4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-P-0047, FDA-2012-P-0468, FDA-2015-P-3400, and FDA-2016-P-1667]

Determination That ANTIVERT Chewable Tablets, 25 Milligrams, and Tablets, 12.5 Milligrams, 25 Milligrams, and 50 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 ANTIVERT (meclizine hydrochloride) chewable tablets, 25 milligrams (mg), and tablets, 12.5 mg, 25 mg, and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness.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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993-0002, 301-796-3977.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, are the subject of NDA 010721, currently held by Casper Pharma LLC, and initially approved on February 14, 1957. ANTIVERT is indicated for the treatment of vertigo associated with diseases affecting the vestibular system.

ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Since 2011, the Agency has received four citizen petitions, submitted under 21 CFR 10.30, requesting that FDA determine whether one or more dosage forms and strengths of ANTIVERT were withdrawn from sale for reasons of safety or effectiveness.

- InvaGen Pharmaceuticals submitted a citizen petition dated January 14, 2011, and amendment dated February 24, 2011 (Docket No. FDA-2011-P-0047), requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, was withdrawn from sale for reasons of safety or effectiveness.
- Modavar Pharmaceuticals LLC submitted a citizen petition dated May 4, 2012, (Docket No. FDA-2012-P-0468) requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) tablets, 12.5 mg and 25 mg, were withdrawn from sale for reasons of safety or effectiveness.
- Lupin Pharmaceuticals, Inc. submitted a citizen petition dated September 18, 2015 (Docket No. FDA-2015-P-3400), requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) tablets, 12.5 mg, 25 mg, and 50 mg, were withdrawn from sale for reasons of safety or effectiveness.
- Zydus Pharmaceuticals submitted a citizen petition dated June 14, 2016 (Docket No. FDA-2016-P-1667), requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) tablets, 12.5 mg and 25 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, were not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, from sale. We have also independently evaluated relevant literature and data for possible post marketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 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 these drug products. Additional ANDAs for these drug products 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-06656 Filed: 4/4/2019 8:45 am; Publication Date: 4/5/2019]