Date: March 22, 2000.

Charles Gollmar,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–7703 Filed 3–28–00; 8:45 am]

BILLING CODE 4163–18–P

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Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.'' The draft guidance provides recommendations for sponsors of investigational new drug applications (IND's) on submitting information about clinical trials for serious or life-threatening diseases to a clinical trials data bank developed by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Section 113 of the Food and Drug Administration Modernization Act (Modernization Act) required the establishment of this data bank and specified what information was to be submitted for it.

DATES: Submit written comments on the draft guidance by May 30, 2000. The deadline for submission of comments on the information collection requirements is May 30, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance or on the collection of information requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,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.

FOR FURTHER INFORMATION CONTACT: Theresa A. Toigo (HF–12), Center for Drug Evaluation and Research, 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: Establishment of a Data Bank.'' The draft guidance is intended to provide recommendations for sponsors of IND's on submitting information about clinical trials for serious or life-threatening diseases to a clinical trials data bank developed by the NLM, NIH.

The Modernization Act (Public Law 105–115), enacted on November 21, 1997, amends section 402 of the Public Health Service Act (the PHS Act) (42 U.S.C. 282) and directs the Secretary of Health and Human Services (the Secretary), acting through the Director of 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 (part 312 (21 CFR part 312)). This Clinical Trials Data Bank expands upon currently available information on federally-sponsored trials in various data bases within NIH (e.g., NIH Intramural Clinical Center Studies, Physician's Data Query/National Cancer Institute) and information about federally and privately sponsored human immunodeficiency virus/acquired immune deficiency syndrome HIV/AIDS trials made available through the AIDS Clinical Trials Information Service (ACTIS).

The NLM is developing the Clinical Trials Data Bank and 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. The new data base can be reached at http://clinicaltrials.gov. It includes primarily NIH-sponsored trials. Later in 2000, data from other Federal agencies and the private sector will be incorporated.

The draft guidance provides recommendations for industry on the submission of protocol information to the Clinical Trials Data Bank. It includes 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. An implementation plan, addressing procedural issues, will be available later in 2000. The implementation plan will include information on how to submit protocols to the Clinical Trials Data Bank, and how to provide 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. It will also discuss 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). Until the implementation guidance document is available, sponsors submitting clinical trials information for inclusion in the ACTIS data bank should continue to follow procedures currently in place. Non-NIH sponsors of clinical trials for other serious or life-threatening diseases need not provide clinical trials information to the data bank until after procedures are described in the implementation plan that will be available later this year. When the procedures are issued, we will establish 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 No. 98D–0293, ''Section 113 NIH Data Bank—Clinical Trials for Serious Diseases.'' A phased approach was used for developing guidance. This first document addresses general information on the scope of the data bank. The second guidance will be on implementation and will be developed

based on the initial data bank experience using NIH-sponsored trials.

In addition to NLM's development of the Clinical Trials Data Bank, NIH will be evaluating options for making available clinical trials information through a toll-free telephone system. Further, section 113(b) of the Modernization Act directed the Secretary to submit a report to Congress to determine the public health need, if any, for inclusion of device investigations in the data bank, and the adverse impact, if any, on device innovation and research in the United States if such information is required to be publicly disclosed. A report entitled ''A Device Clinical Trials Data Bank—Public Health Need and Impact on Industry'' was sent to Congress in November 1999. The report is available on the Modernization Act guidance page at http://www.fda.gov/cdrh/modact/modguid.html.

Section 113(a) of the Modernization Act requires that sponsors of IND's 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 fulfil 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.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). 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, regulations, or both.

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.

II. 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 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 is publishing notice of the proposed collection of information listed below in this document.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.

Description: FDA is issuing a draft guidance to industry on recommendations for IND sponsors on submitting information about clinical trials for serious or life-threatening diseases to a Clinical Trials Data Bank developed by the NLM, NIH. The draft guidance describes procedures for IND sponsors to submit information about clinical trials of experimental treatments for serious or life-threatening diseases. This information is especially important for patients and their families seeking opportunities to participate in clinical trials of new drug treatments for serious or life-threatening diseases.

The draft guidance describes three collections of information: Mandatory submissions, voluntary submissions, and certifications.

A. Mandatory Submissions

Section 113 of the Modernization Act requires that sponsors ''shall'' submit information to the Clinical Trials Data Bank when the clinical trial: (1) Involves a treatment for a serious or life-threatening disease and (2) is intended to assess the effectiveness of the treatment.

The draft guidance discusses how sponsors can fulfill the requirements of section 113 of the Modernization Act. Specifically, sponsors should provide: (1) Information about clinical trials, both federally and privately funded, of experimental treatments (drugs, including biological products) for patients with serious or life-threatening diseases; (2) a description of the purpose of the experimental drug; (3) patient eligibility criteria; (4) the location of clinical trial sites; and (5) a point of contact for patients wanting to enroll in the trial.

B. Voluntary Submissions

Section 113 of the Modernization Act also specifies that sponsors may voluntarily submit information pertaining to results of clinical trials, including information on potential toxicities or adverse effects associated with the use or administration of the investigational treatment. Sponsors may also voluntarily submit studies that are not trials to test effectiveness or not for serious or life-threatening diseases to the Clinical Trials Data Bank. This notice of proposed collection only applies to the voluntary submission of information pertaining to studies that are not trials to test effectiveness or not for serious or life-threatening diseases. Any paperwork burden associated with the voluntary submission of information pertaining to the results of clinical trials will be discussed in the implementation document.

C. Certifications

Section 113 of the Modernization Act specifies that the data bank will not include information relating to a trial if the sponsor certifies to the Secretary that disclosure of the information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary makes a determination to the contrary.

Description of Respondents: A sponsor of a drug or biologic product

regulated by the agency under the Federal Food, Drug, and Cosmetic Act or section 351 of the PHS Act who submits a clinical trial to test effectiveness of a drug or biologic product for a serious or life-threatening disease.

Burden Estimate: The information required under section 113(a) of the Modernization Act is currently submitted to FDA under part 312, and this collection of information is approved by OMB under Control Number 0910–0014 until September 30, 2002, and, therefore, does not represent a new information collection requirement. Instead, preparation of submissions under section 113 of the Modernization Act involves extracting and reformatting information already submitted to FDA. Although the procedures (where and how) for the actual submission of this information have not yet been developed, the agency believes it has an adequate basis for the determination of the hourly burden related to extracting and reformatting this information. The chart below provides an estimate of the annual reporting burden for the submission of information to satisfy requirements of section 113 of the Modernization Act .

CDER is currently receiving 99.2 new protocols per week (mean value, March through May, 1999), or 5,158 new protocols per year. CDER anticipates that protocol submission rates will remain at or near this level in the near future. Of these new protocols, an estimated two-thirds are for serious or life-threatening diseases and would be subject to either voluntary or mandatory reporting requirements under section 113 of the Modernization Act. Two-thirds of 5,158 protocols per year is 3,439 new protocols per year. An estimated 65 percent of the new protocols for serious or life-threatening diseases submitted to CDER are for clinical trials involving assessment for effectiveness, and are subject to the mandatory reporting requirements under section 113 of the Modernization Act. Sixty-five percent of 3,439 protocols per year is 2,235 new protocols per year subject to mandatory reporting. The remaining 2,923 new protocols per year are subject to voluntary reporting.

CBER is currently receiving 29 new protocols per month, or 348 new protocols per year. CBER anticipates that protocol submission rates will remain at or near this level in the near future. An estimated two-thirds of the new protocols submitted to CBER are for clinical trials involving a serious or life-threatening disease, and would be subject to either voluntary or mandatory reporting requirements under section 113 of the Modernization Act. Two-thirds of 348 new protocols per year is 232 new protocols per year. An estimated sixty-five percent of the new protocols for serious or life-threatening diseases submitted to CBER are for clinical trials involving assessments for effectiveness. Sixty-five percent of 232 protocols per year is an estimated 151 new protocols per year subject to the mandatory reporting requirements under section 113. The remaining 197 new protocols per year are subject to voluntary reporting.

The estimated total number of new protocols for serious or life-threatening diseases subject to mandatory reporting requirements under section 113 of the Modernization Act is 2,235 for CDER plus 151 for CBER, or 2,386 new protocols per year. The remainder of protocols submitted to CDER or CBER will be subject to voluntary reporting, including clinical trials not involving a serious or life-threatening disease as well as trials in a serious or life-threatening disease but not involving assessment of effectiveness. Therefore, the total number of protocols (5,506) minus the protocols subject to mandatory reporting requirements (2,386) will be subject to voluntary reporting, or 3,120 protocols.

It is anticipated that original protocol submissions to the data bank will be updated 2.5 times each (mean value, based on an average of 1.5 updates for protocol changes or addition of investigational sites, plus one update regarding completion of recruitment for the protocol), for a total of 13,765 responses (5,965 mandatory responses and 7,801 voluntary responses) per year under section 113 of the Modernization Act.

The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted under section 113(a) of the Modernization Act, including the time it takes to extract and reformat the information. FDA has been advised that some sponsors lack information system capabilities enabling efficient collection of company-wide information on clinical trials subject to reporting requirements under section 113(a) of the Modernization Act. The estimation of burden under section 113(a) reflects the relative inefficiency of this process for these firms.

Based on its experience reviewing IND's, and consideration of the above information, FDA estimates that approximately 5.6 hours on average would be needed per response (mean value), based on an estimated 3.2 hours for data extraction and 2.4 hours for reformatting. Expenditure of 5.6 hours per submission, for 13,765 submissions, results in a total of 77,084 hours spent per year by respondents in response to section 113(a) of the Modernization Act (33,404 hours for mandatory responses and 43,680 hours for voluntary responses).

A sponsor of a study subject to the requirements of section 113 of the Modernization Act will have the option of submitting data under that section or certifying to the Secretary that disclosure of information for a specific protocol would substantially interfere with the timely enrollment of subjects in the clinical investigation. FDA has no means to accurately predict the proportion of protocols subject to the requirements of section 113 of the Modernization Act that will be subject to a certification submission. However, it is anticipated that the burden associated with such certification will be comparable to that associated with submission of data regarding a protocol. Therefore, the overall burden is anticipated to be the same regardless of whether the sponsor chooses data submission or certification for nonsubmission. Table 1 of this document reflects the estimate of this total burden.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submissions	Number of CDER Respondents	Number of CBER Respondents	Total Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Total mandatory submissions	2,235	151	2,386	2.5	5,965	5.6	33,404
Total voluntary submissions	2,923	197	3,120	2.5	7,800	5.6	43,680
Total	5,158	348	5,506	2.5	13,765	5.6	77,084

[1]There are no capital costs associated with this collection of information.

Dated: March 20, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–7654 Filed 3–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (60 FR 56605 as amended November 6, 1995, as last amended at 65 FR 12021–4, dated March 7, 2000).

This notice reflects the organizational and functional changes in the Bureau of Primary Health Care, Division of Program for Special Populations (RCA).

Delete the functional statement for the Division of Program for Special Populations in its entirety and replace with the following: This Division researches issues and develops program plans which identify and address the health care needs of special population groups. Specifically the Division: (1) Develops and implements health care policies and programs for homeless people, substance abusers, the elderly, residents of public housing, at-risk children and youth, Native Hawaiians, Asian Americans and Pacific Islanders, people living with Black Lung Disease, people with mental health disorders, immigrant populations and people living with the threat of lower extremity amputation; (2) coordinates the identification of issues and establishes Agency/Bureau priorities with other Department/ Agency/Bureau programs; (3) directs nationwide efforts to coordinate health care needs of special populations and stimulates State and local assistance in meeting needs; (4) provides guidance and direction in the development of health care partnerships and networks and coordinates management plans with field offices, other Federal programs, State and private organizations and foundations; (5) develops guidance materials and implements plans to assure attainment of measurable outcomes and desired results; (6) coordinates health needs of special populations with other Agency and Bureau programs, ensuring that funds are allocated according to Agency/Bureau priorities and legislative intent; (7) develops and conducts evaluations of service delivery programs for special populations preparing analytic reports and recommendations for increasing scope, effectiveness and efficiency; (8) administers the budget and related grant awards, contracts, and cooperative agreements; and (9) provides leadership and technical guidance in the development and expansion of community-based systems of care that increase access for all and reduce disparities for special populations.

Delegations of Authority

All delegations and redelegations of authority which were in effect immediately prior to the effective date hereof have been continued in effect in them or their successors pending further redelegation.

This reorganization is effective upon date of signature.

Dated: March 21, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–7656 Filed 3–28–00; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Submitted for Office of Management and Budget Review, Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of extension of a currently approved Information Collection (OMB Control Number 1010–0095).

SUMMARY: To comply with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), we are notifying you that we have submitted an information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval. We are also soliciting your comments on this ICR which describes the information collection, its expected costs and burden, and how the data will be collected.

DATES: Written comments should be received on or before April 28, 2000.

ADDRESSES: You may submit comments directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior (OMB Control Number 1010–0095), 725 17th Street, NW, Washington, DC 20503. Copies of these comments should also be sent to David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, PO Box 25165, MS 3021, Denver, Colorado 80225. Courier address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225. Email address is RMP.comments@mms.gov.

Public Comment Procedure: Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include Attn: Request to Exceed Regulatory Allowance Limitation, Form MMS–4393, OMB Control Number 1010–0095, and your name and return address in your