

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