4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-P-0120]

Determination That BUSPAR (Buspirone Hydrochloride) Capsules, 5 Milligrams, 7.5 Milligrams, 10 Milligrams, and 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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, Agency, or we) has determined that BUSPAR (buspirone hydrochloride) capsules, 5 milligrams (mg), 7.5 mg, 10 mg, and 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA) for buspirone hydrochloride capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993-0002, 240-402-4318, Caitlin.Callahan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, are the subject of NDA 021190, held by Bristol Myers Squibb Co., and initially approved on December 20, 2000. BUSPAR is indicated for the management of anxiety disorders or the short-term relief of the symptoms of anxiety.

In correspondence dated December 28, 2012, Bristol Myers Squibb Co. requested withdrawal of NDA 021190 for BUSPAR (buspirone hydrochloride). In the *Federal Register* of December 5, 2014 (79 FR 72186), FDA announced that it was withdrawing approval of NDA 021190, effective January 5, 2015.

Epic Pharma, LLC submitted a citizen petition dated January 10, 2023 (Docket No. FDA-2023-P-0120), under 21 CFR 10.30, requesting that the Agency determine whether BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 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 BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were not withdrawn for reasons of

safety or effectiveness. The petitioner has identified no data or other information suggesting that BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 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 this drug product was not withdrawn from sale for reasons of safety or effectiveness.[1]

Accordingly, the Agency will continue to list BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 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 BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 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: June 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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[1] FDA previously determined that BUSPAR (buspirone hydrochloride) tablets, 5 mg, 10 mg, 15 mg, and 30 mg, approved under NDA 018731 and held by Bristol Myers Squibb Co. Pharmaceutical Research Institute, were not withdrawn from sale for reasons of safety or effectiveness. See 75 FR 64310 (October 19, 2010), 81 FR 61220 (September 6, 2016).