nation's Adoption and Foster Care populations, nor report meaningful and reliable information to Congress about the extent of problems facing these children or the effectiveness of assistance provided to this population, without access to timely and accurate information. Currently, SACWIS support State efforts to meet the following Federal reporting requirements: The Adoption and Foster Care Analysis and Reporting System (AFCARS) required by section 479(b)(2) of the Social Security Act; the National Child Abuse and Neglect Data System (NCANDS); Child Abuse Prevention and Treatment Act (CAPTA); and the Chafee Independent Living Program. These systems also support state efforts to provide the information to conduct the Child and Family Service Reviews. Currently, forty-two States and the District of Columbia have developed, or are developing, a SACWIS with Federal financial participation. The purpose of these reviews is to ensure that all aspects of the project, as described in the approved Advance Planning Document, have been adequately completed, and conform to applicable regulations and policies.

To initiate a review, States will submit the completed SACWIS Assessment Review Guide (SARGE) and other documentation at the point that they have completed system development and the system is operational statewide. The additional documents submitted as part of this process should all be readily available to the State as a result of good project management practices.

The information collected in the SACWIS Assessment Review Guide will allow State and Federal officials to determine if the State's SACWIS meets the requirements for title IV–E Federal Financial Participation (FFP) defined at 45 CFR 1355.50. Additionally, other States will be able to use the documentation provided as part of this review process in their own system development efforts.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of responses	Number of responses per respondent	Average burden hours per response	Total burden hours
Review	1	1	200	200

Estimated Total Annual Burden Hours: 200.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail 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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: July 10, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–16180 Filed 7–16–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Tribal Plan (Form ACF–118–A).

OMB No.: 0970–0198.

Description: The Child Care and Development Fund (CCDF) Tribal Plan serves as the agreement between the applicant (Indian Tribes, tribal consortia and tribal organizations) and the Federal Government that describes how tribal applicants will operate CCDF Block Grant programs. The Tribal Plan provides assurances that the CCDF funds will be administered in conformance with legislative requirements, Federal regulations at 45 CFR parts 98 and 99 and other applicable instructions or guidelines issued by the Administration for Children and Families (ACF). Tribes must submit a new CCDF Tribal Plan every two years in accordance with 45 CFR 98.17.

Respondents: Tribal CODE programs (259 total).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Tribal Plan	259	1	17.5	4,532.5
CCDF Tribal Plan Amendments	259	1	1.5	388.5

Estimated Total Annual Burden Hours: 4,921.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. E-mail 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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: July 10, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–16183 Filed 7–16–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: The OC5E–157 Child Support Enforcement Annual Data Report.

OMB No.: 0970–0177.

Description: The information obtained from this form will be used to: (1) Report Child Support Enforcement activities to the Congress as required by law; (2) calculate incentive measures performance and performance indicators utilized in the program; and (3) assist the Office of Child Support Enforcement in monitoring and evaluating State Child Support programs.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–157 Child Support Annual Data Report	54	1	7	378.

Estimated Total Annual Burden Hours: 378

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail 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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: July 10, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–16197 Filed 7–16–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0208] (formerly Docket No. 2005D–0438)

Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency,'' dated June 2008. The guidance document provides recommendations for the design of clinical trials to assess the safety, efficacy, and pharmacokinetics of immune globulin intravenous (human) (IGIV) products as replacement therapy in primary humoral immunodeficiency. The guidance announced in this notice finalizes the draft guidance of the same title dated November 2005.

DATES: Submit written or electronic comments on agency guidances at any time. Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Denise Sánchez, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency,'' dated June 2008. This guidance provides investigational new drug application (IND) and biologics license application (BLA) sponsors with recommendations for the design of clinical trials to assess the safety, efficacy, and pharmacokinetics of investigational IGIV products when used as replacement therapy in primary humoral immunodeficiency. This