

adoptive placements based on the race, color, or national origin of any of the individuals involved. The enforcement provisions include the execution and completion of corrective action plans when a state is in violation of section 471(a)(18) of the Act. The information collection is needed: (1) To ensure compliance with title IV–E foster care eligibility requirements; (2) to monitor state plan requirements under titles IV–B and IV–E of the Act, as required by federal statute; and (3) to enforce the title IV–E anti-discrimination

requirements through state corrective action plans. The resultant information will allow ACF to determine if states are in compliance with state plan requirements and are achieving desired outcomes for children and families, help ensure that claims by states for title IV–E funds are made only on behalf of title IV–E eligible children, and require states to revise applicable statutes, rules, policies and procedures, and provide proper training to staff, through the development and implementation of corrective action plans. These reviews

not only address compliance with eligibility requirements but also assist states in enhancing the capacities to serve children and families. In computing the number of burden hours for this information collection, ACF based the annual burden estimates on ACF's and states' experiences in conducting reviews and developing program improvement plans.

*Respondents:* State Title IV–B and Title IV–E Agencies.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 1356.7(i) Program Improvement Plan (FCER) .....	2	1	90	180
45 CFR 1366.33(b) Statewide Assessment (CFSR) .....	13	1	120	1,560
45 CFR 1355.33(c) On-site Review (CFSR) .....	13	1	1,186	15,418
45 CFR 1355.35(a) Program Improvement Plan (CFSR) .....	13	1	300	3,900
45 CFR 1355.38(b) and (c) Corrective Action .....	1	1	780	780

Estimated Total Annual Burden Hours: 21,838.

*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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto: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](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Administration for Children and Families

##### Proposed Information Collection Activity; Comment Request

##### Proposed Projects

*Title:* Intergovernmental Reference Guide (IRG).

*OMB No.:* 0970–0209.

*Description:* The Intergovernmental Reference Guide (IRG) is a centralized

and automated repository of state and tribal profiles, which contains high-level descriptions of each state and tribe's child support enforcement (CSE) program. These profiles provide state and tribal CSE agencies, and foreign countries with an effective and efficient method for updating and accessing information needed to process intergovernmental child support cases.

*The IRG information collection activities are authorized by:* (1) 42 U.S.C. 652(a)(7), which requires OCSE to provide technical assistance to state child support enforcement agencies to help them establish effective systems for collecting child and spousal support; (2) 42 U.S.C. 666(f), which requires states to enact the Uniform Interstate Family Support Act; and (3) 45 CFR 303.7, which requires state child support agencies to provide services in intergovernmental cases.

*Respondents:* All state and tribal CSE agencies.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Intergovernmental Referral Guide: State Profile Guidance—(States and Territories) .....	54	18	0.30	291.60
Intergovernmental Referral Guide: Tribal Profile Guidance .....	60	18	0.30	324.00

*Estimated Total Annual Burden Hours:* 615.60.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork

Reduction Act of 1995, 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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto: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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0231]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by November 28, 2014.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:

202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0308. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Adverse Experience Reporting for Licensed Biological Products; and General Records—21 CFR Part 600—(OMB Control Number 0910-0308)—Extension

Under the Public Health Service (PHS) Act (42 U.S.C. 262), FDA may only approve a biologics license application for a biological product that is safe, pure, and potent. When a biological product is approved and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits and risks of the product, and evaluation of this information is important to insure its safe use. FDA issued the Adverse Experience Reporting (AER) requirements in part 600 (21 CFR part 600) to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products.<sup>1</sup>

The primary purpose of FDA's AER system is to identify potentially serious safety problems with licensed biological products. Although the premarket approval process is meant to disclose a general safety profile of a biological product's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. In addition, production and/or distribution problems have contaminated biological products in the past. AER reports are obtained from a variety of sources, including manufacturers, patients,

physicians, foreign regulatory agencies, and clinical investigators. Identification of new and unexpected safety issues through the analysis of the data in AERS contributes directly to increased public health protection. For example, evaluation of these safety issues enables FDA to take focused regulatory action. Such action may include, but is not limited to, important changes to the product's labeling (such as adding a new warning), coordination with manufacturers to ensure adequate corrective action is taken, and removal of a biological product from the market when necessary.

Section 600.80(c)(1) requires licensed manufacturers or any person whose name appears on the label of a licensed biological product to report each adverse experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the licensed manufacturer. These reports are known as postmarketing 15-day Alert reports. This section also requires licensed manufacturers to submit any follow-up reports within 15 calendar days of receipt of new information or as requested by FDA, and if additional information is not obtainable, to maintain records of the unsuccessful steps taken to seek additional information. In addition, this section requires a person who submits an adverse action report to the licensed manufacturer, rather than FDA, to maintain a record of this action.

Section 600.80(e) requires licensed manufacturers to submit a 15-day Alert report for an adverse experience obtained from a postmarketing clinical study only if the licensed manufacturer concludes that there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires licensed manufacturers to report each adverse experience not reported in a postmarketing 15-day Alert report at quarterly intervals, for 3 years from the date of issuance of the biologics license, and then at annual intervals. The majority of these periodic reports are submitted annually since a large percentage of currently licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires licensed manufacturers to maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 requires licensed manufacturers to submit, at an interval of every 6 months, information about the quantity of the product distributed under the biologics

<sup>1</sup> Please note that throughout the regulations referenced in relation to these information collections, licensed biological products refers to biologics licensed under any provision of section 351 of the PHS Act.