Closed Committee Deliberations: On December 2, 1998, from 8 a.m. to 4 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will be briefed on issues that may come before the committee in the near future.

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

FDA regrets that it was unable to publish this notice 15 days prior to the Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner 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.

Dated: November 17, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–31270 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dental Plaque Subcommittee of the 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 is open to the public.

Name of Committee: Dental Plaque Subcommittee of the 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 December 2 and 3, 1998, 8:30 a.m. to 5 p.m.

Location: Advisory Committee Conference Room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Robert L. Sherman or Stephanie A. Mason, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5191, 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 December 2, 1998, the subcommittee will: (1) Review the ingredients triclosan and the combination of triclosan and zinc citrate; (2) review and vote on the combination of zinc chloride, sodium citrate, hydrogen peroxide, and sodium lauryl sulfate; and (3) discuss comments on the draft subcommittee report. On December 3, 1998, the subcommittee will discuss comments on the draft report and adopt the report.

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 November 25, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 25, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the Dental Plaque Subcommittee of the Nonprescription Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Dental Plaque Subcommittee of the Nonprescription Drugs Advisory Committee were available at this time, the Commissioner 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.

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

Dated: November 16, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–31269 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1008]

Guidance for Industry on Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act.'' This guidance document provides an overview of FDA's policy on enforcement of the pharmacy compounding provisions of section 503A of the Federal Food, Drug, and Cosmetic Act (the act) during the transition to full implementation of that section, which was added by the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments on the guidance document may be submitted by February 22, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments to the Dockets Management Branch (HFD–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Lee D. Korb, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Enforcement Policy During Implementation of Section 503A of the