4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-4667]

Determination That Vancomycin Hydrochloride Injection Drug Products, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 VANCOCIN (vancomycin hydrochloride (HCl)) injection, 500 milligrams (mg)/vial, 1 gram (g)/vial, 10 g/vial ("the VANCOCIN drug products"); VANCOLED (vancomycin HCl) injection, 500 mg/vial, 1 g/vial, 2 g/vial, 5 g/vial, and 10 g/vial ("the VANCOLED drug products"); and VANCOCIN HYDROCHLORIDE (vancomycin HCl) injection, 500 mg/vial and 1 g/vial ("the VANCOCIN HCl drug products") (hereinafter collectively "these Vancomycin HCl drug products"), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for these Vancomycin HCl drug products if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Robin Fastenau, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6236, Silver Spring, MD 20993-0002, 240-402-4510, Robin.Fastenau@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.

The VANCOCIN drug products are the subject of ANDA 62-812 held by ANI Pharmaceuticals, Inc., and were initially approved on November 17, 1987. The VANCOLED drug products are the subject of ANDA 62-682 held by Eurohealth International Sàrl and were initially approved on July 22, 1986. The VANCOCIN HCl drug products are the subject of ANDA 60-180 held by ANI Pharmaceuticals, Inc., and were initially approved on November 6, 1964. These Vancomycin HCl drug products are indicated for the treatment of serious or severe

infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci. They are indicated for penicillin-allergic patients; for patients who cannot receive or who have failed to respond to other drugs, including the penicillins or cephalosporins; and for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobial drugs. They are indicated for initial therapy when methicillin-resistant staphylococci are suspected, but after susceptibility data are available, therapy should be adjusted accordingly.

These Vancomycin HCl drug products are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Strides Arcolab Limited submitted a citizen petition dated May 18, 2009 (Docket No. FDA-2009-P-0242), under § 10.30 (21 CFR 10.30), requesting that the Agency determine whether VANCOCIN (Vancomycin HCl) injection, 10 g/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 500 mg/vial and 1 g/vial strengths, these strengths have also been discontinued. On our own initiative, we have also determined whether these strengths were withdrawn for safety or effectiveness reasons. Hospira submitted a citizen petition dated October 5, 2015 (Docket No. FDA-2015-P-3621), under § 10.30, requesting that the Agency determine whether VANCOLED (vancomycin HCl) injection, 10 g bulk packaging, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 500 mg/vial, 1 g/vial, 2 g/vial, and 5 g/vial strengths, these strengths have also been discontinued. On our own initiative, we have also determined whether these strengths were withdrawn from sale for reasons of safety or effectiveness. In addition, the VANCOCIN HCl (Vancomycin HCl), injection, 500 mg/vial, and 1 g/vial drug products have been discontinued from sale and FDA has determined whether these drug products were withdrawn from the market for safety or effectiveness reasons.

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 these Vancomycin HCl drug products were not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that these Vancomycin HCl drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of these Vancomycin HCl drug products 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 these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list these Vancomycin HCl drug products 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 these Vancomycin HCl drug products 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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