explaining the development of their QBP status. The technical report is provided in writing by electronic mail to the MA organization. If, after reviewing the technical report, the MA organization believes that CMS was incorrect in its QBP determination, within 10 calendar days the MA organization may request an appeal to be conducted by a hearing officer designated by CMS. The hearing officer's decision is final and binding on both the MA organization and CMS. The hearing officer is required to issue his/her decision on or before May 15 of the year preceding the year in which the contract for which the QBP to be applied will be offered. *Form Number:* CMS–10346 (OMB control number: 0938–1129); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 500; *Total Annual Responses:* 20; *Total Annual Hours:* 160. (For policy questions regarding this collection contact Sarah Gaillot at 410–786–4637).

Dated: August 30, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–18740 Filed 9–1–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–102 and CMS–105, and CMS–10631]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *November 6, 2017.*

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations; *Use:* We will use the collected information to determine the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation and budget approval. Form CMS–102 is a multi-purpose form designed to capture and record all budget and expenditure data. Form CMS–105 captures the annual projected CLIA workload that the State survey agency will accomplish. Our regional offices also use the information to approve the annual projected CLIA workload. The information is required as part of the section 1864 agreement with the state. *Form Numbers:* CMS–102 and CMS–105 (OMB control number: 0938–0599); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 1,700. (For policy questions regarding this collection contact Jeffrey Pleines at 410–786–0684.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The PACE Organization Application Process in 42 CFR part 460; *Use:* Initial application requirements for the PACE program are currently set forth in 42 CFR 460.12 and in the PACE Manual, Ch. 17. Until recently, the submission of initial and SAE PACE applications and supporting information was in paper format. These

applications are often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient, as staff reviewing different parts of the application are located in different physical locations and must receive hard copies of the material. However, beginning in 2016 and 2017, initial and SAE PACE applications, respectively, are being submitted via a new automated, electronic submission process. As with initial applications, an application also must be submitted for a PO that seeks to expand its service area and/or add a new service site, and with OMB approval, an automated application process will now also be required of PACE organizations submitting service area expansion applications. The collection specific to the application was approved by OMB for a 3-year period, which expires March 31, 2020. Approval is now requested for revisions to this currently-approved collection, which includes modifications to the PACE application. *Form Number:* CMS–10631 (OMB control number: 0938–1326); *Frequency:* Once and occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions) and State, Local, or Tribal Governments; *Number of Respondents:* 730; *Total Annual Responses:* 84; *Total Annual Hours:* 4,626. (For policy questions regarding this collection contact Stacy Davis at 410–786–7813.)

Dated: August 30, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–18738 Filed 9–1–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–1459]

Determination That ENJUVIA (Estrogens, Conjugated Synthetic B) Tablets, 0.625 Milligrams and 1.25 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 milligrams (mg) and 1.25 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Bronwen Blass, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–796–5092.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, is the subject of NDA 021443, held by Teva Branded Pharmaceutical Products R&D, Inc. (Teva), and was initially approved on May 10, 2004. ENJUVIA is indicated for treatment of moderate to severe vasomotor symptoms due to menopause and treatment of moderate to severe vaginal dryness and pain with intercourse, as well as symptoms of vulvar and vaginal atrophy due to menopause.

In 2016, Teva notified FDA that ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, were being discontinued, and FDA moved those drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Foley & Lardner submitted a citizen petition dated March 8, 2017 (Docket No. FDA–2017–P–1459), under 21 CFR 10.30, requesting that the Agency determine whether ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ENJUVIA (estrogens, conjugated synthetic B) tablets, 0.625 mg and 1.25 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.