

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0014]

### Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions; Availability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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions.” FDA is revising its March 2002 guidance for industry of the same title to include guidance for sponsors who will be submitting information required by the Best Pharmaceuticals for Children Act (BPCA). The BPCA amended the Public Health Service Act (PHS Act) to require that additional information be included in the Clinical Trials Data Bank established as required by the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This draft guidance explains how to provide that information.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or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. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Theresa Toigo, Office of Special Health Issues (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 draft guidance for industry entitled “Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions” to assist sponsors who will be submitting information to the Clinical Trials Data Bank established by section 113 of the Modernization Act (42 U.S.C. 282). This draft guidance revises the guidance of the same title issued in March 2002 (67 FR 12022, March 18, 2002) to include assistance on submitting information required by the BPCA (Public Law 107-109). This draft guidance updates the March 2002 guidance.

The BPCA amends section 402(j)(3)(A) of the PHS Act (42 U.S.C. 282(j)(3)(A)) to require that additional information be included in the Clinical Trials Data Bank established as required under section 113 of the

Modernization Act. Additional information to be submitted includes a description of whether, and through what procedure, the manufacturer or sponsor of an investigation of a new drug will respond to requests for a protocol exception, with appropriate safeguards, for single-patient and expanded access use of the investigational drug, particularly in children.

Section 113 of the Modernization Act, enacted November 21, 1997, directs the Secretary of Health and Human Services (the Secretary), acting through the Director of the National Institutes of Health (NIH), to establish, maintain, and operate a data bank of information on clinical trials for drugs to treat serious or life-threatening diseases and conditions. The Clinical Trials Data Bank is intended to be a central resource, providing current information on clinical trials to individuals with serious or life-threatening diseases or conditions, to other members of the public, and to health care providers and researchers.

Specifically, section 113 of the Modernization Act requires that the Clinical Trials Data Bank contain the following information: (1) Information about Federally and privately funded clinical trials for experimental treatments (drug and biological products) for patients with serious or life-threatening diseases or conditions, (2) a description of the purpose of each experimental drug, (3) patient eligibility criteria, (4) a description of the location of clinical trial sites, and (5) a point of contact for patients wanting to enroll in the trial. Section 113 of the Modernization Act also requires that information provided through the Clinical Trials Data Bank be in a form that can be readily understood by the public (42 U.S.C. 282(j)(3)(A)). The BPCA, signed by the President on January 4, 2002, requires that the Clinical Trials Data Bank contain additional information including 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 access use of the investigational drug, particularly in children.

The NIH, through its National Library of Medicine (NLM) and with input from FDA and others, developed the Clinical Trials Data Bank. The first version of the Clinical Trials Data Bank was made available to the public on February 29, 2000, on the Internet at <http://clinicaltrials.gov>. At that time, the data bank included primarily NIH-sponsored trials.

Shortly thereafter, FDA made available two draft guidances. The first draft guidance provided recommendations for industry on the submission of protocol information to the Clinical Trials Data Bank. It included information about the types of clinical trials for which submissions are required under section 113 of the Modernization Act as well as information about the content of those submissions. The second draft guidance addressed procedural issues, including how to submit required and voluntary protocol information to the Clinical Trials Data Bank. It also discussed issues related to submitting certification to the Secretary that disclosure of information for a particular protocol would substantially interfere with the timely enrollment of subjects in the clinical investigation. The second draft guidance also proposed a timeframe for submitting the information. The March 2002 guidance combined the two draft guidances into a single guidance (available at <http://www.fda.gov/cder/guidance/4856fnl.htm> or <http://www.fda.gov/cber/gdlns/clintrial.htm>).

This draft guidance updates the March 2002 guidance to include information on how to comply with new statutory requirements contained in the BPCA, for submitting details about single-patient use and expanded access use contained in the BPCA. This draft guidance also includes several minor

updates to the information in it and to the format. Additional updates on procedural issues not related to the BPCA will be discussed in future revisions to the guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the information program on clinical trials for serious or life-threatening diseases and conditions. 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit two copies of mailed comments, 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 draft 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at *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: January 20, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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