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

Federal Food, Drug, and Cosmetic Act.'' On November 21, 1997, the President signed the Modernization Act (Pub. L. 105–115). Section 127 of the Modernization Act, which adds section 503A to the act (21 U.S.C. 353a), clarifies the status of pharmacy compounding under Federal law. Under section 503A of the act, drug products that are compounded by a pharmacist or physician on a customized basis for an individual patient may be entitled to exemptions from three key provisions of the act: (1) The adulteration provision of section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning the good manufacturing practice requirements), (2) the misbranding provision of section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) the new drug provision of section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug or abbreviated new drug applications).

To qualify for these statutory exemptions, a compounded drug product must satisfy several requirements, some of which are to be the subject of FDA's rulemaking or other actions. FDA is currently working on several rules and other documents necessary to implement section 503A of the act. However, section 503A of the act takes effect on November 21, 1998, and FDA will not have completed its implementation efforts by this date. This guidance document describes FDA's policy on enforcement of section 503A of the act during the transition to full implementation of that provision.

This guidance document is being issued as a Level 1 guidance consistent with FDA's ''Good Guidance Practices'' (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance document is needed to explain to industry the agency's current policy on enforcement of section 503A of the act, which will take effect November 21, 1998. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance document represents the agency's current thinking on enforcement of section 503A of the act during the transition to full implementation. 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 requirements of the applicable statute, regulations, or both.

II. Comments

Interested persons may, on or before February 22, 1999, submit to the Dockets Management Branch (address above) written comments on the guidance document. 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 guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CDER at ''http://www.fda.gov/cder/guidance.htm''.

Dated: November 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–31221 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P–15A & HCFA–37]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* New Collection.

Title of Information Collection: Medicare Information Needs: Supplement to the Medicare Current Beneficiary Survey (MCBS).

Form No.: HCFA–P–15A (OMB# 0938–NEW).

Use: This supplement to the MCBS builds upon the previously fielded Round 18 Supplement, which provided useful information to HCFA's Center for Beneficiary Services on beneficiary information needs and preferences for how to receive information. Results from this data collection will be used by HCFA to guide continued development of communication and education programs for Medicare beneficiaries.

Affected Public: Individuals or Households.

Number of Respondents: 12,000.

Total Annual Responses: 12,000.

Total Annual Hours: 3,000.

(2) *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: Medicaid Program Budget Reports and Supporting Regulations in 42 CFR Section 430.30.

Form No.: HCFA–37 (OMB# 0938–0101).

Use: The Medicaid Program Budget report is prepared by the State Medicaid Agencies and is used by HCFA for (1) developing National Medicaid Budget estimates, (2) quantifying Budget Assumptions, (3) issuing quarterly Medicaid Grant Awards, and (4) collecting projected State receipts of donations and taxes.

Frequency: Quarterly.

Affected Public: State, Local or Tribal Government.

Number of Respondents: 57.

Total Annual Responses: 224.

Total Annual Hours: 7,840.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Dawn Willinghan, Room N2–14–26 7500 Security Boulevard Baltimore, Maryland 21244–1850