4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2018-P-1335 and FDA-2018-P-1361]

Determination That DITROPAN XL (Oxybutynin Chloride) Extended Release Tablets, 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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or Agency) has determined that DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Glen Cheng, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993-0002, 301-796-1494.

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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg, 10 mg, and 15 mg, are the subject of NDA 020897, held by Janssen Pharmaceuticals Inc., and initially approved on December 16, 1998. DITROPAN XL is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, and for the treatment of pediatric patients aged 6 years and older with symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida).

In a letter dated December 14, 2017, Janssen Pharmaceuticals Inc. notified FDA that DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section

of the Orange Book. Although DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg and 10 mg, were also previously listed in the "Discontinued Drug Product List" section of the Orange Book, they are now listed in the "Prescription Drug Product List" section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated March 30, 2018 (Docket No. FDA-2018-P-1335), and Ajanta Pharma Limited submitted a citizen petition dated April 2, 2018 (Docket No. FDA-2018-P-1361), under 21 CFR 10.30, requesting that the Agency determine whether DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg, 10 mg, and 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

As noted, DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg and 10 mg, are no longer listed in the "Discontinued Drug Product List" section of the Orange Book, and therefore we need not determine whether they were withdrawn from sale for reasons of safety or effectiveness.

With regard to DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, 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 DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 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 DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 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 DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 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: August 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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