coming months. The agency has focused its efforts on these sections of the labeling because they typically contain large amounts of important and complex information, and there have been significant differences in their format and content across product classes and individual medical products. Guidances for other labeling sections may be developed later.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on the content and format of the Clinical Studies section of labeling for human prescription drugs and biologics. 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 can be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance.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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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 http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm, or at http://www.fda.gov/cber/guidelines.htm.

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17048 Filed 7–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1033]

Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan.'' The draft guidance discusses procedures for submission of protocol information to the Clinical Trials Data Bank established under section 113 of the Food and Drug Administration Modernization Act (Modernization Act), which required the establishment of this data bank and specified what information was to be submitted for it. Procedural issues discussed in this guidance document were not included in an earlier draft guidance document on the scope of the Data Bank, which published in the **Federal Register** on March 29, 2000 (65 FR 16620).

DATES: Submit written comments on the draft guidance by September 7, 2001. 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 (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 draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Theresa Toigo, Center for Drug Evaluation and Research (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4460.

SUPPLEMENTARY INFORMATION:

I. Description of Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan.'' The draft guidance is intended to provide recommendations for sponsors of investigational new drug applications (INDs) on how to submit information about clinical trials for serious or life-threatening diseases to a clinical trials data bank developed by the National Library of Medicine (NLM), National Institutes of Health (NIH).

The Modernization Act (Pub. L. 105–115), enacted on November 21, 1997, amends section 402 of the Public Health Service Act (42 U.S.C. 282) and directs the Secretary of Health and Human Services (the Secretary), acting through the Director, NIH, to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (hereafter referred to as the Clinical Trials Data Bank).

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, to other members of the public, and to health care providers and researchers. Specifically, the Clinical Trials Data Bank will contain information about both federally and privately funded studies of experimental treatments for patients with serious or life-threatening diseases conducted under FDA's IND regulations (21 CFR part 312).

The NIH, through NLM and with input from FDA and others, developed the Clinical Trials Data Bank and is implementing it in a phased approach. 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. It included primarily NIH-sponsored trials.

In the **Federal Register** of March 29, 2000, FDA published 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 will be required under section 113 of the Modernization Act, as well as the types of information to be submitted. The draft guidance stated that an implementation plan, addressing procedural issues, would be available later. The draft guidance stated that the implementation plan would include: (1) Information on how to submit protocols to the Clinical Trials Data Bank, (2) information about providing 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, (3) discussion about issues related to the voluntary submission of information not required by section 113 of the Modernization Act (e.g., study results, trials for non-serious or non-life-threatening diseases), and (4) a timeframe for submitting the information.

In developing a plan for making publicly available information from the Clinical Trials Data Bank, FDA and NIH considered comments submitted to Docket Nos. 98D–0293 and 00D–1033, ''Section 113 NIH Data Bank—Clinical Trials for Serious Diseases.'' A phased approach was used for developing guidance. A first draft guidance (the March 29, 2000, draft guidance) addressed general information on the scope of the data bank. The draft guidance being made available by this notice discusses procedures that were not included in the first guidance. This draft guidance was developed based on the initial data bank experience using NIH-sponsored trials. A final guidance will be developed that combines the informational and procedural draft guidances and considers comments received on both of the draft guidances.

Section 113(a) of the Modernization Act requires that sponsors of INDs submit to the Clinical Trials Data Bank a description of the purpose of each experimental drug, eligibility criteria for participation in the trial, the location of clinical trial sites, and a point of contact for those wanting to enroll in the trial. The statute requires that the information be provided in a form that can be readily understood by members of the public. This draft guidance provides information on how IND sponsors can fulfill the requirements of section 113(a) of the Modernization Act by submitting information in the following four areas: (1) Descriptive information, (2) recruitment information, (3) location and contact information, and (4) administrative information. FDA and NIH developed these data elements based on the legislative requirements and comments submitted to Docket No. 98D–0293. Information will be submitted to the Clinical Trials Data Bank through a Web-based Protocol Registration System (PRS). For a preview of the PRS system see http://prsinfo.clinicaltrials.gov/.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on submitting information on clinical trials for serious or life-threatening diseases to a Clinical Trials Data Bank developed by the NLM. 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 Dockets Management Branch (address above) written comments on the draft 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 draft 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. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA published notice of a proposed collection of information, along with the first draft guidance, in the **Federal Register** on March 29, 2000. On November 9, 2000 (65 FR 67385), FDA published a notice that the proposed collection of information was submitted to OMB for review. The report considered comments received on the proposed collection of information. On March 23, 2001 (66 FR 16251), as corrected on April 17, 2001 (66 FR 19788), FDA announced OMB's approval of the agency's information collection activities for the program (OMB Control No. 0910–0459).

IV. 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: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.