

address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: September 27, 2011.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Refugee Data Submission System for Allocation of Formula Funds.

OMB No.: 0970-0043.

Description: The Refugee Data Submission System for Allocation of Formula Funds is designed to satisfy the statutory requirements of the Immigration and Naturalization Act (INA). Section 412(a)(3) of the Act requires that the Director of the Office of Refugee Resettlement (ORR) make a periodic assessment of the needs of refugees for assistance and services and the resources available to meet those needs. This assessment includes compiling and maintaining data on secondary migration of refugees within the United States after arrival. Further,

INA 412(c)(1)(B) states that formula funds shall be allocated based on the total number of refugees in each State, taking into account secondary migration.

In order to meet these statutory requirements, ORR requires each State to submit disaggregated individual records containing certain data elements for eligible populations. ORR uses the information collected through the Web site to determine secondary migration for the purposes of formula funds allocation to States.

The submission of individual records via the Refugee Data Submission System for Allocation of Formula Funds is a reliable and secure process for collecting data for the purposes of tracking secondary migration and allocating formula funds. Data submitted by the States via the Web site are also compiled and analyzed for inclusion in ORR's Annual Report to Congress.

Respondents: States, Wilson/Fish Alternative Projects, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Data Submission for Formula Funds Allocations	50	1	20	1,000

Estimated Total Annual Burden Hours: 1,000.

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 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.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0691]

Draft Guidance on Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs." This draft guidance is intended to help manufacturers of PET drugs meet the requirements for the Agency's current good manufacturing practice regulations for PET drugs.

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