DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Annual Report/ACF 204 (State MOE) (OMB #0970–0248).

OMB No.: 0970–0248.

Description: The Administration for Children and Families (ACF) is requesting a three-year extension of the ACF–204 (Annual MOE Report). The report is used to collect descriptive program characteristics information on the programs operated by States and Territories in association with their Temporary Assistance for Needy Families (TANF) programs. All State and Territory expenditures claimed toward States and Territories MOE requirements must be appropriate, *i.e.,* meet all applicable MOE requirements. The Annual MOE Report provides the ability to learn about and to monitor the nature of State and Territory expenditures used to meet States and Territories MOE requirements, and it is an important source of information about the different ways that States and Territories are using their resources to help families attain and maintain self-sufficiency. In addition, the report is used to obtain State and Territory program characteristics for ACFs annual report to Congress, and the report serves as a useful resource to use in Congressional hearings about how TANF programs are evolving, in assessing State the Territory MOE expenditures, and in assessing the need for legislative changes.

Respondents: The 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–204	54	1	118	6,372

Estimated Total Annual Burden Hours: 6,372.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–23635 Filed 10–29–19; 8:45 am]

BILLING CODE 4184–82–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3953]

Providing Regulatory Submissions in Electronic Format: Investigational New Drug Application Safety Reports; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' The draft guidance describes the electronic format sponsors will be required to use when they electronically submit to FDA investigational new drug (IND) safety reports to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) for serious and unexpected suspected adverse reactions that are required under the Agency's regulations. FDA is establishing the electronic format requirements described in this guidance under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The draft guidance, once finalized and effective, will require sponsors submitting the specified IND safety reports electronically to submit the reports to FDA using the FDA Adverse Event Reporting System (FAERS) as structured data elements and will provide sponsors with a reporting format that is consistent with the International Council for Harmonisation (ICH) E2B(R2) format guidelines and reporting requirements to other regulatory agencies. Additional technical specification documents and instructions for submitting IND safety reports, including ''Electronic Submission of IND Safety Reports Technical Conformance Guide'' and an updated technical specifications document entitled ''Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments'' are available on the FAERS Electronic Submission web page (available at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm*).

DATES: Submit either electronic or written comments on the draft guidance by December 30, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2019–D–3953 for ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Meredith K. Chuk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MD 20993–0002, 301–796–2340; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' The draft guidance describes the electronic format sponsors will be required to use when they electronically submit to FDA IND safety reports to CDER and CBER for serious and unexpected suspected adverse reactions that are required under 21 CFR 312.32(c)(1)(i). FDA is establishing the electronic format requirements described in this guidance under section 745A(a) of the FD&C Act. In section 745A(a) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the format for the electronic submissions required under that section. The draft guidance, once finalized, will require sponsors submitting the specified IND safety reports electronically to submit the reports to FDA using FAERS as structured data elements. Additional technical specification documents and instructions for submitting IND safety reports, including ''Electronic Submission of IND Safety Reports Technical Conformance Guide'' and an updated technical specifications document entitled ''Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments,'' are available on the FAERS Electronic Submission web page (available at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm*)).

The draft guidance, when finalized, will represent the current thinking of FDA on ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' The electronic format requirements specified in this guidance will be effective 24 months after the publication of the final guidance on this topic. Before the effective date of this requirement, FDA will accept the IND safety reports described in this guidance to FAERS as part of a voluntary submission program.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information under 21 CFR 312.10 for submitting waiver requests and under 21 CFR 312.32 for submitting IND safety reports and reporting serious and unexpected adverse events has been approved under OMB control number 0910–0014. The collection of information for submitting Forms FDA 3500 and 3500A has been approved under OMB control number 0910–0291. The collection of information for submitting periodic adverse drug experience reports has been approved under OMB control number 0910–0230.

The collection of information for FDA adverse event reporting and electronic submissions using the Electronic Submission Gateway and the Safety Reporting Portal has been approved under OMB control number 0910–0645.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: October 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23666 Filed 10–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0221]

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 November 29, 2019.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

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: Family Planning Annual Report (FPAR).

Type of Collection: Renewal with change.

OMB No.: 0990–0221.

Abstract: The Office of Population Affairs within the Office of the Assistant Secretary for Health is requesting an extension on a currently approved Family Planning Annual Report (FPAR) data collection and reporting tool (OMB No. 0990–0221). This annual reporting requirement is for family planning services delivery projects authorized and funded by the Title X Family Planning Program [''Population Research and Voluntary Family Planning Programs'' (Pub. L. 91–572)], which was enacted in 1970 as Title X of the Public Health Service Act (Section 1001; 42 U.S.C. 300). The FPAR data collection and reporting tool will include a new module to collect substance use disorder (SUD) screening data in this request to extend an OMB approval to collect essential, annual data from Title X grantees.

Need and Proposed Use of the Information

The Title X Family Planning Program (''Title X program'' or ''program'') is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services (*e.g.,* screening for breast and cervical cancer, sexually transmitted diseases (STDs), and human immunodeficiency virus). By law, priority is given to persons from low-income families (Section 1006[c] of Title X of the Public Health Service Act, 42 U.S.C. 300). The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

Likely Respondents: Respondents for this annual reporting requirement are centers that receive funding directly from OPA for family planning services authorized and funded under the Title X Family

This weighted average hour burden accounts for differences in reporting burden by type of grantee agency grantee (*e.g.,* public health department or private agency), as found in the *2009 FPAR Burden Study.* For purposes of this estimate, the average hour burden ranges between 39 hours (public health department) and 32 hours (private agency).

ANNUALIZED BURDEN HOUR TABLE

Type of respondents	Form name	Number of respondents	Number of responses per respondents	Average annualized burden per response (hours)	Annualized total burden (hours)
Grantees	FPAR	93	1	36	3,348
Total		93	1	36	3,348

Terry Clark,

Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–23675 Filed 10–29–19; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,