

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]

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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/>

ucm126461.htm). The applicants and other holders of approved applications for pemoline products ceased marketing the products at that time.

On August 10, 2018, the applicants listed in the table below requested that FDA withdraw approval of the pemoline ANDAs listed in the table under § 314.150(d) (21 CFR 314.150(d)), and, in doing so, waived their opportunity for a hearing. For the reasons discussed

above, which the applicants do not dispute in their withdrawal request letters, and pursuant to the applicants' requests, FDA is withdrawing approval of the ANDAs listed in the table, and all amendments and supplements thereto, under § 314.150(d). Tablet strengths listed in the table below include all strengths FDA has identified as being previously approved under these ANDAs. In each case, approval of the

entire application is withdrawn, including any strengths inadvertently missing from the table. Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d), respectively).

Application No.	Drug	Applicant
ANDA 075030	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 075287	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Watson Laboratories, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 075555	Pemoline Chewable Tablets, 37.5 mg	Teva Pharmaceuticals USA, Inc.
ANDA 075595	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Actavis Elizabeth LLC, 425 Privet Rd., Horsham, PA 19044.
ANDA 075678	Pemoline Chewable Tablets, 37.5 mg	Do.

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-11519 Filed 6-3-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0049]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 5, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the

OMB control number 0910-0732. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, *PRASStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0732—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act), enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (final deeming rule) (81 FR 28974).

Chapter IX of the FD&C Act now applies to newly regulated products, including sections 904(a)(3) and (c)(1) (21 U.S.C. 387d(a)(3) and (c)(1)). Section 904(a)(3) of the FD&C Act requires the submission of an initial report from each tobacco product manufacturer or importer, or agents thereof, listing all constituents, including smoke constituents as applicable, identified as a harmful and potentially harmful constituent (HPHC) to health by FDA. Reports must be by brand and by quantity in each brand and subbrand. We note that for cigarettes, smokeless tobacco, cigarette filler, and RYO tobacco products, this initial reporting was completed in 2012.

Section 904(c)(1) of the FD&C Act provides that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide the information reportable under section 904(a)(3) at least 90 days prior to introducing the product into interstate commerce.¹

FDA has taken several steps to identify HPHCs to be reported under section 904 of the FD&C Act, including issuing a guidance discussing FDA's current thinking on the meaning of the

¹ Note that section 904(c)(1) testing and reporting requirements are separate from the requirements that must be satisfied before a new tobacco product (sections 905 and 910 of the FD&C Act (21 U.S.C. 387e and 387j)), or modified risk tobacco product (section 911 of the FD&C Act (21 U.S.C. 387k)) may be marketed.