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.

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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