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under 21 CFR 10.30, requesting that the Agency determine whether SULFADIAZINE (sulfadiazine) tablet, 500 mg, was withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that SULFADIAZINE (sulfadiazine) tablet, 500 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness.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 We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.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

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 29, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0016. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael Ellison, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–2093, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Submission of Petitions

Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Form FDA 3503—21 CFR 21 CFR 70.25, 71.1, and 171.1 and 21 CFR parts 172, 173, 179, and 180

OMB Control Number 0910–0016—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) the additive and its use, or intended use, are in conformity with a regulation issued under section 409 that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) is effective. Food additive petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 (21 CFR parts 172, 173, 179, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f). Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the Agency's regulations (21 CFR 71.1) specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, cosmetics, or medical devices be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food, or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review CAPs to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.

Respondents may transmit FAP or CAP regulatory submissions in electronic format or paper format to the Human Foods Program (HFP) using Form FDA 3503. Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review. Form FDA 3503 can also be used to organize information within a master file submitted in support of petitions according to the items listed on the form. Master files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden for food and color additive approvals.

We improved the information collection by using the HFP Centralized Online Submission Module (COSM). COSM provides a real-time user interface process that assists respondents in preparing and making submissions to HFP. COSM, available 24 hours a day and 7 days a week, is a web-based tool that supports electronic submissions, thereby eliminating the need for printing and mailing of paper submissions. Further information about COSM, including user instruction, is available on the internet at: *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/centralized-online-submission-module-cosm.*

Description of Respondents: Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

In the **Federal Register** of April 10, 2026 (91 FR 18466), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was not PRA-related and will not be addressed here.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section; or Form No.	Numbers of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Submission of Petitions: Color Additive Including Labeling—70.25, 71.1	4	1	4	1,337	5,348	$11,200
Submission of Petitions: Food Additive Including Labeling—171.1	3	1	3	7,093	21,279	0
Form FDA 3503[2]	5	1	5	1	5	0

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR section; or Form No.	Numbers of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Total					26,632	$11,200

[1]There are no capital costs associated with this collection of information.
[2]Form FDA 3503 is used for both CAPs and FAPs.

Based on a review of the information collection since our last request for OMB approval, we have adjusted our burden estimate for CAPs since the average number submitted has increased over the last 10 years. Due to the increase of submissions, we estimate that 4 CAPs will be submitted annually. Thus, the estimated burden for the information collection reflects an overall increase of 2,674 hours. Our estimate of burden attributable to FAPs or CAPs is based on our experience with the information collection, which FAPs has not changed since our last review and reflects the average number of petitions we have received annually over a period of 10 years. The attendant burden we estimate also reflects an industry average, although burden associated with individual petitions may vary depending on the complexity of the petition, and the amount and type of data needed for scientific analysis.

CAPs are subject to fees. The listing fee for a CAP ranges from $1,600 to $3,000, depending on the intended use of the color additive and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of two Category A and two Category B CAPs are expected per year. The maximum CAP fee for a Category A petition is $2,600, and the maximum CAP fee for a Category B petition is $3,000. Because an average of four CAPs are expected per calendar year, the estimated total annual operating and maintenance cost burden to petitioners for this startup cost would be less than or equal to $11,200 ((2 × $2,600) + (2 × $3,000) listing fees). There are no capital costs associated with CAPs.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling so that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19850 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–10132]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects and Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the tracking of medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by November 30, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.