395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0312. 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, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents—21 CFR 1140.30

OMB Control Number 0910–0312—Extension

This is a request for an extension of OMB approval for the information collection requirements contained in FDA's regulations for cigarettes and smokeless tobacco containing nicotine. The regulations that are codified at 21 CFR part 1140 are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31). Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions including that subpart C (which included 21 CFR 897.24) and 21 CFR 897.32(c) be removed from the reissued rule (section 102(a)(2)(B)). The reissued final rule was published in the **Federal Register** of March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30 (21 CFR 1140.30), which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the regulations and not originally described in the March 19, 2010, final rule. Section 1140.30 requires manufacturers, distributors, and retailers to (1) observe certain format and content requirements for labeling and advertising and (2) notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in § 1140.30 is sufficiently broad to encompass most forms of advertising.

In the **Federal Register** of May 17, 2019 (84 FR 22496), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related. The commenter stated that this program is ineffective and has no effect on whether Americans smoke. FDA disagrees. Section 1140.30 is intended to help protect children and adolescents by reducing the appeal of cigarettes and smokeless tobacco to them. Section 1140.30, in part, contains a comprehensive list of permissible forms of advertising and labeling; in the unlikely event that a person wishes to use a form of advertising or labeling that is not described in § 1140.30, the section directs respondents to notify FDA of the form of advertising or labeling they intend to use.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30—Scope of permissible forms of labeling and advertising	25	1	25	1	25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden hour estimates for this collection of information were based on industry-prepared data and information regarding cigarette and smokeless tobacco product advertising expenditures.

FDA estimates that approximately 25 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice. Therefore, FDA estimates that the total time required for this collection of information is 25 hours.

We have adjusted our burden estimate to approximately 25 notifications annually, which more accurately reflects the current number of submissions under this regulation. This is a decrease to the currently approved burden. The decrease in notifications is not unexpected given that the regulation applies to cigarettes and smokeless tobacco and many of the alternative media notifications have been made in previous years.

Dated: October 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23934 Filed 10–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–2982]

Determination That MEXITIL (Mexiletine Hydrochloride) Capsules, 150 Milligrams, 200 Milligrams, and 250 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, Agency, or we) has determined that MEXITIL (mexiletine hydrochloride) capsules, 150 milligrams (mg), 200 mg, and 250 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 MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carlarease Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3702, *Carlarease.Hunter@fda.hhs.gov.*

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.

MEXITIL (mexiletine hydrochloride) is the subject of NDA 018873, held by Boehringer Ingelheim Pharmaceuticals, Inc., and initially approved on December 30, 1985. MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, are indicated for the treatment of documented ventricular arrhythmias, such as sustained ventricular tachycardia, that, in the judgment of the physician, are life-threatening.

MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hetero Labs Limited submitted a citizen petition dated June 19, 2019 (Docket No. FDA–2019–P–2982), under 21 CFR 10.30, requesting that the Agency determine whether MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 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 MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, were not withdrawn for reasons of safety or effectiveness.

The petitioner has identified no data or other information suggesting that MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 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 MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 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.

Dated: October 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23923 Filed 10–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0880]

Assessing User Fees Under the Generic Drug User Fee Amendments of 2017; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Assessing User Fees under the Generic Drug User Fee Amendments of 2017.'' This draft guidance provides stakeholders information regarding the implementation of the Generic Drug User Fee Amendments of 2017 (GDUFA II) and policies and procedures surrounding its application. This draft guidance revises and replaces FDA's draft guidance for industry entitled ''Assessing User Fees under the Generic Drug User Fee Amendments of 2017,'' published in October 2017.

DATES: Submit either electronic or written comments on the draft guidance by December 31, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for