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is hereby provided an opportunity for a hearing to show why the approval of the NDA listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by this NDA.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]

BILLING CODE 4166–14–P

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.