4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-P-0578]

Determination That BRETYLIUM TOSYLATE Injection, 50 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Drug Administration (FDA) has determined that BRETYLIUM TOSYLATE injection, 50 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for BRETYLIUM TOSYLATE injection, 50 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

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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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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

BRETYLIUM TOSYLATE injection, 50 mg/mL, is the subject of NDA 19-030, held by Hospira, Inc., and initially approved on April 16, 1986. BRETYLIUM TOSYLATE injection, 50 mg/mL, is indicated in the prophylaxis and therapy of ventricular fibrillation and in the

treatment of life-threatening ventricular arrhythmias, such as ventricular tachycardia, that have failed to respond to adequate doses of a first-line antiarrhythmic agent, such as lidocaine.

In a letter dated June 17, 2010, Hospira, Inc. requested withdrawal of NDA 19-030 for BRETYLIUM TOSYLATE injection, 50 mg/mL. In the Federal Register of June 8, 2011 (76 FR 33310), FDA announced that it was withdrawing approval of NDA 019030, effective July 8, 2011.

Academic Pharmaceuticals, Inc. submitted a citizen petition dated July 27, 2011 (Docket No. FDA-2011-P-0578), under 21 CFR 10.30, requesting that the Agency determine whether BRETYLIUM TOSYLATE injection, 50 mg/mL, was 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 BRETYLIUM TOSYLATE injection, 50 mg/mL, was not withdrawn for reasons of safety or effectiveness. We have carefully reviewed the information provided by the petitioner and our files for records concerning the withdrawal of BRETYLIUM TOSYLATE injection, 50 mg/mL, 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 product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BRETYLIUM TOSYLATE injection, 50 mg/mL, 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 bretylium tosylate injection, 50 mg/mL, 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: December 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-32367 Filed 12/16/2011 at 8:45 am; Publication Date: 12/19/2011]