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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

[FR Doc. 2026–23414 Filed 11–17–26; 8:45 am]

BILLING CODE 4164–01–P

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.

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.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No FDA–2026–N–9703 for ''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.'' The request for a hearing will be placed in the docket and publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

The NDA holder may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov* or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments as follows:

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.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–9703 for ''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.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holder of an approved NDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved NDA under § 314.81 (21 CFR 314.81). Salerno Pharmaceuticals has repeatedly failed to submit the required annual reports and has not responded to the Agency's request for submission of the reports.

Therefore, notice is given to Salerno Pharmaceuticals, 2431 East 61st St., Suite 300, Tulsa, OK 74136, the holder of the approved NDA 206679 for Flolipid suspension, 20 mg/5 mL and 40 mg/5 mL, and to all other interested persons that the Director of CDER

proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of this NDA and all amendments and supplements thereto on the grounds that the NDA holder has failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the NDA holder is hereby provided an opportunity for a hearing to show why the approval of the NDA listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by this NDA.

An NDA holder who decides to seek a hearing must file the following: (1) a written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an NDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the NDA and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the NDA, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov*.

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Michael Davis,

Director Center for Drug Evaluation and Research.

[FR Doc. 2026–23413 Filed 11–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Catastrophic Health Emergency Fund (CHEF) Fiscal Year 2027 Threshold

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the Catastrophic Health Emergency Fund (CHEF) threshold established at $20,258 for Fiscal Year 2027 CHEF requests.

SUPPLEMENTARY INFORMATION: The Indian Health Service (IHS) administers the CHEF pursuant to section 202 of the Indian Health Care Improvement Act (IHCIA). The purpose of the CHEF is to meet the extraordinary medical costs associated with the treatment of victims of disasters or catastrophic illnesses who are within the responsibility of the Service. The CHEF was established by section 202 of the IHCIA, Public Law 94–437 (25 U.S.C. § 1621a). The Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (collectively, the Affordable Care Act or ''the ACA''), reauthorized the IHCIA and amended the CHEF, directing the Secretary to promulgate regulations governing the administration of the CHEF. The final CHEF regulation (2024–19421 (89 FR 70527)) was published on August 30, 2024, in the **Federal Register**, establishing the threshold cost of $19,000 for Fiscal Year (FY) 2024. See 42 CFR § 136.503(a). The threshold amount in subsequent years is calculated from the threshold amount of the previous year, and increased by the percentage increase in the medical care expenditure category of the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with December of the previous year. See 42 CFR 136.503(b). The Consumer Price Index is released monthly. For FY 2027, ''December of the previous year'' is December 2025, because December 2026 is part of FY 2027. The ''12-month period ending with December of the previous year'' is therefore December 2024 to December 2025. The medical care expenditure category for this 12-month period was 3.2%, thereby increasing the threshold from $19,630 for FY 2026 to $20,258 for FY 2027 CHEF requests. See *https://www.federalregister.gov/documents/2026/03/12/2026-04827/catastrophic-health-emergency-fund-chef-fiscal-year-2026-threshold* for the FY 2026 CHEF Threshold Notice.

Mark Cruz,

Director, Indian Health Service.

[FR Doc. 2026–23466 Filed 11–17–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

30-Day Proposed Information Collection: Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on a new information collection titled, ''Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions,'' Office of Management and Budget (OMB), Control Number 0917–0028. The purpose of this notice is to announce the IHS's intent to submit this information collection to OMB and to allow 30 days for public comment to be sent directly to OMB. A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID IHS_FRDOC_0001-0293).

DATES: December 18, 2026. Any comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.