4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-P-3118]

Determination That MYSOLINE (Primidone) Suspension, 250 Milligrams/5 Milliliters, Was Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA, Agency, or we) has determined that MYSOLINE (primidone) suspension, 250 milligrams (mg)/5 milliliters (mL), was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for primidone suspension, 250 mg/5 mL.

FOR FURTHER INFORMATION CONTACT: Aaron Young, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993-0002, 301-796-8083, aaron.young@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

MYSOLINE (primidone) suspension, 250 mg/5 mL, is the subject of NDA 010401, held by FHTA LLC, and initially approved on July 5, 1956. MYSOLINE, used alone or concomitantly with other anticonvulsants, is indicated in the control of grand mal, psychomotor, and focal epileptic seizures. It may control grand mal seizures refractory to other anticonvulsant therapy.

MYSOLINE (primidone) suspension, 250 mg/5 mL, is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated December 8, 2022 (Docket No. FDA-2022-P-3118), under 21 CFR 10.30, requesting that the Agency determine whether MYSOLINE (primidone) suspension, 250 mg/5 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 MYSOLINE (primidone) suspension, 250 mg/5 mL, was withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MYSOLINE (primidone) suspension, 250 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MYSOLINE

(primidone) suspension, 250 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events.

MYSOLINE (primidone) suspension, 250 mg/5 mL, was discontinued in 2001 after antimicrobial effectiveness testing raised concerns about potential microbial contamination, in particular with Pseudomonas aeruginosa. As a scientific matter, before MYSOLINE (primidone) suspension, 250 mg/5 mL, could be considered for reintroduction to the market, a reformulation would be required including establishment of preservative content acceptance criteria and correlation with passing antimicrobial effectiveness testing results. The NDA holder for MYSOLINE (primidone) suspension, 250 mg/5 mL, would have to demonstrate the safety and effectiveness of the reformulated product. At this time, no new formulation has been approved for MYSOLINE (primidone) suspension, 250 mg/5 mL.

Accordingly, under § 314.162 the Agency will remove MYSOLINE (primidone) suspension, 250 mg/5 mL, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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