PSA AUDITOR CONTRACTORS

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Preaudit Questionnaire and Audit Documentation Requested Checklist (Form M–17A)	8	7.50	3.00	180.00
Instructions for Site Visit and Facility Tour (Form M–17B)	8	7.50	1.00	60.00
Interview Guide: Random Sample of Staff Interview (Form M–17C)	8	30.00	1.00	240.00
Interview Guide: Program Director (Form M–17D)	8	7.50	1.00	60.00
Interview Guide: PSA Compliance Manager (Form M–17E)	8	7.50	1.00	60.00
Interview Guide: Specialized Staff (Form M–17F)	8	15.00	1.00	120.00
Interview Guide: Unaccompanied Alien Child (Form M–17G)	8	75.00	0.50	300.00
PSA Audit Corrective Action Report (Form M–17H)	8	7.50	2.00	120.00
Estimated Annual Burden Hours Total				1,140.00

DELICENSED FACILITY MONITOR CONTRACTORS

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Corrective Action Report (Form M–1)	19	9.47	5.00	899.65
Site Visit Guide Tool (Form M–7A)	19	3.89	29.00	2,143.39
Foster Care Site Visit Guide (Form M–7C)	19	0.84	21.00	335.16
Personnel File Checklist (Form M–10A)	19	0.63	1.00	11.97
Supplement to Personnel File Checklist (Form M–10B)	19	0.63	1.00	11.97
Program Staff Questionnaires (Forms M–11A to M–11K)	19	1.47	1.00	27.93
Interpreter Questionnaire (Form M–11P)	19	0.21	0.50	2.00
Unaccompanied Child Questionnaires (Forms M–12A to M–12B & M–12E)	19	1.05	0.50	9.98
Legal Service Provider Questionnaire (Form M–13C)	19	0.21	1.00	3.99
Case Coordinator Questionnaire (Form M–13E)	19	0.21	1.00	3.99
Monitoring & Compliance Core Application Elements (Form M–20)	19	4.74	0.75	67.55
Monitoring Site Assessment (Form M–21)	19	2.26	8.00	343.52
Monitoring Interview (Form M–23)—Child	19	27.89	1.00	529.91
Monitoring Interview (Form M–23)—Staff	19	50.21	1.00	953.99
Monitoring Interview (Form M–23)—Foster Parent	19	4.00	1.00	76.00
Monitoring Interview (Form M–23)—Stakeholder	19	22.32	0.75	318.06
Monitoring File Checklist (Form M–22)—Child	19	13.58	6.00	1,548.00
Monitoring File Checklist (Form M–22)—Staff	19	13.58	1.00	258.00
Monitoring File Checklist (Form M–22)—Foster Parent	19	2.84	1.00	54.00
Estimated Annual Burden Hours Total				7,599.06

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR part 410; 45 CFR part 411; *Flores* v. *Reno Settlement Agreement,* No. CV85–4544–RJK (C.D. Cal. 1996)

Samantha L. Illangasekare,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–23460 Filed 11–17–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–3202]

Determination That BROMFED–DM (Brompheniramine Maleate; Dextromethorphan Hydrobromide; Pseudoephedrine Hydrochloride) Syrup, 2 Milligrams/5 Milliliters; 10 Milligrams/5 Milliliters; 30 Milligrams/5 Milliliters, 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 BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 milligrams (mg)/5 milliliters (mL); 10 mg/5 mL; 30 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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.

BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 mg/5 mL; 10 mg/5 mL; 30 mg/5 mL, is the subject of ANDA 088811, held by Pharmobedient Consulting LLC, and initially approved on June 07, 1985. BROMFED–DM is indicated for relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.

In a letter dated January 8, 2026, Pharmobedient Consulting LLC notified FDA that BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 mg/5 mL; 10 mg/5 mL; 30 mg/5 mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Steranco Healthcare Pvt. Ltd. submitted a citizen petition dated March 26, 2026 (Docket No. FDA–2026–P–3202), under 21 CFR 10.30, requesting that the Agency determine whether BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 mg/5 mL; 10 mg/5 mL; 30 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 BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 mg/5 mL; 10 mg/5 mL; 30 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 mg/5 mL; 10 mg/5 mL; 30 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 mg/5 mL; 10 mg/5 mL; 30 mg/5 mL, 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 BROMFED–DM (brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride) syrup, 2 mg/5 mL; 10 mg/5 mL; 30 mg/5 mL, 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2026–N–9703]

Salerno Pharmaceuticals; Proposal To Withdraw Approval of a New Drug Application for Flolipid Suspension, 20 Milligrams/5 Milliliters and 40 Milligrams/5 Milliliters; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of new drug application (NDA) 206679 for Flolipid suspension, 20 milligrams (mg)/5 milliliters (mL) and 40 mg/5 mL and is announcing an opportunity for the NDA holder, Salerno Pharmaceuticals, 2431 East 61st St., Suite 300, Tulsa, OK 74136, to request a hearing on this proposal. The basis for the proposal is that Salerno Pharmaceuticals has repeatedly failed to file required annual reports for NDA 206679.

DATES: The NDA holder may submit a request for a hearing by December 18, 2026. Submit all data, information, and analyses upon which the request for a hearing relies by January 19, 2027. Submit electronic or written comments by January 19, 2027.

ADDRESSES: The request for a hearing may be submitted by the NDA holder by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including any attachments to the request for a hearing, will be posted to the docket unchanged.