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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

[Docket No. 00D-1033]

**Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions." The document provides guidance for industry on procedures for submitting protocol information to the Clinical Trials Data Bank established by section 113 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). Section 113 of the Modernization Act creates a public resource for information on studies of drugs for serious or life-threatening diseases and conditions conducted under FDA's investigational new drug (IND) regulations.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or 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, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBER-FAX. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

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20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Theresa Toigo, Office of Special Health Issues, Office of the Commissioner (HF-12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4460.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions.” The agency has finalized the guidance after considering comments received on two draft guidance documents. In the **Federal Register** of March 29, 2000 (65 FR 16620), FDA published the notice of availability of a draft guidance entitled “Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.” The March 29, 2000, draft guidance provided recommendations for industry on the submission of protocol information to the clinical trials data bank. It included information on the types of clinical trials for which submissions are required under section 113 of the Modernization Act (42 U.S.C. 282) and on the content of those submissions.

Notice of the availability of the second draft guidance entitled “Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan,” was published on July 9, 2001 (66 FR 35798). It addressed procedural issues, including how to submit required and voluntary protocol information to the Clinical Trials Data Bank through a Web-based Protocol Registration System (PRS) available at <http://prsinfo.clinicaltrials.gov/>.

This guidance, which is a combination of the informational and procedural draft guidances, was finalized after consideration of comments received on both draft guidances. The comments received addressed the following topics: (1) Scope of data requirements, (2) international trial sites, (3) voluntary information, (4) compliance, (5) timeframes, (6) procedural issues (e.g. contact names

and intermediaries), and (7) burden estimate. Revisions made in the guidance are intended to clarify issues raised in the comments and to make the document clearer.

We note that Senate 1789, “Best Pharmaceuticals for Children Act” (Public Law 107–109), which was signed by the President on January 4, 2002, provides for a description of whether, and through what procedure, the manufacturer or sponsor of an IND will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the investigational drug, particularly in children. The agency intends to issue a revised guidance in the future to address this provision.

Along with the first draft guidance, FDA published a notice in the **Federal Register** of March 29, 2000, announcing a proposed collection of information. On November 9, 2000 (65 FR 67385), FDA published a notice stating that the proposed collection of information was submitted to the Office of Management and Budget (OMB) for review. The report considered comments received on the proposed collection of information. On March 23, 2001 (66 FR 16251), FDA announced OMB’s approval of the agency’s information collection activities for the program (OMB Control No. 0910–0459). This approval expires March 31, 2004. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

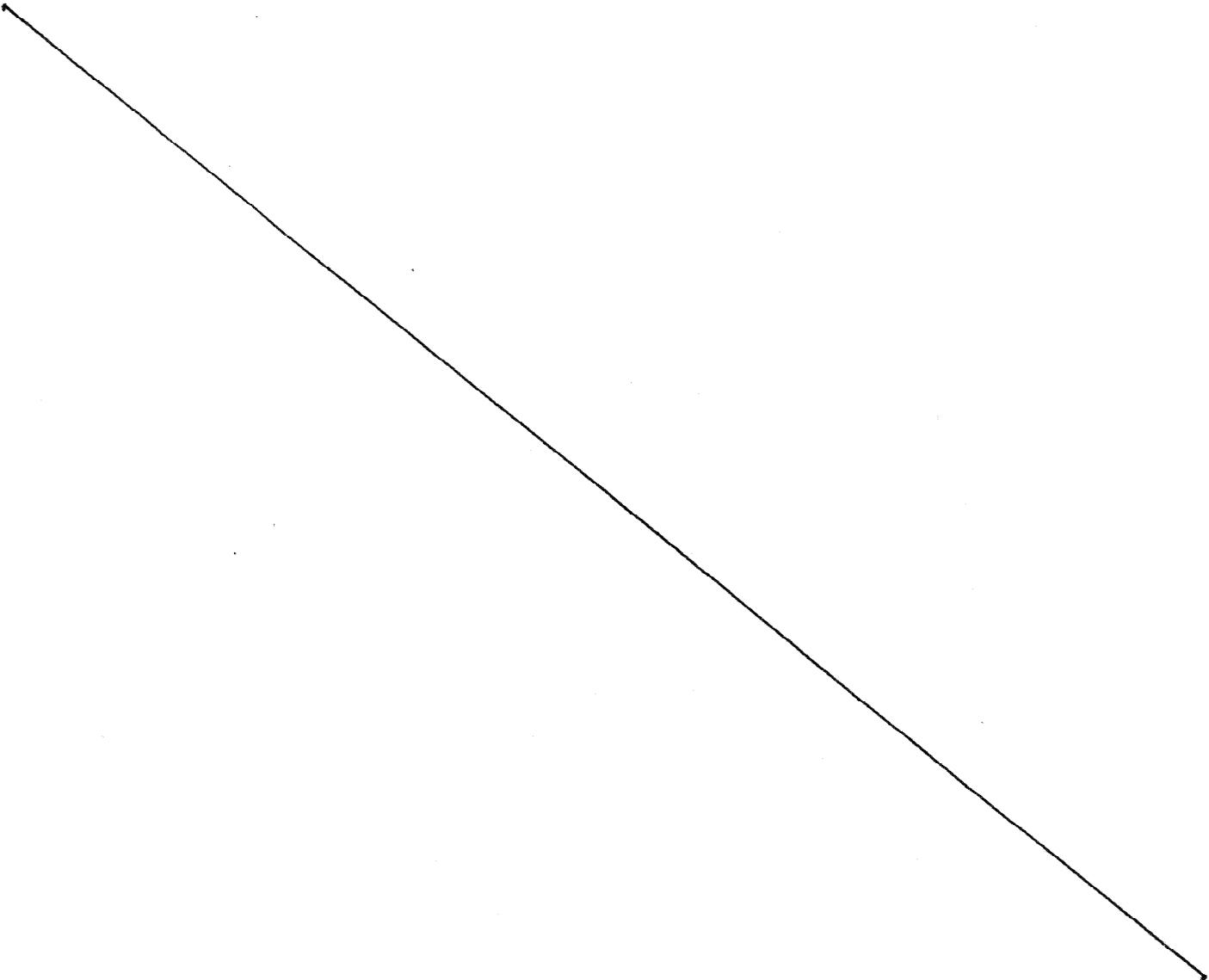
This level 1 final guidance is being issued in accordance with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on compliance with section 113 of Modernization Act, i.e., submitting information on clinical trials for serious or life-threatening diseases and conditions to a Clinical Trials Data Bank developed by the National Library of Medicine, National Institutes of Health. 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. Comments**

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m and 4 p.m., Monday through Friday.

## **III. Electronic Access**

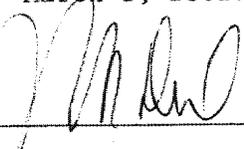
Persons with access to the Internet may obtain the document at either <http://www.fda.gov/>



cder/guidance/index.htm, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 3/1/02

March 1, 2002.

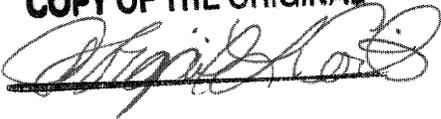
  
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Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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