

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.

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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.

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.

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

Dated: August 5, 2010.

Robert Sargis,

Reports Clearance Officer.

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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 oira_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.

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