submit the SF–425 Federal Financial Report, which provides aggregate expenditure and obligation data. This proposed new data collection would replace the current requirement for the SF–425 with a report form that would collect the same expenditures and obligations data separately for each of the four CMA program components: refugee cash assistance, refugee medical assistance, cash and medical assistance administration, and services for unaccompanied minors. This breakdown of financial status data will allow ORR to track program expenditures in greater detail to anticipate any funding issues and to meet the requirements of ORR regulations at CFR 400.211 to collect these data for use in estimating future costs of the refugee resettlement program. ORR must implement the methodology at CFR 400.211 each year after receipt of its annual appropriation to ensure that appropriated funds will be adequate for reimbursement to States of the costs for assistance provided to entering refugees. The estimating methodology prescribed in the regulations requires the use of actual past costs by program component. In the event that the methodology indicates that appropriated funds are inadequate, ORR must take steps to reduce federal expenses, such as by limiting the number of months of eligibility for Refugee Cash Assistance and Refugee Medical Assistance. This proposed single-page financial report will allow ORR to collect the necessary data to ensure that funds are adequate for the projected need and thereby meet the requirements of both the Refugee Act and ORR regulations, as well as provide the data currently required in aggregate by the SF–425.

Respondents: State governments, Wilson/Fish Alternative Projects.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR Financial Status Report	58	4	0.50	116

Estimated Total Annual Burden Hours: 116

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email 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 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–31872 Filed 12–12–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Annual Survey of Refugees (Form ORR–9).

OMB No.: 0970–0033.

Description: The Annual Survey of Refugees collects information on the social and economic circumstances of a random sample of refugees, Amerasians, and entrants who arrived in the United States in the five years prior to the date of the survey. The survey focuses on the refugees training, labor force participation, and welfare utilization rates. Dates are segmented by region of origin, State of resettlement, and number of months since arrival. From the responses, the Office of Refugee Resettlement reports on the economic adjustment of refugees to the American economy. These data are used by Congress in its annual deliberations for refugee admissions and funding and by program managers in formulating policies for the future direction of the Refugee Resettlement Program.

Respondents: Refugees, entrants, Amerasians, and Havana parolees.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–9 Annual Survey of Refugees	2,000	1	0.63	1,253.20
Request for Participation Letter	2,000	1	0.04	80

Estimated Total Annual Burden Hours: 1,333.20.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447,

Attn: ACF Reports Clearance Officer. Email 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 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–31871 Filed 12–12–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0847]

Draft Guidance for Industry and Food and Drug Administration Staff on Humanitarian Use Device Designations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Humanitarian Use Device (HUD) Designations.'' Devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Devices that receive HUD designation may be eligible for marketing approval under the Humanitarian Device Exemption (HDE) marketing pathway. This guidance document is intended to assist applicants in the preparation and submission of HUD designation requests and FDA reviewers in evaluating such requests.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 12, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Orphan Products Development (OOPD), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric Chen, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993, (301) 796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Humanitarian Use Device (HUD) Designations.'' Devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. (See section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)); 21 CFR 814.102). This guidance document is intended to assist applicants in the preparation and submission of HUD designation requests to FDA, OOPD. This guidance is also intended to assist FDA reviewers in the evaluation and analysis of HUD designation requests.

Topics addressed in this guidance include: (1) Demonstrating in HUD requests that the device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year; (2) how this demonstration varies, depending on whether the device is intended for therapeutic or diagnostic purposes; (3) how properties of the device may affect this demonstration; and (4) delineating a medically plausible subset of persons with a given disease or condition.

Devices that receive HUD designation may be eligible for marketing approval under an HDE application. An HDE application is a premarketing application that is similar to a premarket approval (PMA) application in that the applicant must demonstrate a reasonable assurance of safety, but in an HDE application, the applicant seeks an exemption from the PMA requirement to demonstrate a reasonable assurance of effectiveness. A device is eligible for HDE approval if, among other criteria, the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. (See section 520(m) of the FD&C Act; 21 CFR 814.104(b)(2)). Although a HUD designation is a prerequisite to submitting an HDE application, it is only one of many required elements of the application (21 CFR 814.104). Receipt of a HUD designation does not guarantee that the HDE marketing application will be approved.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on humanitarian use device designations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division