(2) Copies of relevant background material, including any legislative history, hearing reports, or similar materials pertinent to enactment, promulgation, or issuance of the requirement, to enable the Commissioner to determine the intent behind the State or local requirement.

(3) Copies of any judicial or administrative interpretations of the State or local requirement.

(4) A comparison of the requirement of the State or political subdivision and any Federal requirements under the act or the final rule to show similarities and differences.

(5) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(6) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(a) The requirement is more stringent than a requirement applicable to cigarettes or smokeless tobacco under the act or the final rule. If the State or political subdivision relies upon this basis for exemption from preemption, the application should include information or an explanation as to how and why the requirement of the State or political subdivision is more stringent than requirements under the act or the final rule.

(b) The requirement is required by compelling local conditions, and compliance with the requirement would not cause cigarettes or smokeless tobacco to be in violation of any applicable requirement under the act or the final rule. If the State or political subdivision relies upon this basis for exemption from preemption, the application should include information or an explanation as to why compliance with the requirement of the State or political subdivision would not cause cigarettes or smokeless tobacco to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions.

(7) The title of the chief administrative or legal officers of the State or local agency that has primary responsibility for administration of the requirement.

(8) If requested by FDA, any records concerning administration of the requirement.

(9) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(10) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(11) For local requirements that have been preempted under State law, a copy of the relevant State preemptive provision and an explanation of why the local requirement is no longer preempted under State law.

IV. Procedures for Processing Applications

Because FDA anticipates that the issues raised within each group by the applications for exemption will be similar or related, the agency intends to consolidate all of the applications within each group and to use a separate proceeding for each of the two groups. FDA notes that the agency has consolidated proceedings on such matters in the past (e.g., hearing aids). The process for each consolidated proceeding will be as follows:

(1) Upon receipt of an application, FDA will evaluate the application on its own merits and the circumstances applicable to the jurisdiction submitting the application in order to determine whether to grant or deny an exemption.

(2) FDA will issue a single Federal Register document (proposed rule) for each group that will, for each applying State or local government, propose to grant or deny exemptions from preemption for existing State and local government requirements that fall within that group. At the same time, FDA will issue a notice in the Federal Register providing an opportunity to request an oral hearing. If a hearing is granted, it will cover all applications for exemption from preemption for those requirements that fall within the applicable group, and it will be conducted under FDA regulations in 21 CFR parts 15 and 808.

(3) For each group, FDA will review all written comments submitted on the proposed rule and the administrative record of the oral hearing, if an oral hearing is granted, and will publish in the Federal Register a final rule identifying each requirement for which an exemption from preemption is granted, conditionally granted, or denied.

Specific details regarding the procedures under which applications will be processed can be found in § 808.25.

Applications submitted after the applicable dates set forth in this document will be considered by FDA in the order that they are received after the agency completes the proceedings described in this document.

Dated: November 1, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28681 Filed 11–6–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94P–0429]

Additional Data Regarding the Composition of Conjugated Estrogens; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that additional materials have been submitted to Docket No. 94P–0429, the docket established for a citizen petition filed on November 30, 1994, on behalf of Wyeth-Ayerst Laboratories, Division of American Home Products Corp. These materials include amendments to the petition and data supporting the petition submitted by Wyeth-Ayerst as well as data submitted to the docket by FDA and other interested persons. Among the documents submitted to the docket by FDA is a document entitled ''Preliminary Analysis of Scientific Data on the Composition of Conjugated Estrogens.'' The agency is requesting comments on this document as well as on the citizen petition, amendments to the petition, and other materials in the docket.

DATES: Written comments by December 9, 1996.

ADDRESSES: Submit written requests for single copies of the document entitled ''Preliminary Analysis of Scientific Data on the Composition of Conjugated Estrogens'' to the Drug Information Branch, Division of Communications Management (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the materials submitted to the docket to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Materials related to the Wyeth-Ayerst citizen petition on conjugated estrogens are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Diane Sullivan-Ford, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish

Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: On November 30, 1994, a citizen petition was filed on behalf of Wyeth-Ayerst Laboratories, Division of American Home Products Corp. The petition was amended on December 2, 1994; September 26, 1995; November 6, 1995; March 8, 1996; March 15, 1996; and June 27, 1996. The citizen petition requests, among other things, that FDA: (1) Determine that sodium delta 8,9-dehydroestrone sulfate (delta 8,9–DHES) is a concomitant component in conjugated estrogens tablets; (2) officially recommend that the United States Pharmacopeial Convention amend the United States Pharmacopeia (USP) monograph for conjugated estrogens and conjugated estrogens tablets to include delta 8,9–DHES as a concomitant component comprising at least 2 percent but not more than 6 percent of the estrogens in these products; and (3) not accept for filing or receive or approve any new drug application (NDA) or abbreviated new drug application (ANDA) for a conjugated estrogens product in which delta 8,9–DHES does not comprise at least 2 percent but not more than 6 percent of its estrogens. Amendments to the petition raised issues concerning the contribution of delta 8,9–DHES to the clinical effect of Premarin. FDA is inviting comments on this as well as any other issues raised in the citizen petition and amendments as well as on issues raised in comments received on the petition.

In addition, FDA has placed in the docket a document entitled ''Preliminary Analysis of Scientific Data on the Composition of Conjugated Estrogens'' which addresses some of the issues and data submitted in the citizen petition and amendments. This document presents the agency's preliminary analysis of certain currently available data relating to the contribution of estrone sulfate, equilin sulfate, and delta 8,9–DHES to the clinical effects of Premarin, including effects on bone mineral density. The document does not respond to the citizen petition nor does it announce any action with regard to any pending application or accepting any future application for a conjugated estrogens drug product or indication for use of such a product.

Interested persons may, on or before December 9, 1996, submit to the Dockets Management Branch (address above) written comments regarding materials submitted to the docket. 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. Materials related to the Wyeth-Ayerst citizen petition on conjugated estrogens and received comments may be seen in the office above between a.m. and 4 p.m., Monday through Friday. Comments submitted after December 9, 1996 may not be considered by the agency.

Dated: October 31, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28682 Filed 11–04–96; 3:24 pm]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA–3427]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the 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:* Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection:* Survey Report Form (CLIA), and supporting regulations 42 CFR 493.1 through 493.1804; *Form No.:* HCFA–1557; *Use:* Clinical Laboratory Certification and Recertification: This survey form is an instrument used by the State agency to record data collected in order to determine compliance with CLIA; *Frequency:* Biennially; *Affected Public:* Business or other for profit, not for profit institutions, Federal government and State, local or tribal governments; *Number of Respondents:* 30,225; *Total Annual Hours:* 16,322.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Laboratory Personnel Report (CLIA) and supporting regulations 42 CFR 493.1 through 493.1804; *Form No.:* HCFA–209; *Use:* This form is used by the State agency to determine a laboratory's compliance with personnel qualifications under CLIA. This information is needed for a laboratory's CLIA certification and recertification; *Frequency:* Biennially; *Affected Public:* Business or other for profit, not for profit institutions, Federal, State, local or tribal governments; *Number of Respondents:* 26,250; *Total Annual Hours:* 13,125.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare/Medicaid Hospital Survey Report Form and supporting regulations 42 CFR 482.1 through 482.66; *Form No.:* HCFA–1537; *Use:* Section 1861(e) of the Social Security Act provides that hospitals participating in Medicare must meet specific requirements. These requirements are presented as conditions of participation. State agencies must determine compliance with these conditions through the use of this report form; *Frequency:* Annually; *Affected Public:* State, local or tribal governments; *Number of Respondents:* 1,322; *Total Annual Hours Requested:* 4,296.50.

4. *Type of Information Collection Request:* Reinstatement, with change, of previously approved collection for which approval has expired; *Title of Information Collection:* Medicare Managed Care Disenrollment Form; *Form No.:* HCFA–566; *Use:* This form is used to process a beneficiaries request of disenrollment action from a health maintenance organization or competitive medical plan and to update the beneficiaries' health insurance master record; *Frequency:* On occasion; *Affected Public:* Individuals and households, business or other for profit, not for profit institutions, Federal government, State, local, or tribal governments; *Number of Respondents:* 24,000; *Total Annual Responses:* 24,000; *Total Annual Hours:* 792.

5. *Type of Information Collection Request:* Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection:* Ambulatory Surgical Center (ASC) Request for Certification and Survey Report and Supporting regulation 42 CFR 416; *Form*