

firms 4 hours per review each quarter, the total burden of this activity, for firms that choose to review their plans annually, is 2,320 (145 x 4 x 4) hours per year. This annual burden is shown in row 6 of table 1 of this document.

Dated: August 5, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-19747 Filed 8-10-10; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* ORR Requirements for Refugee Cash Assistance; and Refugee Medical Assistance (45 CFR Part 400).

*OMB No.:* 0970-0036.

*Description:* As required by section 412(e) of the Immigration and Nationality Act, the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is requesting the information from Form ORR-6 to determine the effectiveness of

the State cash and medical assistance, child welfare, social services, and targeted assistance programs. State-by-State Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA) utilization rates derived from Form ORR-6 are calculated for use in formulating program initiatives, priorities, standards, budget requests, and assistance policies. ORR regulations require that State Refugee Resettlement and Wilson-Fish agencies, and local and Tribal governments complete Form ORR-6 in order to participate in the above-mentioned programs.

*Respondents:* State Refugee Resettlement and Wilson-Fish Agencies, local, and Tribal governments.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-6 .....	50	3	3.88	582

*Estimated Total Annual Burden Hours:* 582.

*Additional Information:* Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@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.

*Fax:* 202-395-7285.

*Email:*

[OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV).

*Attn:* Desk Officer for the Administration for Children and Families.

Dated: August 5, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2010-19748 Filed 8-10-10; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0198]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification**

**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 September 10, 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 [oir\\_a\\_submission@omb.eop.gov](mailto:oir_a_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0120. 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](mailto: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 Notification—(OMB Control Number 0910-0120)—Extension**

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) 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. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol, Humanitarian Device Exemption (HDE), Petition for Evaluation of Automatic Class III Designation (de novo) or be reclassified

into class I or class II before being marketed. FDA makes the final decision of whether a device is substantially equivalent or not equivalent.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is:

- Introducing a device to the market for the first time;
- Introducing a device into commercial distribution for the first time by a person who is required to register; and
- Introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Section 807.87 specifies information required in a premarket notification submission.

Section 204 of the Food and Drug Administration Modernization Act (FDAMA) amended section 514 of the act (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA

and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. FDA Form FDA 3654, the 510(k) Standards Data Form, standardizes the format for submitting information on consensus standards that a 510(k) submitter chooses to use as a portion of their premarket notification submission (The Form FDA 3654 is not for declarations of conformance to a recognized standard). FDA believes that use of this form will simplify the 510(k) preparation and review process for 510(k).

Form FDA 3514, a summary coversheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, and HDEs. Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement). If the 510(k) submitter includes a 510(k) statement in the 510(k) submission, § 807.93 requires that the official correspondent of the firm make

available within 30 days of a request, all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any person within 30 days of a request if the device described in the 510(k) submission is determined to be substantially equivalent. The information provided will be a duplicate of the 510(k) submission including any safety and effectiveness information, but excluding all patient identifiers and trade secret and commercial confidential information. According to § 807.90, submitters may request information on their 510(k) review status 90 days after the initial log-in date of the 510(k). Thereafter, the submitter may request status reports every 30 days following the initial status request. To obtain a 510(k) status report, the submitter should complete the status request form, Form FDA 3541, and fax it to the Center for Devices and Radiological Health office identified on the form. The most likely respondents to this information collection will be specification developers and medical device manufacturers.

In the **Federal Register** of May 5, 2010 (75 FR 24708), 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<sup>1</sup>

21 CFR Section	Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807 sub-part E		3,800	1	3,800	79	300,200
807.87	FDA Form 3514	1,956	1	1,956	0.5	978
807.90 (a)(3)	FDA Form 3541	218	1	218	0.25	55
807.87(d) and (f)	FDA Form 3654	1,500	1	1,500	10	15,000
807.92 and 807.93		2,000	10	2,000	10	20,000
Total						336,233

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 5, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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