4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-P-3691]

Determination That CHLOR-TRIMETON ALLERGY 12 HOUR (Chlorpheniramine Maleate) Extended Release Tablets, 8 Milligrams and 12 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 or Agency) has determined that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 milligrams (mg) and 12 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993-0002, 301-796-1054.

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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg and 12 mg, are the subject of NDA 007638, held by Bayer HealthCare LLC (Bayer) and initially approved on August 15, 1950. CHLOR-TRIMETON ALLERGY 12 HOUR is indicated for temporary relief of the following symptoms due to hay fever or other upper respiratory allergies: sneezing; runny nose; itchy, watery eyes; itching of the nose or throat.

In the 2005 NDA 007638 Annual Report received on October 14, 2005, Bayer notified FDA that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In a letter dated February 8, 2018, Bayer notified FDA that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 12 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Avanthi, LLC, c/o KVK-TECH, INC., submitted a citizen petition dated September 27, 2018 (Docket No. FDA-2018-P-3691), under 21 CFR 10.30, requesting that the Agency determine whether CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 12 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

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 CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg and 12 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, were withdrawn for reasons of safety or effectiveness.

We have carefully reviewed our files for records concerning the withdrawal of CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg

and 12 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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: March 27, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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