in persons exposed to aerosolized *B. anthracis* who do not yet have established disease.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on this topic.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. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance by May 17, 2002. 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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 either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: January 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–6319 Filed 3–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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.

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 20852. Submit electronic comments tohttp://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronicaccess 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: March 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–6421 Filed 3–15–02; 8:45 am]

BILLING CODE 4160–01–S

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, Public Law 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.

Proposed Project: Uniform Data System (OMB No. 0915–0193)—Revision

This is a request for a revision of approval of the Uniform Data System (UDS), which contains the annual reporting requirements for the cluster of primary care grantees funded by the Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Outreach and Primary Health Services for Homeless Children and Public Housing Primary Care, and Healthy Schools Healthy Communities. Authorizing Legislation is found in Public Law 104–299, Health Center Consolidation Act of 1996, enacting Section 330 of the Public Health Service Act.

The Bureau of Primary Health Care collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The UDS includes two components: the Universal Report, completed by all grantees, provides data on services, staffing, and financing; and the Grant Report, completed by grantees funded under the Homeless, Public Housing Program or Health Schools Health Communities as well as one of the other programs, provides data on characteristics of users whose services fall within the scope of the Homeless, Public Housing Program, Healthy Schools Healthy Communities grant. Grantees are also asked to provide information on the charges, collections, bad debt write off and contractual disallowances by payor sources (Medicaid, Medicare, self pay and private insurance). In addition, grantees need to include categories to some of the lists (e.g., services, ICD codes, CPT codes) and annotating the forms to indicate which lines are subtotals and the lines to which they sum.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hours
Universal Report	757	24	18,168
Grant Report	114	16	1,824
Total	757		19,992