Determination That NOVANTRONE (Mitoxantrone Hydrochloride) Injection, Equivalent to 25 Milligrams Base/12.5 Milliliter and Equivalent to 30 Milligrams Base/15 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

Apr 12, 2011

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration (FDA) has determined that NOVANTRONE (mitoxantrone hydrochloride) Injection, equivalent to (EQ) 25 milligrams (mg) base/12.5 milliliters (mL) and EQ 30 mg base/15 mL, was not withdrawn from sale for reasons of safety or effectiveness.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:

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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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

NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, is the subject of NDA 19-297, held by EMD Serono, and initially approved on December 23, 1987. NOVANTRONE is indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (*i.e.,* patients whose neurologic status is significantly abnormal between relapses). NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, is currently listed in the "Discontinued Drug Product List" section of the Orange Book. There are approved ANDAs for NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL; these ANDAs are listed in the Orange Book.

Apotex, Inc., submitted a citizen petition dated September 3, 2008 (Docket No. FDA-2008-P-0485), under 21 CFR 10.30, requesting that the Agency determine whether NOVANTRONE (mitoxantrone hydrochloride) Injection, 25 mg/12.5 mL and 30 mg/15 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NOVANTRONE Start Printed Page 20686(mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 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 NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to NOVANTRONE Injection. Additional ANDAs for mitoxantrone hydrochloride injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, 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: April 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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