E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 16, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–23894 Filed 9–23–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care and Development Fund Plan for States/Territories for FFY 2012–2013 (ACF–118).

OMB No.: 0970–0114.

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for States and Territories is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101–508, Pub. L. 104–193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF–118, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the States or the Territories child care program. The ACF–118 is currently approved through April 30, 2012, making it available to States and Territories needing to submit Plan Amendments through the end of the FY 2011 Plan Period. However, on July 1, 2011, States and Territories will be required to submit their FY 2012–2013 Plans for approval by September 30, 2011. Consistent with the statute and regulations, ACF requests extension of the ACF–118 with minor corrections and modifications. The Tribal Plan (ACF–118a) is not affected by this notice.

Respondents: State and Territorial CCDF Lead Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–118	56	0.50	162.50	4,550

Estimated Total Annual Burden Hours: 4,550.

In compliance with the requirements of Section 506(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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@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: September 20, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–23889 Filed 9–23–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0250]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

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 October 25, 2010.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0231. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Premarket Approval of Medical Devices—21 CFR Part 814/Food and Drug Administration Modernization Act of 1997 (FDAMA) Sections 201, 202, 205, 208, and 209 (OMB Control Number 0910–0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either pre-amendments devices that have been classified into class III, or post-amendments devices which are not substantially equivalent to a pre-amendments device, or transitional devices. Class III devices are devices such as implants, life sustaining or life supporting devices, and/or devices which otherwise present a potentially unreasonable risk of illness or injury, and/or are of substantial importance in preventing impairment of human health. Most premarket approval applications (PMAs) are for post-amendments class III devices.

Under section 515 of the act, an application must contain certain specific information, including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties of the principles of operation for such a device. In addition, the application should also include a full description of the methods used in, and the facilities and controls used for the manufacture and processing of the device and labeling specimens. The implementing regulations, contained in part 814 (21 CFR part 814), further specifies the contents of a PMA for a class III medical device and the criteria FDA sets forth in approving, denying, or withdrawing approval of a PMA as well as supplements to PMAs. The purpose of this regulation is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval) medical devices. The regulations under part 814 facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the disapproval of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval. FDAMA (Public Law 105–115) was enacted on November 21, 1997, to implement revisions to the act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Several provisions of this act affect the PMA process, such as section 515(d)(6) of the act. This section provided that PMA supplements were required for all device changes that affect safety and effectiveness of a device unless such changes are modifications to manufacturing procedures or method of manufacture. This type of manufacturing change now requires a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

To make the PMA process more efficient, in the past several years FDA has done the following: (1) Made changes to the PMA program based on comments received, (2) complied with changes to the program mandated by FDAMA and the Medical Device User Fee Modernization Act, and (3) worked toward completion of its PMA reinvention efforts.

Respondents to this information collection are persons filing a PMA application or a PMA supplement with FDA for approval of certain class III medical devices. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include entities meeting the definition of manufacturers such as manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments). In addition, hospitals that reuse single use devices (SUDs) are also included in the definition of manufacturers. It is expected that FDA will receive one PMA application from hospitals that remanufacture SUDs annually. This figure has been included in table 1 of this document, as part of the reporting burden in § 814.20.

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year (FY) annual rate of receipt of 36 PMA original applications, 532 PMA supplements, and 505 30-day notices using FY 2005 through 2009 data. The burden data for PMAs is based on data provided by manufacturers by device type and cost element in an earlier study. The specific burden elements for which FDA has data are as follows:

- Clinical investigations—67 percent of total burden estimate;
- Submission of additional data or information to FDA during a PMA review—12 percent;
- Additional device development cost (e.g., testing)—10 percent; and
- PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data—11 percent.

Reporting Burden

The reporting burden can be broken out by certain sections of the PMA regulation as follows:

- *§ 814.15—Research Conducted Outside the United States*

Approximately 20 percent of the clinical studies submitted in support of a PMA application are conducted outside the United States. Each study should be performed in accordance with the "Declaration of Helsinki" or the laws and regulations of the country in which the study was conducted. If the study was conducted in accordance with the laws of the country, the PMA applicant is required to explain to FDA in detail the differences between the laws of the country and the "Declaration of Helsinki." Based on the number of PMAs received that contained studies from overseas, FDA estimates that the burden estimate necessary to meet this requirement is 20 hours.

- *Application in § 814.20(a) through (c) and (e)*

The majority of the 24,048 hourly burden estimate is due in part to this requirement. Included in this requirement are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 36 manufacturers, including hospital re-manufacturers of SUDs, will be affected by these requirements which are based on the actual average of FDA receipt of new PMA applications in FY 2005 through 2009. FDA's estimate of the hours per response (668) was derived through FDA's experience and consultation with industry and trade associations. In addition, FDA also based its estimate on the results of an earlier study which accounts for the bulk of the hourly burden for this requirement, which is identified by manufacturers.

- *§ 814.37—PMA Amendments and Resubmitted PMAs*

As part of the review process, FDA often requests the PMA applicant to submit additional information regarding the device necessary for FDA to file the PMA or to complete its review and make a final decision. The PMA applicant may, also on their own initiative, submit additional information to FDA during the review process. These amendments contain information ranging from additional test results, re-analysis of the original data set to revised device labeling. Almost all PMAs received by the Agency have

amendments submitted during the review process. FDA estimates that 6,012 burden hours are necessary to satisfy this requirement.

• *PMA Supplements in § 814.39(a)*

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 20 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 40,200 hours of burden are needed to complete the requirements for regular PMA supplements.

• *Special PMA Supplements—Changes Being Affected in § 814.39(d)*

These types of supplements are intended to enhance the safety of the device or the safe use of the device. The number of PMA supplements received that fit this category averaged 68 per year based on the numbers received from FY 2005 through FY 2009. Because of the minimal data required to be included in this type of supplement, FDA estimates that the burden hours necessary to satisfy this requirement are 408 hours.

• *30-Day Notice in § 814.39(f)*

Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under § 814.39(a) and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 (21 CFR part 820). The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice, that it is not adequate. FDA estimates the burden to satisfy this requirement is 8,080 hours.

• *Post-Approval Requirements in § 814.82(a)(9)*

Post-approval requirements concern approved PMAs that were not reclassified and require a periodic report. After approval, all PMAs require a submission of an annual report. On average, approximately half of the submitted PMAs (18), require associated post-approval studies, i.e., followup of patients used in clinical trials to support the PMA or additional preclinical information, that is labor-intensive to compile and complete; the remaining PMAs require minimal information. Based on experience and consultation with industry, FDA has estimated that preparation of reports and information required by this section requires 2,430 hours.

• *Reports in § 814.84(b)*

Post-approval requirements described in § 814.82(a)(7) require submission of an annual report for each approved PMA. FDA estimates that respondents will average about 10 hours in preparing their reports to meet this requirement. This estimate is based on FDA's experience and consultation with industry. Thus, FDA estimates that the periodic reporting burden required by this section will take 6,480 hours.

Statutory Reporting Burden Estimate (FDAMA)

The total statutory reporting burden under the requirements of sections 201, 202, 205, 208, and 209 of FDAMA is estimated to be 1,230 hours. This burden estimate was based on actual real and estimated FDA data tracked from FY 2005 through FY 2009, and an estimate was also derived to forecast future expectations with regard to this statutory data.

Recordkeeping in § 814.82(a)(5) and (a)(6)

The recordkeeping burden under this section requires the maintenance of records, used to trace patients and the organization and the indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved with 90 percent of these having original clinical trial data. Therefore, approximately 25 PMAs a year would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of an active PMA application must maintain these records.

PMAs have been required since 1976, and there are 698 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 698 holders of approved original PMAs, therefore, is 11,866 hours.

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

In the **Federal Register** of June 8, 2010 (75 FR 32476), FDA published a 60-day notice requesting public comment 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]

21 CFR Section/ FDAMA Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.15(b)	8	1	8	2	16
814.20	36	1	36	668	24,048
814.37(a) through (c) and (e)	36	1	36	167	6,012
814.39(a)	670	1	670	60	40,200
814.39(d)	68	1	68	6	408
814.39(f)	505	1	505	16	8,080

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section/ FDAMA Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.82(a)(9)	18	1	18	135	2,430
814.84(b)	648	1	648	10	6,480
Section 201 (FDAMA) Agreement Meeting	3	1	3	50	150
Section 202 (FDAMA) Expedited Review Request	5	1	5	10	50
Section 205 (FDAMA) Effectiveness Meeting	5	1	5	50	250
Section 208 (FDAMA) Classification Panel Meetings	20	1	20	30	600
Section 209 (FDAMA) 100-day meeting	28	1	28	10	280
Totals	2,050	13	2,050	1,214	89,004

[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
814.82(a)(5) and (a)(6)	698	1	698	17	11,866

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

Dated: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23912 Filed 9–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: ANA Consultant and Evaluator Qualifications Form.

OMB No.: 0970–0265.

Description: The ANA Consultant and Evaluator Qualifications Form is used to collect information from prospective proposal reviewers in compliance with 42 U.S.C. 2991d–1. The form allows the Commissioner of ANA to select qualified people to review grant applications for Social and Economic Development Strategies (SEDS), Native Language Preservation and Maintenance, and Environmental Regulatory Enhancement. The panel review process is a legislative mandate in the ANA grant funding process.

Respondents: Native Americans, Native Alaskans, Native Hawaiians and other Pacific Islanders.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Consultant and Evaluator Qualifications Form	300	1	1	300

Estimated Total Annual Burden Hours: 300.

In compliance with the requirements of Section 506(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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@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