obtained NPIs to review their NPPES records to ensure that the information they furnished when applying for their NPIs is up-to-date and accurate.

B. Impact on FOIA-Releasable NPPES Data

The NPPES Data Dissemination notice identified both the provider location address and provider gender code as NPPES data elements that must be released under FOIA. The changes to these data elements described in section II. of this notice do not affect HHS's assessment of their releasability under FOIA and the data elements will continue to be made available to the public through the NPI registry and the NPI downloadable files.

III. Collection of Information Requirements

This document imposes new information for collection and recordkeeping requirements. It makes reference to an existing information collection request that will be revised as a result of the revised data elements discussed in this notice. Specifically, we will submit a non-substantive change request to OMB for review and approval of the data element revisions associated with the information collection request currently approved under 0938–0931.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on February 27, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–04517 Filed 3–1–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Head Start REACH: Strengthening Outreach, Recruitment, and Engagement Approaches With Families—Mixed Methods Study (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 and Families (ACF) within the U.S. Department of Health and Human Services (HHS) is proposing to collect data on different approaches that Head Start programs use to recruit, select, and enroll families, and the ways in which such practices reflect programs' community contexts. We are not attempting to recruit a nationally representative sample. Instead, the study will aim to obtain a variety of eligibility, recruitment, selection, enrollment, and attendance (ERSEA) practices and experiences to explore how these practices and experiences intersect with different adversities, demographic characteristics, and community contexts.

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 *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Building on information collected previously through case studies (OMB #0970–0580), the Head Start REACH: Strengthening Outreach, Recruitment, and Engagement Approaches with Families Project is proposing to conduct a mixed-methods study to expand understanding of (1) how Head Start programs implement recruitment, selection, and enrollment practices; and (2) the ways in which practices reflect programs' community contexts. The mixed-methods study would achieve several goals including (1) providing in-depth contextual information about recruitment, selection, and enrollment practices and experiences; (2) identifying promising recruitment, selection, and enrollment practices and experiences; and (3) informing training and technical assistance regarding recruitment, selection, and enrollment challenges and needs. We will aim to collect information from 60 Head Start and Early Head Start programs in 15 geographic areas in states, from Head Start regions I–X, located in census tracts where the rate of deep poverty is high.

We will collect information about the characteristics of families in Head Start programs and their communities; programs' enrollment numbers and goals; programs' use and perceived effectiveness of and challenges with recruitment, selection, and enrollment practices; promising recruitment, selection, and enrollment practices for potential future replication; families' reasons for choosing Head Start and experiences with and perceptions of recruitment, selection, and enrollment practices; and how community partner staff support recruitment, selection, and enrollment of families into Head Start. The findings are intended to help Head Start programs understand how to support the needs of families facing adversities. We will disseminate findings in a report, research brief, and presentations or briefings.

Respondents: Head Start program directors (one per program), ERSEA lead staff (one per program), Head Start parents/caregivers (up to 10 per program), and staff from community organizations with which Head Start programs partner for ERSEA activities (four in each geographic area).

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)
Program director survey (*Instrument 1)*	60	1	0.17	10.2
ERSEA lead staff survey (*Instrument 2)*	60	1	0.75	45
Onsite coordination [a]	60	1	1.5	90
Head Start parent/caregiver survey *(Instrument 3)*	600	1	0.5	300
Community partner survey *(Instrument 4)*	60	1	0.25	15

ANNUAL BURDEN ESTIMATES—Continued

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)
ERSEA lead staff focus group guide *(Instrument 5)*	24	1	1.5	36
Estimated Total Annual Burden Hours				496.2

[a] There is no instrument associated with this activity. We will ask each program director to nominate a staff person who will help coordinate data collection activities. This line accounts for the time of the onsite coordinator.

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 C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–04520 Filed 3–1–24; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–E–2460]

Determination of Regulatory Review Period for Purposes of Patent Extension; SOTYKTU

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 SOTYKTU and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 must submit either electronic or written comments and ask for a redetermination by May 3, 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 September 3, 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 May 3, 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 No. FDA–2023–E–2460 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SOTYKTU.'' 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