



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA-2025-P-6392]

Determination That METHERGINE (Methylergonovine Maleate) Injection, 0.2

Milligram/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 or Agency) has determined that METHERGINE (methylergonovine maleate) injection, 0.2 milligram (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for methylergonovine maleate injection, 0.2 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993-0002, 240-402-9674, Sungjoon.Chi@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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, is the subject of NDA 006035, held by Edison Therapeutics LLC, and initially approved on November 19, 1946. METHERGINE is indicated for routine management of uterine atony, hemorrhage, and subinvolution of the uterus following delivery of the placenta. It is also indicated for control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Gland Pharma Limited submitted a citizen petition dated November 21, 2025 (Docket No. FDA-2025-P-6392), under 21 CFR 10.30, requesting that the Agency determine whether METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, was 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 METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the

withdrawal of METHERGINE (methylergonovine maleate) injection, 0.2 mg/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 drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list METHERGINE (methylergonovine maleate) injection, 0.2 mg/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. ANDAs that refer to METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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