via a 510(k) and were not exempted from this requirement (§ 807.81(a)(1) or (a)(2));

9. A major change or modification in the intended use of the device (§ 807.81(a)(3)(ii)); or

10. Electronic products that emit radiation as defined in 21 CFR 1000.3.

Domestic device inspection reports, with endorsements, that identify possible 510(k) violations of § 807.81(a)(3)(i) (a change or modification in the device that could significantly affect the safety or effectiveness of the device) and/or possible labeling violations should be forwarded to the Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), HFZ–306. If CDRH believes that a warning letter situation exits, OC will notify the establishment via an untitled letter within 30 working days. The untitled letter will inform the establishment of the need to correct the violation by submitting either a new 510(k) or an appropriate labeling change. CDRH will send a copy of this letter to the home district. If a warning letter situation/correction is not warranted, OC will notify the district by memorandum, facsimile, or electronic mail. The district will inform the establishment, in writing, that no correction is required.

Firms will have 15 working days from the date of a CDRH untitled letter to respond. CDRH will have 30 working days to evaluate the firm's response. An exception to this timeframe may occur if CDRH has to consult with the district and/or the firm. If CDRH determines that a firm's response is satisfactory, a warning letter should not be issued. If CDRH is essentially satisfied with the firm's response but needs further clarification, it may seek additional information via telephone or untitled correspondence.

If a firm fails to respond to CDRH's untitled letter, a warning letter should be sent to the establishment by CDRH when the 15 working day timeframe has expired. If CDRH receives a response to the untitled letter within 15 working days, CDRH has 30 working days from the receipt date to determine whether the response is satisfactory. If the written response is determined to be unsatisfactory, CDRH should send a warning letter to the establishment.

When no warning letter is issued by CDRH due to a firm's satisfactory written response, a postinspectional notification letter should be sent by CDRH to the establishment, with

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]

BILLING CODE 4160–01–F