4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-P-0980]

Determination That REYATAZ (Atazanavir Sulfate) Capsules, 100 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA or Agency) has determined that REYATAZ (atazanavir sulfate) capsules, 100 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 atazanavir sulfate, 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Na'Im R. Moses, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6224, Silver Spring, MD 20993-0002, 240-402-3990.

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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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

REYATAZ (atazanavir sulfate) capsules, 100 mg, is the subject of NDA 21-567, held by Bristol-Myers Squibb, and initially approved on June 20, 2003. REYATAZ is a protease inhibitor indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in patients 3 months and older weighing at least 10 kilograms.

In a letter dated August 19, 2014, Bristol-Myers Squibb notified FDA that REYATAZ (atazanavir sulfate) capsules, 100 mg, had been discontinued. The REYATAZ 150-, 200-, and 300-mg capsule strengths continue to be marketed by Bristol-Myers Squibb. The 100-mg dosage

strength of this drug product is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated July 7, 2014 (Docket No. FDA-2014-P-0980), under 21 CFR 10.30, requesting that the Agency determine whether REYATAZ (atazanavir sulfate) capsules, 100 mg, were 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 REYATAZ (atazanavir sulfate) capsules, 100 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REYATAZ (atazanavir sulfate) capsules, 100 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REYATAZ (atazanavir sulfate) capsules, 100 mg, 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 the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REYATAZ (atazanavir sulfate) capsules, 100 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 REYATAZ (atazanavir sulfate) capsules, 100 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: December 30, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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