which it partners to support these activities. This study aims to present an internally valid description of RSER approaches used by six purposively selected programs, not to promote statistical generalization to different sites or service populations.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The Head Start REACH: Strengthening Outreach, Recruitment and Engagement Approaches with Families project is proposing to conduct qualitative case studies to examine the approaches used by Head Start programs to recruit, select, enroll, and retain families experiencing adversities and the implementation of these approaches, including supporting factors and barriers. Adversities is a broad term that refers to a wide range of circumstances or events that pose a threat to a child or caregiver's physical or psychological well-being. The adversities that families experience are often intertwined with poverty, may co-occur, and are affected by systematic factors, such as structural racism. Common examples include (but are not limited to) families experiencing homelessness; involvement in child welfare, including foster care; and affected by substance use, mental health issues, and domestic violence.

We will collect information from six sites; each site will include (1) a Head Start program that has demonstrated success in the RSER of families experiencing adversities and (2) up to four of its community partner organizations that serve families experiencing adversities.

We will collect information on how programs determine which adversities to focus on for their RSER efforts; RSER approaches programs use, focusing specifically on families experiencing adversities; RSER-related training and support that Head Start staff receive; partnerships that programs form with organizations in the community to support these activities; and supporting factors and barriers to participation of enrolled and non-enrolled families who face adversities.

Respondents: Head Start program directors, Head Start staff conducting eligibility, recruitment, selection, enrollment, attendance (ERSEA) activities, staff from community organizations with which Head Start programs partner for ERSEA activities, Head Start-eligible parents enrolled in Head Start, and those not enrolled in Head Start.

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 recruitment call protocol (Instrument 1)	6	1	0.50	3.0
Program staff interview protocol: Program director (Instrument 2) [a]	6	1	1.0	6.0
Program staff interview protocol ERSEA staff (Instrument 2) [a]	24	1	1.5	36
Head Start program study activities and focus group coordination [b]	6	1	8.0	48
Head Start enrolled families focus group guide (Instrument 3)	60	1	1.5	90
Community partner recruitment call protocol (Instrument 4)	24	1	0.17	4.0
Community partner staff interview protocol (Instrument 5)	24	1	0.75	18
Community partner focus group coordination [b]	6	1	3.0	18
Families not enrolled in Head Start focus group guide (Instrument 6) [c]	60	1	1.5	90

[a] There is one interview protocol for both the program director and the ERSEA staff and the interviewer will tailor it to the respondent(s).
[b] There is no instrument, only a document of duties associated with this activity.
[c] If needed, we will offer the option of a 45-minute one-on-one interview; however, as we do not expect to have to use the interview option often, the table reflects a 90-minute burden for all families not enrolled in Head Start.

Estimated Total Annual Burden Hours: 313.

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

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–18917 Filed 8–31–21; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0860]

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 4, 2021, from 10 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings

may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0860. The docket will close on November 3, 2021. Submit either electronic or written comments on this public meeting by November 3, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 3, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 3, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 21, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

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–2021–N–0860 for ''Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7973, Fax: 301–847–8533, email: *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 214812, for carbetocin nasal spray, submitted by Levo Therapeutics, Inc., for the proposed treatment of hyperphagia, anxiety, and distress behaviors associated with Prader-Willi syndrome.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 21, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 13, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 14, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Frimpong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18892 Filed 8–31–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Components Study of REAL Essential Curriculum.

Type of Collection: New.

OMB No. 0990–NEW—Office of Population Affairs—OASH—OS.

Abstract: The Office of Population Affairs (OPA), U.S. Department of Health and Human Services (HHS) is requesting 3 years of approval by OMB on a new collection. The Components Study of REAL Essential Curriculum will identify the components that matter the most for promoting positive health behaviors and outcomes among adolescents. The study will examine program components (for example, content and dosage), implementation components (for example, attendance and engagement), and contextual components (for example, participant characteristics) to determine which components influence participant outcomes the most. In addition, the study will measure youth engagement in programming from various perspectives and examine the role of engagement as a mediating factor to achieving youth outcomes. Sites participating in the study will use the REAL Essentials Advance (REA) relationship curriculum, a popular program among federal pregnancy prevention grantees. The study will enroll schools from spring to fall 2022 (and possibly spring 2023, if necessary). The study will collect youth surveys at baseline, at program exit, and 6 months following the completion of the program. The study will also collect extensive implementation data, which includes youth engagement exit ticket surveys after REA sessions, focus groups with youth, program facilitator logs, and attendance records. Study staff will also interview facilitators and site leadership.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Youth outcome survey	498	3	40/60	996
Youth-focus groups	133	1	90/60	200
Youth-engagement exit ticket	533	12	2/60	213
Program Facilitators—Fidelity log	13	24	10/60	52
Program Facilitators—interview topic guide	5	2	1	10
District/School/CBO leadership- interview topic guide	11	2	45/60	17
Total	1193	44	.....	1488