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

guidance is intended to assist sponsors in the preparation of the clinical/biostatistical and human pharmacokinetic sections of a BLA. This guidance does not address additional sections of a BLA, such as chemistry, manufacturing, and controls and pre-clinical toxicology, for an IGIV product for this indication.

In the **Federal Register** of December 1, 2005 (70 FR 72124), FDA announced the availability of the draft guidance of the same title dated November 2005. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: Recommendations for compliance with the Pediatric Research Equity Act of 2007, refinements to the criteria for diagnosing serious infections, refinements to the recommended safety analyses of adverse experiences temporally related to infusions, and additional guidance on the methodology of pharmacokinetic studies. The guidance announced in this notice finalizes the draft guidance dated November 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 collections of information regarding BLAs (21 CFR part 601) have been approved under OMB control number 0910–0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: July 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16395 Filed 7–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0434] (formerly Docket No. 2003D–0420)

Medical Devices: Radiology Devices; Class II Special Controls Guidance Document: Bone Sonometers; Guidance for Industry and Food and Drug Administration Staff

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers.'' The guidance document describes a means by which bone sonometers may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying these devices from class III (premarket approval) into class II (special controls).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3666.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 15, 2006 (71 FR 7894), FDA's Center for Devices and Radiological Health (CDRH) published a proposed rule to reclassify bone sonometers from class III (premarket approval) into class II (special controls) after reviewing current technological and scientific developments. Specifically, CDRH reviewed recent studies addressing performance characteristics of bone sonometers manufactured by different companies and determined that, when combined with mitigation measures to offset the risks of use associated with these devices, special controls would be adequate to assure the safety and effectiveness of bone sonometers. To support the reclassification, CDRH issued a draft class II special controls guidance document entitled ''Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers'' (71 FR 7976). Interested persons were invited to comment on the proposed rule and guidance by May 16, 2006, and the agency received three comments. The comments FDA received were supportive of the proposed reclassification, but made specific suggestions on the guidance's content. The agency considered the suggestions and made appropriate revisions. FDA is now identifying the guidance document entitled ''Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Bone Sonometers'' as the guidance document that will