

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, including each proposed extension of an existing 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 set forth in this document.

With respect to the following collection of information, FDA invites comments 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 of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Maintaining a Databank—(OMB Control Number 0910-0459)—Extension

Description: In the **Federal Register** of March 18, 2002 (65 FR 12022), FDA issued a final guidance to industry on recommendations for investigational new drug application (IND) sponsors 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, National Institutes of Health (NIH). 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 final guidance describes three collections of information: Mandatory submissions, voluntary submissions, and certifications.

II. Mandatory Submissions

Section 113 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public

Law 105-115) 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 final 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.

Senate 1789, "Best Pharmaceuticals for Children Act" (BPCA) (Public Law 107-109) established a new requirement for the Clinical Trials Data Bank mandated by section 113 of the Modernization Act. Information submitted to the data bank must now include "a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children." The final guidance will be updated to include a discussion of how sponsors can fulfill the BPCA requirements.

III. 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.

IV. 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 of Health and Human Services (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 Public Health Service Act (42 U.S.C. 262) 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 21 CFR part 312, and this collection of information is approved under OMB Control No. 0910-0014 until January 31, 2006, 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. Procedures (where and how) for the actual submission of this information to the Clinical Trials Data Bank are addressed in the final guidance.

The Center for Drug Evaluation and Research (CDER) received 3,957 new protocols in 2002. CDER anticipates that protocol submission rates will remain at or near this level in the near future. Of these new protocols, an estimated two-thirds¹ 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 3,957 protocols per year is 2,638 new protocols per year. An estimated 50 percent¹ 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. Fifty percent of 2,638 protocols per year is 1,319 new protocols per year subject to mandatory reporting. The remaining 2,638 new protocols per year are subject to voluntary reporting.

The Center for Biologics Evaluation and Research (CBER) received 910 new protocols in 2002. CBER anticipates that protocol submission rates will remain at or near this level in the near future. An estimated two-thirds² 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 910 new protocols per year is 607 new protocols per year. An

¹Estimate obtained from a review of 2,062 protocols submitted to CDER between January 1, 2002, and September 30, 2002.

²Estimate obtained from a review of 2,062 protocols submitted to CBER between January 1, 2002, and September 30, 2002.