strategies; (3) monitors and evaluates programs to improve the public's health; and (4) ensures the agency's scientific credibility, reputation, and needs are respected and supported by policy makers, program partners, and stakeholders.

Delete in its entirety the functional statement for the *Office of the Director (CAQ1),* and insert the following:

Office of the Director (CAQ1). (1) Provides strategic advice to CDC leadership on agency direction and drives CDC towards actions to reduce leading preventable causes of morbidity and mortality; (2) ensures effectiveness of policy, program, performance, and strategy across the agency; (3) builds capacity throughout CDC for policy, program, performance, and strategy; (4) leads the development and management of policy and programmatic agendas with federal agencies and other organizations; (5) establishes and maintains strategic partnerships with key organizations and individuals working on public health policies and programs.

Delete in its entirety the title and functional statement for the *Office of Health System Collaboration (CAQ12).*

Delete in its entirety the functional statement for the *Policy Research, Analysis, and Development Office (CAQB),* and insert the following:

Policy Research, Analysis, and Development Office (CAQB). (1) Identifies and assists CDC leadership in informing policy at multiple levels (*e.g.,* federal, state, local, global, and private sector); (2) gathers and disseminates knowledge about statutes, regulations, and sub-regulatory guidance that can increase the policy impact of CDC programs; (3) conducts analyses, including regulatory, legal, and economic and develops strategies for CDC policy priorities; (4) supports policy implementation through the provision of expertise, guidance, reviews, and tools; (5) monitors and evaluates the impact of CDC policies; (6) builds policy analysis and development capacity within CDC and the larger public health community; (7) leads CDC's public health policy research agenda; (8) manages selected partner cooperative agreements and contracts that focus on policy; and (9) incubates innovative programs that emerge from policy priorities identified by CDC leadership.

Delete in its entirety the *Program Performance and Evaluation Office (CAQD)* and insert the following:

Program Performance and Evaluation Office (CAQD). (1) Serves as an advisor to CDC leadership on program effectiveness to guide science, policy, and programmatic efforts; (2) provides agency-wide direction, standards, and technical assistance for program planning, performance and accountability; (3) supports the harmonization of performance measurement, accountability, and program evaluation; (4) guides the collection and analysis of economic, performance, and accountability data; (5) facilitates continuous improvement based on program evaluation and performance measurement; (6) manages the CDC evaluation fellowship; (7) provides economic evaluation support to CDC leadership; (8) drives short-term and long-term strategic program planning; (9) supports evidence-driven program design with expertise, analyses, and tools; (10) promotes standardization of shared programmatic activities to improve efficiency; (11) coordinates action planning for high impact initiatives; and (12) facilitates information sharing and collaboration between programs and CDC leadership.

After the functional statement for the *Program Performance and Evaluation Office (CAQD),* insert the following:

Office of Population Health and Healthcare (CAQE). (1) Engages multi-sectoral partners (*e.g.*, private sector, non-profit, transportation, housing, healthcare providers and insurance plans, foundations) to create collaborative opportunities that improve health outcomes; (2) uses data, subject matter expertise and convening power to inform the development of policies, programs and tools; (3) provides agency wide guidance on approaches and partners that can help achieve CDC aims; (4) builds capacity to use CDC data analysis and interpretation expertise to explore gaps in health outcomes and develop population health/healthcare solutions; and (5) creates linkages and synergies between CDC programs to maximize population health impact.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–11548 Filed 6–3–19; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10697]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 August 5, 2019.

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' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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 N. 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**).

CMS–10697 Medicare Coverage of Items and Services for Coverage With Evidence Development

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: New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Coverage of Items and Services for Coverage with Evidence Development; *Use:* CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. When an NCD requires CED under 1862(a)(1)(E), it is because the available evidence about a particular item or service is insufficient to support coverage outside the context of a well-designed clinical research study. Sponsors could build interim analyses and final analyses into their study design and communicate these results to CMS.

Section 1142 of the Act describes the authority of the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research on outcomes, effectiveness, and appropriateness of services and procedures to identify the most effective and appropriate means to prevent, diagnose, treat, and manage diseases, disorders, and other health conditions. That section includes a requirement that the Secretary assure that AHRQ research priorities under Section 1142 appropriately reflect the needs and priorities of the Medicare program.

The coordination of AHRQ priorities under section 1142 with the needs and priorities of the Medicare program is accomplished through direct collaboration between the AHRQ and CMS. AHRQ reviews all CED NCDs established under Section 1862(a)(1)(E) of the Act. Consistent with section 1142, AHRQ also indicates its support for clinical research studies that CMS determines address the CED questions and meet the general standards for CED studies. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review the study protocol and supporting materials, as needed. *Form Number:* CMS–10697 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 15,000. (For policy questions regarding this collection contact Xiufen Sui at 410–786–3136.)

Dated: May 30, 2019,

William N. Parham, III,

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

[FR Doc. 2019–11630 Filed 6–3–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1707]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications for Pemoline Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of five abbreviated new drug applications (ANDAs) for products containing pemoline. The holders of the applications requested withdrawal of the applications and have waived their opportunity for a hearing.

DATES: Approval is withdrawn as of June 4, 2019.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: FDA approved the following ANDAs for pemoline tablets for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which these ANDAs relied:

- ANDA 075030 approved on January 29, 1999
- ANDA 075287 approved on September 18, 2000
- ANDA 075595 approved on February 28, 2000

FDA approved the following ANDAs for pemoline chewable tablets for the conditions of use in the labeling of NDA 017703, the reference listed drug on which these ANDAs relied:

- ANDA 075555 approved on February 18, 2000
- ANDA 075678 approved on July 26, 2000

On October 24, 2005, FDA issued a *Postmarket Drug Safety Information for Healthcare Professionals* communication stating its conclusion that the overall liver toxicity risk of CYLERT (NDAs 016832 and 017703) and generic pemoline products outweighed the benefits of these products (*https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/DrugsDrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/*