other relevant considerations. 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 that sets forth the amount of funds granted, the terms and conditions of the grant award, the effective date of the award, and the budget period for which support is given, and the total project period for which support is provided. Organizations whose applications will not be funded will be notified in writing by the Commissioner, ACF. 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. A signed cover letter. The application must include a cover letter that includes the announcement number, contact information for the applicant, and information about the entity that has designated the Local Council (local government, Indian Tribe, Regional Corporation, or Native Hawaiian entity). The letter must be signed by an individual authorized to act for the applicant agency and to assume responsibility for the obligations imposed by terms and conditions of the grant award.

2. 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: Early Learning Opportunities Act, 93.577.

3. 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.

4. Standard Form 424B, ''Assurances: Non-Construction Programs.'' A duly authorized representative of the applicant organization must certify that the applicant is in compliance with these assurances and certifications.

5. Assurances/Certifications. The applicant must certify its compliance with: (1) Drug-Free Workplace Requirements; (2) Debarment and Other Responsibilities; (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. In addition, applicants must provide a certification concerning Lobbying. Prior to receiving an award in excess of $100,000, applicants shall furnish an executed copy of the lobbying certification. Applicants must sign and return the certification with their applications.

6. Table of Contents.

7. 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 that 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.

8. The Project Description. The applicant is strongly encouraged to use the evaluation criteria in Part V to organize its response to Part IV, the Uniform Project Description. Specific information should be provided that addresses all components of each criterion. It is in the applicant's best interest to ensure that the project description is easy to read, logically developed in accordance with the evaluation criteria, and adheres to page limitations. In addition, the applicant should be mindful of the importance of preparing and submitting applications using language, terms, concepts, and descriptions that are generally known to the field of early learning as defined under this announcement.

9. The pages of the project description must be numbered and are limited to 40 typed pages, double spaced, printed on only one side, with at least 1/2 inch margins. Pages over the limit will be removed from the application and will not be reviewed. In addition, please note that previous attempts by applicants to circumvent space limitations or to exceed page limits by using small print have resulted in negative responses from reviewers because of the difficulty in reviewing the application.

10. Documents of Support. The maximum number of pages for supporting documentation is 30 pages, double-spaced, exclusive of letters of support or agreement. These documents must be numbered and might include excerpts from the needs and resources assessment, resumes, photocopies of news clippings, evidence of the program's efforts to coordinate child care services at the local level, etc. Documentation over the 30-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.

Dated: April 24, 2001.

Gail E. Collins,

Acting Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–10640 Filed 4–27–01; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0176]

Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies

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 GLP for Nonclinical Laboratory Studies regulations.

DATES: Submit written or electronic comments on the collection of information by June 29, 2001.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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: 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: 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.

Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies—(21 CFR Part 58)—(OMB Control Number 0910–0119)—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts onsite audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
58.35(b)(7)	300	60.25	18,075	1	18,075
58.185	300	60.25	18,075	27.65	499,774
Total					517,849

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
58.29(b)	300	20	6,000	.21	1,260
58.35(b)(1) through (b)(6) and (c)	300	270.56	81,228	3.36	279,926
58.63(b) and (c)	300	60	18,000	.09	1,620
58.81(a) through (c)	300	301.8	90,540	.14	12,676
58.90(c) and (g)	300	62.7	18,810	.13	2,445
58.105(a) and (b)	300	5	1,500	11.8	17,700
58.107(d)	300	1	300	4.25	1,275
58.113(a)	300	15.33	4,599	6.8	31,273
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					793,308

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

Dated: April 24, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–10623 Filed 4–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0178]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification 510(k) Submissions

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 information collection requirements for premarket notification 510(k) submissions.

DATES: Submit written or electronic comments on the collection of information by June 29, 2001.

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 Dockets Management Branch (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 Schlosburg, Office of Information Resources Management (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: (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.

Premarket Notification 510(k) Submissions (21 CFR Part 807) (OMB Control No. 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) requires a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. The definition of ''person'' has been expanded to include hospitals who reuse or remanufacture single-use medical devices. The estimated submissions below include those submitted by hospitals remanufacturing single-use medical devices.

Section 510(k) of the act allows for exemptions to the 510(k) submissions (i.e., a premarket notification submission would not be required if FDA determines that premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process). Under 21 CFR 807.85, ''Exemption from premarket notification,'' a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling and advertising by the manufacturer, importer, or distributor for commercial distribution. In addition, the device must meet one of the following