under 21 CFR 1240.63(a)(2)(ii) will be 480 hours (120 respondents x 4 hours per response = 480 hours).

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3485 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0136]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adoption of the FDA Food Code By Local, State, and Tribal Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adoption of the FDA Food Code by Local State and Tribal Governments,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 2, 2003 (68 FR 56844), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0448. The approval expires on January 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3486 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0360]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information Program on Clinical Trials for Serious or Life-threatening Diseases: Maintaining of a Databank

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 22, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION:

I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

In the **Federal Register** of March 18, 2002 (65 FR 12022), FDA issued a 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 the 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 guidance describes the following three collections of information: (1) Mandatory submissions, (2) voluntary submissions, and (3) 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 the following: (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 number 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 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-thirds[1] 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 percent[1] 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-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 910 new protocols per year is 607 new protocols per year. An estimated 50 percent[1] of the new protocols for serious or life-threatening diseases submitted to CBER are for clinical trials involving assessments for effectiveness. Fifty percent of 607 protocols per year is an estimated 304 new protocols per year subject to the mandatory reporting requirements under section 113 of the Modernization Act. The remaining 606 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 1,319 for CDER plus 304 for CBER, or 1,623 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 (4,867) minus the protocols subject to mandatory reporting requirements (1,623) will be subject to voluntary reporting, or 3,244 protocols. Our total burden estimate includes multi-center studies and accounts for the quality control review of the data before it is submitted to the data bank. The number of IND amendments submitted in 2002 for protocol changes (e.g., changes in eligibility criteria) was 4,750 for CDER and 1,646 for CBER. The number of IND amendments submitted in 2002 for new investigators was 9,419 for CDER and 1,773 for CBER. The number of protocol changes and new investigators was apportioned proportionally between mandatory and voluntary submissions. We (FDA) recognize that single submissions may include information about multiple sites. Generally, there is no submission to FDA when an individual study site is no longer recruiting study subjects. For this analysis, we assumed that the number of study sites closed each year is similar to the number of new investigator amendments received by FDA (9,419 CDER and 1,773 CBER). Generally, there is no submission to FDA when the study is closed to enrollment. We estimate the number of protocols closed to enrollment each year is similar to the number of new protocols submitted (3,957 CDER and 910 CBER). 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 INDs, consideration of the information previously presented, and further consultation with sponsors who submit protocol information to the Clinical Trials Data Bank, FDA estimated that approximately 4.6 hours on average would be needed per response. The estimate incorporates 2.6 hours for data extraction and 2.0 hours for reformatting based on data collected from organizations currently submitting protocols to the Clinical Trials Data Bank. We considered quality control issues when developing the current burden estimates of 2.6 hours for data extraction and the 2.0 hours estimated for reformatting. Additionally, the internet-based data entry system developed by NIH incorporates features that further decrease the sponsor's time requirements for quality control procedures. The Clinical Trials Data Bank was set up to receive protocol information transmitted electronically by sponsors. Approximately 10 percent of sponsors electronically transmit information to the Clinical Trials Data Bank. If the sponsor chooses to manually enter the protocol information, the data entry system allows it to be entered in a uniform and efficient manner primarily through pull-down menus. As sponsor's familiarity with the data entry system increases, the hourly burden will continue to decrease. 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

[1] Estimate obtained from a review of 2,062 protocols submitted to CDER between January 1, 2002, and September 20, 2002.

requirements of section 113 of the Modernization Act that will be subject to a certification submission. To date, no certifications have been received. 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 reflects the estimate of this total burden.

In the **Federal Register** of August 25, 2003 (68 FR 51020), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received. Some of the estimates in table 1 of this document have been changed due to a miscalculation in the 60-day notice. The total burden, however, remains unchanged.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

New Protocols	Recruitment Complete	Protocol Changes	New Investigators	Site Closed	Total Responses	Hours per Response	Total Hours
CDER (mandatory); 1,319	1,319	1,568	3,108	3,108	10,422	4.6	47,941
CBER (mandatory); 304	304	543	585	585	2,321	4.6	10,677
CDER (voluntary); 2,638	2,638	3,182	6,311	6,311	21,080	4.6	96,968
CBER (voluntary); 606	606	1,103	1,188	1,188	4,691	4.6	21,579
Total	4,867				38,514		177,165

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We believe the estimate, 177,165 hours per year (38,514 responses x 4.6 hours per response) accurately reflects the burden. We recognize that companies who are less familiar with the data entry system and the Clinical Trials Data Bank will require greater than 4.6 hours per response. However, as sponsor familiarity with the system increases, the hourly estimate will decrease.

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3488 Filed 2–18–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0034]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Submit written and electronic comments on the collection of information by April 19, 2004.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under 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, 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 these topics: (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.