

between the publication of the notice and the associated files being publicly available. For this reason, we are publishing the 30-day notice again. *Form Number:* CMS-2540-24 (OMB control number: 0938-0463); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 14,189; *Total Annual Responses:* 14,189; *Total Annual Hours:* 2,866,178. (For policy questions regarding this collection contact Luann Piccione at 410-786-5423.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Early Childhood Development (ECD), Office of Head Start (OHS), and Office of Child Care (OCC), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Head Start Act, notice is hereby given of one joint Tribal consultation session to be held between HHS/ACF ECD, OHS, and OCC leadership and the leadership of Tribal governments operating Tribal Maternal, Infant, and Early Childhood Home Visiting; Tribal Child Care and Development Fund; and Head Start and Early Head Start programs. The purpose of this consultation session is to discuss ways to better meet the needs of Tribal children and their families and issues affecting the delivery of early childhood services in their geographic locations. The consultation will also provide an opportunity for discussion on the review and promulgation of Head Start Program Performance Standards, as required under the Head Start Act. To meet this legislative requirement, one Tribal consultation will be held as part of HHS/ACF or ACF Tribal consultation sessions.

DATES: The meetings will take place July 9 and 10, 2024, at the following times:

- July 9 from 9 a.m.–5 p.m. Mountain Standard Time; and
- July 10 from 9 a.m.–3 p.m. Mountain Standard Time

ADDRESSES: The meetings are in-person in Fort McDowell, Arizona, at: We-Ko-Pa Casino Resort, 10438 WeKoPa Way, Fort McDowell, AZ 85264

FOR FURTHER INFORMATION CONTACT: Todd Lertjuntharangool, Regional Program Manager, Region 11, Office of Head Start, email Todd.Lertjuntharangool@acf.hhs.gov, or phone (866) 763-6481. Additional information and online meeting registration will be forthcoming.

SUPPLEMENTARY INFORMATION: In accordance with section 640(l)(4) of the Head Start Act, 42 U.S.C. 9835(1)(4), ACF announces a joint Tribal consultation session to be held between HHS/ACF ECD, OHS, and OCC leadership and the leadership of Tribal governments operating Tribal Maternal, Infant, and Early Childhood Home Visiting; Tribal Child Care and Development Fund; and Head Start and Early Head Start programs.

The agenda for the scheduled joint consultation reflects the statutory purposes of Head Start Tribal consultations related to meeting the needs of American Indian and Alaska Native (AIAN) children and families and will include the opportunity to discuss topics such as the Tribal Request for Information and recent changes to AIAN Head Start eligibility requirements. The consultation will also provide an opportunity for discussion on the review and promulgation of Head Start Program Performance Standards under section 641A(a)(2)(D) of the Head Start Act. OHS will also highlight the progress made in addressing issues and concerns raised in the previous OHS Tribal consultations.

The consultation session includes elected or appointed leaders of Tribal governments and their designated representatives. Designees must have a letter from the Tribal government authorizing them to represent the Tribe. Tribal governments must submit the designee letter at least 3 days before the consultation session to AIANheadstart@acf.hhs.gov. Other representatives of Tribal organizations and Native non-profit organizations are welcome to attend as observers.

Within 45 days of the consultation session, a detailed report of each consultation session will be available for all Tribal governments receiving funds for Head Start and Early Head Start programs. Tribes can submit written testimony for the report to AIANheadstart@acf.hhs.gov prior to each consultation session or within 30 days of each meeting. OHS will summarize oral testimony and comments from the consultation

sessions in each report without attribution, along with topics of concern and recommendations.

Khari M. Garvin,

Director, Office of Head Start.

Megan E. Steel,

ACF Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-2149]

Agency Information Collection Activities; Proposed Collection; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 the information collection provisions related to the De Novo Classification Process.

DATES: Either electronic or written comments on the collection of information must be submitted by July 29, 2024.

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 July 29, 2024. 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,