

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM

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Certifier A. Corbin

[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 The guidance announced in this notice finalizes the draft guidance of the same title dated November 2005.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

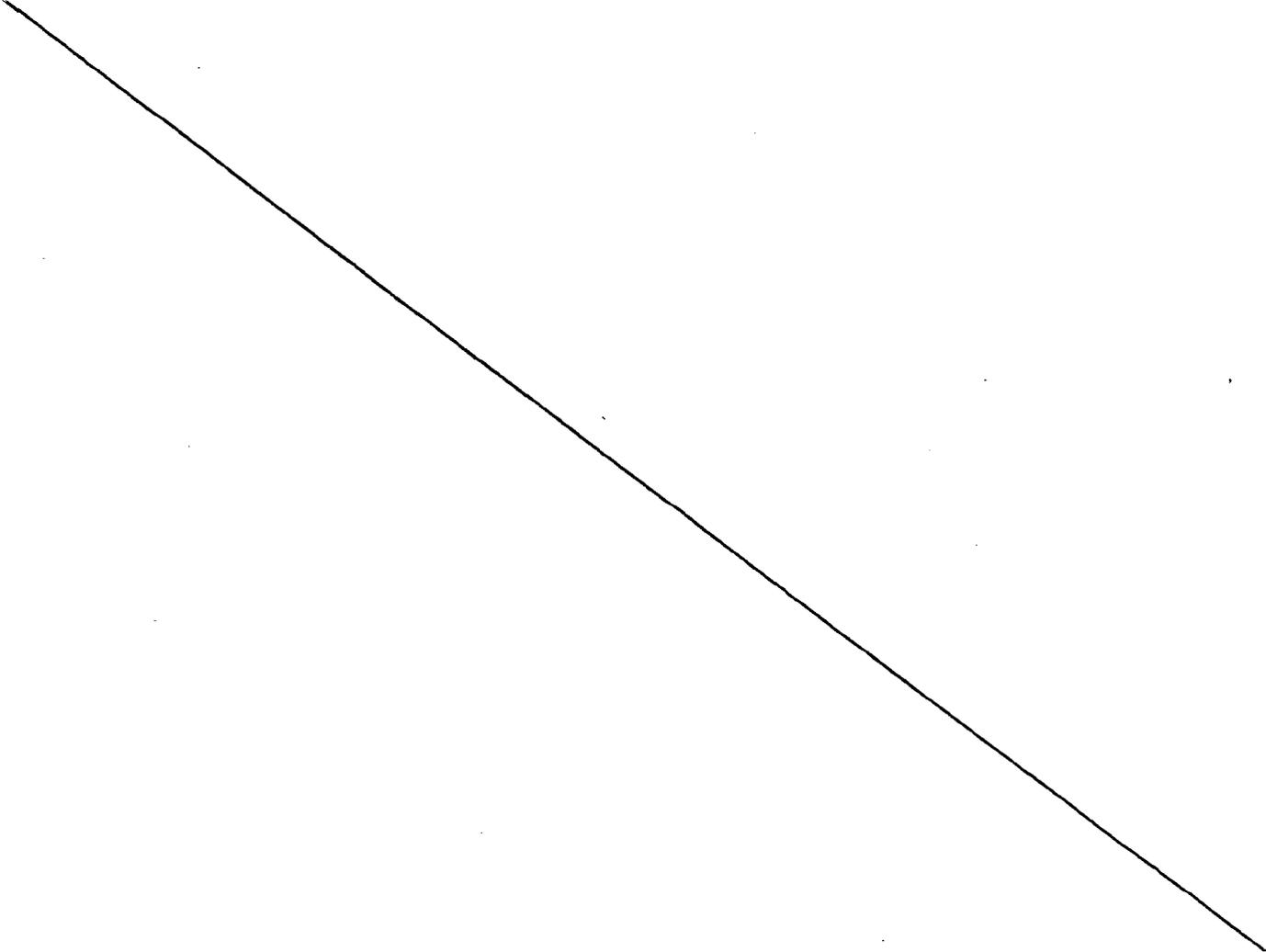
This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding 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: 7/11/08

July 11, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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