4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-P-3575]

Determination That TOLECTIN DS (Tolmetin Sodium) Capsule, Equivalent to 400 Milligrams Base, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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, Agency, or we) has determined that TOLECTIN DS (tolmetin sodium) capsule, equivalent to (EQ) 400 milligrams (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for tolmetin sodium, capsule, EQ 400 mg base, 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, a drug is 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, is the subject of NDA 018084, held by Ortho-McNeil-Janssen Pharmaceuticals, Inc., and initially approved on October 30, 1979. TOLECTIN DS is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis. TOLECTIN DS is indicated in the treatment of acute flares and the long-term management of the chronic disease. TOLECTIN DS is also indicated for treatment of juvenile rheumatoid arthritis. The safety and effectiveness of TOLECTIN DS have not been established in pediatric patients under 2 years of age.

In a letter dated May 29, 2008, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., on behalf of Ortho-McNeil-Janssen Pharmaceuticals, Inc., requested withdrawal of NDA 018084 for TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base. In the *Federal Register* of June 8, 2011 (76 FR 33310), FDA announced that it was withdrawing approval of NDA 018084, effective July 8, 2011.

Senores Pharmaceuticals, Inc., submitted a citizen petition dated September 5, 2025 (Docket No. FDA-2025-P-3575), under 21 CFR 10.30, requesting that the Agency determine whether TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, 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 TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, 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 TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, 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 TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, 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.

[FR Doc. 2026-03213 Filed: 2/17/2026 8:45 am; Publication Date: 2/18/2026]