CMS–576 and CMS–576A forms. A Centers for Medicare & Medicaid Services (CMS) approved (OPO) is an organization that is certified by CMS and responsible for facilitating the procurement, recovery, and distribution of human organs for transplantation. They must abide by CMS regulations and undergo regular inspections to ensure compliance with performance standards.

Organizations seeking initial designation from CMS as a qualified and approved OPO, as per §§ 371(a) and 1138 of the Social Security Act (''the Act'') must complete and submit the CMS–576 form, titled ''Organ Procurement Organization (OPO) Request for Designation as An OPO Under § 1138 Of the Social Security Act.'' After designation as an OPO, the organization must sign a ''Health Insurance Benefits Agreement'' (CMS–576A form) in order to be reimbursed by Medicare for their services.

The CMS–576A form requires OPOs to agree to comply with current CMS regulations. This includes an agreement to maintain compliance with the requirements of titles XVIII and XIX of the Act, § 1138 of the Act, applicable regulations including the conditions set forth in Part 486, subpart G, title 42 of the Code of Federal Regulations, those conditions of the Organ Procurement and Transplantation Network established under § 372 of the Public Health Service Act that have been approved by the Secretary, and to report promptly to CMS. *Form Number:* CMS–576 and 576A (OMB Control Number: 0938–0512); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 16; *Total Annual Responses:* 16; *Total Annual Hours:* 32. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

2. Type *of Information Collection Request:* Extension of currently approved; Title of Information Collection: Home Health Agency Cost Report; *Use:* The Form CMS–1728–20 cost report is used to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. The Form CMS–1728–20 cost report is also used for annual rate setting and payment refinement activities, including developing a home health market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the home health cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the HHA PPS, and to conduct additional analysis of the HHA PPS.

The primary function of the cost report is to implement the principles of cost reimbursement which require that HHAs maintain sufficient financial records and statistical data for proper determination of costs payable under the program. The S series of worksheets collects the provider's location, CBSA, date of certification, operations, and unduplicated census days. The A series of worksheets collects the provider's trial balance of expenses for overhead costs, direct patient care services by level of care, and non-revenue generating cost centers. The B series of worksheets allocates the overhead costs to the revenue and non-revenue generating cost centers using functional statistical bases. The C series of worksheets computes the average cost per visit for HHA services. The D series of worksheets are Medicare specific and are used to determine reimbursement due to the provider or program. The F series of worksheets collect data from a provider's balance sheet and income statement. *Form Number:* CMS–1728–20 (OMB control number: 0938–0022); *Frequency:* Yearly; Affected Public: Private Sector—Business or other for-profits, Not-for-profit institutions; Number of Respondents: 12,240; Total Annual Responses: 12,240; Total Annual Hours: 2,421,900. (For policy questions regarding this collection contact LuAnn Piccione at (410) 786–5423.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–19913 Filed 9–28–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–0394]

Determination That SULFADIAZINE (Sulfadiazine) Tablet, 500 Milligrams, 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 SULFADIAZINE (sulfadiazine) tablet, 500 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for SULFADIAZINE (sulfadiazine) tablet, 500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Madeleine Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 240–863–8976, *Madeleine.Giaquinto@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.

SULFADIAZINE (sulfadiazine) tablet, 500 mg, is the subject of NDA 004122, held by Eli Lilly and Co., and initially approved on August 26, 1941. SULFADIAZINE is indicated for the treatment of infections as specified in its labeling.

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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4164–01–P

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