4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-P-1515]

Determination That ZOVIRAX (Acyclovir Sodium) Injection, Equivalent to 250 Milligrams Base/Vial, 500 Milligrams Base/Vial, and 1 Gram Base/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 ZOVIRAX (acyclovir sodium) Injection, equivalent to (EQ) 250 milligrams (mg) base/vial, 500 mg base/vial, and 1gram (g) base/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1 g base/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6206, Silver Spring, MD 20993-0002, 240-402-0978.

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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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

ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, is the subject of NDA 18-603, held by GlaxoSmithKline and initially approved on October 22, 1982. ZOVIRAX (acyclovir sodium) is indicated for the treatment of herpes and varicella-zoster (shingles) in immunocompromised patients.

In a letter dated June 20, 2005, GlaxoSmithKline notified FDA that ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated November 15, 2013 (Docket No. FDA-2013-P-1515), under 21 CFR 10.30, requesting that the Agency determine whether ZOVIRAX (acyclovir sodium) Injection, EQ 1 g base/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 250 mg and 500 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

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 ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1 g base/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, 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 products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, 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 ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, 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: April 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-08148 Filed 04/10/2014 at 8:45 am; Publication Date: 04/11/2014]