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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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that the Agency determine whether MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, were withdrawn from sale for reasons of safety or effectiveness.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]

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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

information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–0880 for ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Keith Verrett, Division of User Fee Management and Budget Formulation Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, Rm. 2179, Silver Spring, MD 20993, 301–796–7900, *CDERCollections@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assessing User Fees under the Generic Drug User Fee Amendments of 2017.'' GDUFA II (Pub. L. 115–52, Title III), signed into law by the President on August 18, 2017, continues FDA's and industry's goal to improve public access to safe and effective generic drugs and to improve upon the predictability of the review process. GDUFA II extends FDA's authority to collect user fees from fiscal year (FY) 2018 to FY 2022 and introduces a number of technical revisions that affect what fees are collected and how some fees are collected.

The draft guidance announced in this notice revises and replaces the draft guidance for industry on ''Assessing User Fees under the Generic Drug User Fee Amendments of 2017.'' This draft guidance addresses changes in user fee assessments from GDUFA I, user fees incurred by industry under GDUFA II, payment procedures, reconsideration and appeals, and other additional information to assist industry in complying with GDUFA II. Clarifying language was added to the revised draft guidance based on the public comments submitted for the draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The draft guidance refers to collections of information for filling out and submitting Form FDA 3913 (User Fee Payment Refund Request), previously approved under OMB control number 0910–0805, and Form FDA 3914 (User Fee Payment Transfer Request), previously approved under OMB control number 0910–0805.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23875 Filed 10–31–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4042]

Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment; 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 ''Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in all phases of development of antiviral drugs for the treatment of chronic hepatitis D virus (HDV) infection. This guidance is intended to provide consistent FDA advice to stakeholders regarding HDV drug development strategies.

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: