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That MEXITIL (mexiletine hydrochloride) capsules, 150 Milligrams, 200 Milligrams, and 250 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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we) has determined that MEXITIL (mexiletine hydrochloride) capsules, 150 milligrams (mg), 200 mg, and 250 mg, were not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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: 10/31/2019 8:45 am; Publication Date: 11/1/2019]