selection of the applications to be funded. The Commissioner may also elect not to fund any applicants having known management, fiscal, reporting, program, or other problems which make it unlikely that they would be able to provide effective services.

Successful applicants will be notified through the issuance of a Financial Assistance Award which will set forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, and the budget period for which initial support will be given.

Organizations whose applications will not be funded will be notified in writing by the Commissioner of the Administration on Children, Youth and Families. Every effort will be made to notify all unsuccessful applicants as soon as possible after final decisions are made.

Part VII. Application Content and Submission Instructions

A. Application Content

Each application must contain the following items in the order listed:

1. Application for Federal Assistance (Standard Form 424, REV 4–92). Follow the instructions in the Application Kit. In Item 8 of Form 424, check ''New.'' In Item 10 of the 424, clearly identify the *Catalog of Federal Domestic Assistance* (CFDA) program title and number: Child Care and Development Block Grant, 93.575.

2. Budget and Budget Justification (Standard Form 424A, REV 4–92). Follow the instructions in the Application Kit. The budget justification should be typed on standard size plain white paper, provide breakdowns for major budget categories and justify significant costs. List amounts and sources of all funds, both Federal and non-Federal, to be used for this project.

3. Project Summary/Abstract (one page maximum). Clearly mark this page with the applicant name as shown on item 5 of the SF 424, identify the title of the proposed project as shown in item 11 and the service area as shown in item 12 of the SF 424. The summary description should not exceed 300 words.

Care should be taken to produce a summary which accurately and concisely reflects the proposed project. It should describe the objectives of the project, the approach to be used and the results and benefits expected.

4. Assurances/Certifications. The applicant must sign and return a SF 424B, Assurances—non-Construction Programs form and the Certification Regarding Lobbying form and return them with the application. A duly authorized representative of the applicant organization must certify that the applicant is in compliance with these assurances and certifications. *Note:* Although construction is an allowable cost if approved by ACF (see Part III, G), the non-construction assurances are required for purposes of this application. All requirements related to construction will be addressed through the separate application process for construction and renovation.

In addition, the applicant must certify its compliance with: (1) Drug-Free Workplace Requirements; (2) Debarment and Other Responsibilities; and (3) Pro-Children Act of 1994 (Certification Regarding Environmental Tobacco Smoke). A signature on the SF 424 indicates compliance with the Drug Free Workplace Requirements, Debarment and Other Responsibilities and Environmental Tobacco Smoke Certifications. A signature on the application constitutes an assurance that the applicant will comply with the pertinent Departmental regulations contained in 45 CFR Part 74.

5. Documents of Support. The maximum number of pages for supporting documentation is 10 pages, double-spaced, exclusive of letters of support or agreement. These documents must be numbered and might include resumes, photocopies of news clippings, evidence of the program's efforts to coordinate child care services at the local level, etc. Documentation over the ten-page limit will not be reviewed. The applicant may, however, include as many letters of support or agreement as are appropriate.

B. Application Submission

To be considered for funding, the applicant must submit one signed original and two additional copies of the application, including all attachments, to the application receipt point specified above. The original copy of the application must have original signatures, signed in *black* ink. Each copy must be stapled (back and front) in the upper left corner. All copies of an application must be submitted in a single package.

Because each application will be duplicated, do not use or include separate covers, binders, clips, tabs, plastic inserts, maps, brochures or any other items that cannot be processed easily on a photocopy machine with an automatic feed. Do not bind, clip, staple, or fasten in any way separate subsections of the application, including supporting documentation. Applicants are advised that the copies of the application submitted, not the original, will be reproduced by the Federal government for review.

(Catalog of Federal Domestic Assistance: Child Care and Development Block Grant, 93.575)

Dated: November 3, 2000.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 00–28798 Filed 11–08–00; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1033]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 December 11, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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

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.

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

In the **Federal Register** of March 29, 2000 (65 FR 16620), FDA issued a draft 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 draft guidance describes three collections of information: Mandatory submissions, voluntary submissions, and certifications.

I. Mandatory Submissions

Section 113 of the Food and Drug Administration Modernization Act (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 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.

II. 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.

III. 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 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. The Center for Drug Evaluation and Research (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.

The Center for Biologics Evaluation and Research (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 65 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 of the Modernization Act. 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 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, the agency requested comments on the proposed collection of information. One comment was received. The comments 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. We estimated that 5,506 new protocols are submitted each year and each new protocol is updated 2.5 times per year with information that would necessitate

a change in the data bank. We further estimated that each change requires an average of 5.6 hours resulting in 77,084 hours spent by respondents per year. These estimates included protocols subject to mandatory and voluntary reporting requirements.

For the revised justification, we reviewed actual IND data from 1997 to 1999, and as a result of our reanalysis we incorporated new estimates that consider multicenter studies. The average number of IND amendments submitted annually for protocol changes (e.g., changes in eligibility criteria) was 4,019 for CDER and 1,441 for CBER. The average number of IND amendments submitted annually for new investigators was 7,745 for CDER and 1,349 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 (7,745 CDER and 1,349 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 (5,158 CDER and 348 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, and consideration of the above information, FDA estimated 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. We considered quality control issues when developing the original burden estimates of 3.2 hours for data extraction and the 2.4 hours estimated for reformatting. Additionally, the data entry system being developed incorporates features that will further decrease the sponsor's time requirements for quality control procedures. No new estimates for quality control are included in the reanalysis.

The new estimate continues to use an average of 5.6 hours per response for calculations related to new submissions. Changes related to the addition and deletion of investigational sites will involve minimal resource commitments from the sponsor. Further, many protocol changes will not require changes to the data bank. Other protocol changes will require minimal time to make changes to the data bank (e.g., modification of eligibility criteria). The 5.6 hours per response estimate for these types of responses is high.

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. The table below 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	Sites Closed	Total Responses	Hours per Response	Total Hours
CDER (mandatory)	2,235	2,235	1,728	3,330	3,330	12,858	5.6	72,005
CBER (mandatory)	151	151	620	580	580	2,082	5.6	11,659
CDER (voluntary)	2,923	2,923	2,291	4,415	4,415	16,967	5.6	95,015
CBER (voluntary)	197	197	821	769	769	2,753	5.6	15,417
Total								194,096

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

The revised burden estimate for responses (34,660) is 2.5 times the original estimate (13,765).

We believe that the original burden estimate of 77,084 hours spent per year underestimated the burden. The new estimate, 194,096 hours per year (34,660 responses x 5.6 hours per response), more accurately reflects the burden.

NIH and FDA are considering a pilot program for the electronic submission of protocol information over the Internet. The purpose of the pilot project is twofold. First, the pilot project will allow FDA to test its systems for receiving electronic submissions under section 113 of the Modernization Act. Second, the pilot project will provide opportunities for volunteers to gain experience in using the prototype system that will enable them to provide technical feedback on how well the system is working, and also to offer suggestions for change. The experience gained from this pilot project also will facilitate the development of the implementation plan.

FDA anticipates that up to 25 sponsors will volunteer to participate in a pilot program involving the electronic submission of protocol information over the Internet. Protocol information entered into the system during the pilot project will be included in the Clinical Trials Data Bank (ClinicalTrials.gov). We estimate that each sponsor will include 10 protocols in the data bank. We estimate that each protocol will be modified two times and add three new sites. It is assumed that the sites will remain open for the duration of the pilot. The one-time burden estimate for the pilot program is 8,400 (1,500 responses x 5.6 hours/response). Since

the pilot protocols will be included in the ClinicalTrials.gov data bank, the estimated annual burden for the first year will be reduced by the number of protocols included in the pilot.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN [1]

	New Protocols	Protocol Changes	New Investigators	Total Annual Responses	Hours per Response	Total Hours
CDER	200	400	600	1,200	5.6	6,720
CBER	50	100	150	300	5.6	1,680
Total						8,400

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

Dated: November 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–28851 Filed 11–8–00; 8:45 am]

BILLING CODE 4160–01–F /

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1441]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 December 11, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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.

Infant Formula Requirements (OMB Control Number 0910–0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) requires manufacturers of infant formula to: (1) Establish and adhere to quality control procedures, (2) notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and (3) keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. In a document published in the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

In the **Federal Register** of August 18, 2000 (65 FR 50539), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Federal Food, Drug, and Cosmetic Act (the Act) or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 412(d) of the act	4	7	28	10	280
106.120(b)	4	0.25	1	4	4
107.10(a) and 107.20	4	7	28	8	224
107.50(b)(3) and (b)(4)	3	4	12	4	48
107.50(e)(2)	3	0.33	1	4	4
Total					560

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