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is hereby provided an opportunity for a hearing to show why the approval of the NDA listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by this NDA.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

FOR FURTHER INFORMATION CONTACT: Randolph Beasley, Director, Division of Personnel Security and Eligibility, by one of the following methods:

- *Mail:* Indian Health Service, HQ 5600 Fishers Ln 6NEH03, Rockville, MD 20852.
- *Phone:* 301–204–6488.
- *Email: Randolph.Beasley@ihs.gov.*

SUPPLEMENTARY INFORMATION: The IHS is submitting the proposed information collection to OMB for review, as required by section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995. This notice is soliciting comments from members of the public and affected agencies as required by 44 U.S.C. 3506(c)(2)(A) concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

The Agency's 60-day notice (90 FR 41585) soliciting comments on the information collection was published in the **Federal Register** on August 26, 2025. No comments were received.

Title of Proposal: Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions.

Type of Information Collection Request: Reinstatement, without revision, of information collection, 0917–0028, Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions. There are no program changes or adjustments in burden hours.

OMB Control Number: 0917–0028.

Need and Use of Information Collection: This is a request for approval of the collection of information as required by section 408 of the Indian Child Protection and Family Violence Prevention Act, Public Law (Pub. L.) 101–630, 104 Stat. 4544, 4551, codified as amended at 25 United States Code (U.S.C.) § 3207; the Crime Control Act of 1990, Pub. L. 101–647, title II, subtitle E, section 231, 104 Stat. 4789, 4808, codified as amended at 34 U.S.C. 20351 (formerly codified at 42 U.S.C. 13041, which was transferred to 34 U.S.C. 20351); and 42 CFR part 136, subpart K.

The IHS is required to compile a list of all authorized positions within the IHS where the duties and responsibilities involve regular contact with, or control over, Indian children; and to conduct an investigation of the character of each individual who is employed, or is being considered for employment, in a position having regular contact with, or control over, Indian children. 25 U.S.C. 3207(a)(1) and (2). Section 3207(a)(3) of Title 25 requires regulations prescribing the minimum standards of character for individuals appointed to positions involving regular contact with, or control over, Indian children, and section 3207(b) provides that such standards shall ensure that no such individuals have been found guilty of, or entered a plea of nolo contendere or guilty to, any felonious offense, or any two or more misdemeanor offenses, under Federal, State, or Tribal law involving crimes of violence; sexual assault, molestation, exploitation, contact or prostitution; crimes against persons; or offenses committed against children.

In addition, 34 U.S.C. 20351 requires each agency of the Federal Government, and every facility operated by the Federal Government (or operated under contract with the Federal Government), that hires (or contracts for hire) individuals involved with the provision of child care services to children under the age of 18 to assure that all existing and newly hired employees undergo a criminal history background check. The background investigation is to be initiated through the personnel program of the applicable Federal agency. 34 U.S.C. 20351(b)(1)(C). The statute requires employment applications for individuals who are seeking work for an agency of the Federal Government, or for a facility or program operated by (or through contract with) the Federal Government, in positions involved with the provision of child care services to children under the age of 18, to contain a question asking whether the individual has ever been arrested for or charged with a crime involving a child, and if so, requiring a description of the disposition of the arrest or charge. 34 U.S.C. 20351(d)(1).

Status of the Proposed Information Collection:

Form(s): Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions.

Agency Form Numbers: OF 306.

Members of Affected Public: Individuals and households.

The table below provides: Type of data collection instrument, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hour(s).

Data collection instrument(s)	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden responses (in hours)
Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions (OMB 0917–0028)	3,000	1	12/60	600
Total	3,000			600

There are no direct costs to respondents to report.

Mark Cruz,

Director, Indian Health Service.

[FR Doc. 2026–23468 Filed 11–17–26; 8:45 am]

BILLING CODE 4166–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,