age and older through educating and training first responders and other key community sectors on the prevention of prescription drug/opioid overdose-related deaths, including the purchase and distribution of naloxone. SAMHSA is funding the grant and CDC is responsible for conducting the grantee evaluation.

The intended use of the resulting data is to increase CDC and SAMHSA understanding of the scope and impact of the program on overdose fatalities and how program effectiveness may vary among different sub-populations and settings, and to increase knowledge of barriers and facilitators to program implementation.

Researchers will use key informant interviews and focus groups with participants in the activities enacted by the twelve state grant recipients. Participants will include state administrators of the grant and other PDO/Naloxone stakeholders including advisory council members, first responders, social service providers, laypersons including end users and their family and friend. All focus groups and interviews will be analyzed through qualitative content analysis, including utilization of a systematic coding scheme.

Total burden in hours for this collection is 381. There are no costs to respondents other than their time. CDC requests a three-year OMB approval to collect the necessary project-related information.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
PDO/Naloxone Advisory Committee Members and Grantees.	Focus Group Discussion Guide	140	1	1.5
PDO/Naloxone Grantees	Key Informant Interview Guide for Grantees	36	1	1
PDO/Naloxone Stakeholders and Partners	Key Informant Interview Guide for Partners	84	1	1
PDO/Naloxone Laypersons	Key Informant Interview Guide for Laypersons.	24	1	1
All participants (PDO Naloxone grantees, advisory committee, stakeholders and partners, laypersons).	Recruitment contact script	284	1	5/60
PDO/Naloxone Grantees	Key Informant Selection Tool	12	1	15/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–27257 Filed 12–18–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: ACF Generic Clearance for Mandatory Grant Financial Reports.

OMB No.: 0970—New.

Description: OMB has granted permission for ACF to submit a request for a generic clearance to be used for the financial reports used in the administration of mandatory grants. This clearance supports the Departments initiative of *Generating Efficiencies through Streamlined Processes* by employing an abbreviated process.

If approved program offices will be at liberty to tailor a financial report to their specific needs rather than adhering to a standard form.

Respondents: States and Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Mandatory Grant Financial Reports	900	4	5	18,000

Estimated Total Annual Burden Hours:

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap. 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–27306 Filed 12–18–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6716]

New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products.'' The purposes of the workshop are to present the outcomes from the research projects conducted under the Generic Drug User Fee Amendments (GDUFA) Regulatory Science Research Program; discuss how regulatory science initiatives have helped address regulatory science knowledge gaps by providing insights on factors that influence the performance of generic orally inhaled and nasal drug products (OINDPs); share the Agency's experience on the utility of novel analytical tools and methods developed under the regulatory science initiative for generic OINDP product development and bioequivalence assessments; and obtain input from the public on what, when, where, and how analytical methods and procedures should be applied in the development and review of abbreviated new drug applications (ANDAs) for complex OINDPs.

DATES: The public workshop will be held on January 9, 2018, from 8:30 a.m. to 4:30 p.m. Individuals who wish to attend the workshop must register by December 30, 2017. Submit either electronic or written comments on this public workshop by February 14, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 B+C), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 14, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 14, 2018. 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.

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–2017–N–6716 for ''New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products.'' 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.

- 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 available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this 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.gpo.gov/fdsys/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.