In a letter dated May 16, 1996, Lilly Research Laboratories notified FDA that SULFADIAZINE (sulfadiazine) tablet, 500 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Rising Pharma Holdings, Inc. submitted a citizen petition dated February 4, 2025 (Docket No. FDA–2025–P–0394), under 21 CFR 10.30, requesting that the Agency determine whether SULFADIAZINE (sulfadiazine) tablet, 500 mg, was withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that SULFADIAZINE (sulfadiazine) tablet, 500 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SULFADIAZINE (sulfadiazine) tablet, 500 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 We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SULFADIAZINE (sulfadiazine) tablet, 500 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 this drug product 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. 2026–19921 Filed 9–28–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10505]

FHTA LLC; Withdrawal of Approval of New Drug Application for MYSOLINE (Primidone) Suspension, 250 Milligrams/5 Milliliters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) 010401 for MYSOLINE (primidone) suspension, 250 milligrams (mg)/5 milliliters (mL), held by FHTA LLC (FHTA). FHTA agreed to withdrawal of approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of September 29, 2026.

FOR FURTHER INFORMATION CONTACT: Aaron Young, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–8083, *aaron.young@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA initially approved NDA 010401 for MYSOLINE (primidone) suspension, 250 mg/5 mL, on July 5, 1956. In 2001, MYSOLINE (primidone) suspension, 250 mg/5 mL, was discontinued after antimicrobial effectiveness testing raised concerns about potential microbial contamination, in particular with Pseudomonas aeruginosa. In the **Federal Register** of January 2, 2026 (91 FR 148), FDA determined that MYSOLINE (primidone) suspension, 250 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness. FDA noted that, 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. FDA stated that the NDA holder for MYSOLINE (primidone) suspension, 250 mg/5 mL, would have to demonstrate the safety and effectiveness of the reformulated product. FDA further stated that, at that time, no new formulation had been approved for MYSOLINE (primidone) suspension, 250 mg/5 mL.

On June 12, 2026, FDA asked FHTA whether it intended to reformulate MYSOLINE (primidone) suspension, 250 mg/5 mL, to establish preservative content acceptance criteria and correlation with passing antimicrobial effectiveness testing results, or whether FHTA would agree to waive the opportunity for hearing and permit FDA to withdraw approval of NDA 010401 under 21 CFR 314.150(d) (§ 314.150(d)). FDA referred to its determination that MYSOLINE (primidone) suspension, 250 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness in connection with concerns regarding potential microbial contamination, in particular with Pseudomonas aeruginosa. On June 22, 2026, FHTA responded that it was not seeking a hearing and agreed to withdrawal of NDA 010401 pursuant to § 314.150(d).

For the reasons discussed above, which FHTA does not dispute in its response, and in accordance with FHTA's response, approval of NDA 010401 for MYSOLINE (primidone) suspension, 250 mg/5 mL, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of MYSOLINE (primidone) suspension, 250 mg/5 mL, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19912 Filed 9–28–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2743]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the