SUMMARY: The Office of Early Childhood Development (ECD), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting Office of Management and Budget (OMB) approval of the Tribal Early Childhood Facilities Combined Application Guide for joint applications for construction and major renovation projects using both Head Start and Child Care and Development Fund (CCDF) resources.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Funding for facilities under the CCDF is authorized by section 658O(c)(6) of the Child Care and Development Block Grant (CCDBG) Act, 42 U.S.C. 9858(c)(6), and is managed by the Office of Child Care (OCC). Funding for Head Start facilities projects is authorized by 45 CFR part 1303 (subpart E) Head Start Program Performance Standards and is managed by the Office of Head Start (OHS). The guide streamlines the process for Tribal CCDF Lead Agencies and American Indian and Alaska Native (AI/AN) Head Start programs submitting collaborative, joint applications to use federal CCDF and Head Start funds for facilities projects where funds can be used for reasonable costs and fees related to planning for a facilities project and to support the application development in tribal communities. Both funds aim to construct or improve early childhood facilities, often serving the same children, but application submission and review processes are currently unique to each respective funding stream. The proposed information collection will provide instructions to Tribal CCDF Lead Agencies and AI/AN Head Start programs on submitting joint plans for how proposed facilities projects will enable the programs to better serve current AI/AN families or increase enrollment currently limited by inadequate facilities. The guide will provide critical information and resources, so recipients understand the requirements of each program and develop plans that reflect the needs of their communities. Reducing and streamlining administrative burdens for tribal constituents follows policy priorities laid out in the 2022 HHS Equity Action Plan and is in alignment with Executive Order 14095—Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers.

Respondents: AI/AN Head Start Facilities and Tribal CCDF Lead Agencies (information collection does not include direct interaction with individuals or families that receive the services).

Annual Burden Estimates: We estimate at most 10 applications per year and have estimated burden based on this maximum number.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal Early Childhood Facilities Application Guide	10	1	100	1,000

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 9858(c)(6); 45 CFR part 1303 subpart E.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–26307 Filed 11–29–23; 8:45 am]

BILLING CODE 4184–87–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Survey of Staff Recruitment, Training, and Professional Development in Early Head Start (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children & Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to conduct a nationally representative survey of Early Head Start (EHS) grant recipients regarding their recruitment, hiring, and professional development practices.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, the ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The *Survey of Staff Recruitment, Training, and Professional Development in EHS* is a nationally representative survey that will describe how EHS programs ensure staff have the qualifications and competencies to deliver high-quality services to infants, toddlers, and their families. The information collection will examine how EHS grant recipients search for and hire qualified teaching and home visiting staff and support staff in their ongoing professional development and career advancement. The information collection aims to identify successful strategies or approaches as well as challenges faced as EHS programs search for, hire, and train teaching and home visiting staff. Findings are intended to inform program planning, training and technical assistance, and research.

Respondents: EHS program directors or their designee.

Annual Burden Estimates:

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Survey instrument for center-based programs only	232	1	.5	116
Survey instrument for home-based programs only	56	1	.5	28
Survey instrument for programs with center-based and home-based options	312	1	.75	234

Estimated Total Annual Burden Hours: 378.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Head Start Act section 640 [42 U.S.C. 9835].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–26297 Filed 11–29–23; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–0656; FDA–2022–E–0657; FDA–2022–E–0658; FDA–2022–E–0659; FDA–2022–E–0660; and FDA–2022–E–0680]

Determination of Regulatory Review Period for Purposes of Patent Extension; Amondys 45

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Amondys 45 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 January 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, 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 Nos. FDA–2022–E–0656; FDA–2022–E–0657; FDA–2022–E–0658; FDA–2022–E–0659; FDA–2022–E–0660; FDA–2022–E–0680 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AMONDYS 45.'' 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