

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*

No.: HCFA-377, HCFA-378; *Use*: The HCFA-377 is the application used by an ASC wanting to participate in the Medicare program. The HCFA-378 is the survey form used by State survey agencies to determine ASC compliance with individual conditions of coverage. 42 CFR 416 is the regulation supporting the data collected on the HCFA-377 and HCFA 378; *Frequency*: Annually; *Affected Public*: State, local, or tribal governments, business or other for profit, not-for-profit institutions; *Number of Respondents*: 1,900; *Total Annual Responses*: 1,900; *Total Annual Hours*: 475.

6. *Type of Information Collection Request*: Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection*: Medigap Complaint Database and Supporting Regulation 42 CFR 403.210 (b); *Form No.*: HCFA-R-156; *Use*: The Medigap database is maintained by the National Association of Insurance Commissioners, which in turn, sends the Medigap-relevant data to HCFA. The information is used to monitor State handling of Medigap related complaints; *Frequency*: Quarterly; *Affected Public*: Business or other for-profit; *Number of Respondents*: 1; *Total Annual Responses*: 4; *Total Annual Hours*: 160.

7. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Information Collection Requirements in 42 CFR 485.56, 485.58, 485.60; *Form No.*: HCFA-359, HCFA-360, HCFA-R-55; *Use*: In order to participate in the Medicare program as a CORF, providers must meet Federal conditions of participation. The certification form is needed to

determine if providers meet at least preliminary requirements. The survey form is used to record provider compliance with the individual conditions and report findings to HCFA; *Frequency*: Annually; *Affected Public*: Business or other for profit, not for profit institutions, State, local, or tribal governments; *Number of Respondents*: 162; *Total Annual Responses*: 324; *Total Annual Hours*: 526 (reporting), 77,014 (record keeping).

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 28, 1996
Edwin J. Glatzel,
Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96-28621 Filed 11-6-96; 8:45 am]

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Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the

Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Evaluation of the Ryan White HIV/AIDS Dental Reimbursement Program—Title 776(b) of the Public Health Service Act authorizes the Secretary to make grants to assist accredited dental schools and post-doctoral dental programs to meet uncompensated costs for providing oral health care to HIV infected individuals. A survey will be conducted to determine the effect this reimbursement program has had on the conduct of HIV/AIDS education and services within institutions and their graduates receiving these funds.

The survey will assess the effect the Program has had on (1) the support and commitment of institutions to HIV/AIDS education and the provision of care; (2) the scope, content and conduct of HIV/AIDS education in participating institutions, (3) increasing the access to oral health care by HIV/AIDS patients; and (4) improving the integration of oral health care with health care and long-term HIV/AIDS case management under other components of the Ryan White Act. The survey will compare dental schools and hospitals awarded Ryan White HIV/AIDS dental reimbursement monies with eligible institutions which did not participate in the reimbursement program. An initial mail questionnaire will be followed up by a telephone interview. The telephone interview will use Computer Assisted Telephone Interview (CATI) technology. Burden estimates are as follows:

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Telephone Interview	204	1	204	.75	153
Service Delivery/Program Questionnaire	204	1	204	2.00	408
Total	204	2	408	1.375	561

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 30, 1996.
J. Henry Montes,
Associate Administrator for Policy Coordination.
[FR Doc. 96-28637 Filed 11-6-96; 8:45 am]
BILLING CODE 4160-15-P

Availability of Funds to Provide Technical and Non-financial Assistance to Federally Funded Migrant Health Centers

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

CFDA #: 93.129.