Washigton, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: *lauren_wittenberg@omb.eop.gov.*

Dated: August 19, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–21630 Filed 8–22–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities.

OMB No.: 0980–0270.

Description: Required by Federal statute and regulation. Each State Protection and Advocacy System must prepare and submit to public comment a Statement of Goals and Priorities (SGP). The final version of this SGP for the coming fiscal year is submitted to the Administration on Developmental Disabilities (ADD). The information in the SGP will be aggregated into a national prospective profile of where Protection and Advocacy Systems are going. It will provide ADD with an overview of program direction, and permit ADD to track accomplishments against objectives/targets, permitting the formulation of technical assistance and compliance with the Government Performance and Results Act. ADD is currently in the process of coordinating with other federal funding agencies to develop a more comprehensive SGP format.

Respondents: State and Tribal Governments.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SGP	57	1	44	2,508

Estimated Total Annual Burden Hours: 2,508.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 19, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–21631 Filed 8–22–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0360]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Maintaining a Databank

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in the final guidance entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Maintaining a Databank,'' dated March 18, 2002.

DATES: Submit written or electronic comments on the collection of information by October 24, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm.* 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: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION:

I. Background

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: (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-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[2] 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

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

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

estimated 50 percent[2] 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.

It was originally estimated that the protocol submissions to the data bank will be updated 2.5 times per year under section 113 of the Modernization Act.

In the **Federal Register** of March 29, 2000 (65 FR 16620), the agency requested comments on the proposed collection of information. One comment was received. The comment stated that FDA greatly underestimated the burden by excluding multicenter studies and not accounting for the quality control review of the data before it is submitted to the data bank. Our final burden estimate incorporated these concerns and included a revised burden estimate.

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 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 IND's, consideration of the above information, 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 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

New Protocols	Recruitment Complete	Protocol Changes	New Investigators	Site Closed	Total Responses	Hours per Reponse	Total Hours
CDER (mandatory); 1,306	1,306	1,568	3,108	3,108	10,396	4.6	47,822
CBER (mandatory); 300	300	543	585	585	2,313	4.6	10,640
CDER (voluntary); 2,651	2,651	3,182	6,311	6,311	21,106	4.6	97,088
CBER (voluntary); 610	610	1,103	1,188	1,188	4,699	4.6	21,615
Total							177,165

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

We believe the estimate, 177,165 hours per year (38,514 responses × 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: August 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21624 Filed 8–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0200]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Export of Medical Devices—Foreign Letters of Approval

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: Submit written comments on the collection of information by September 24, 2003.

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

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

Export of Medical Devices—Foreign Letters of Approval (OMB Control Number 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States.

FDA uses the written authorization from the foreign country or the certification from a responsible company official in the United States to determine whether the foreign country has any objection to the importation of the device into their country.

The respondents to this collection of information are companies that seek to export medical devices.

In the **Federal Register** of June 3, 2003 (68 FR 33161), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801(e)(2)	20	1	20	2.5	50

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

Dated: August 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21625 Filed 8–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0038]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Device User Fee Cover Sheet; Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device User Fee Cover Sheet; Form FDA 3601'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of May 21, 2003 (68 FR 27818), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An