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.

[FR Doc. 2011–25274 Filed 9–29–11; 8:45 am]

BILLING CODE 4120–01–P

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.

[FR Doc. 2011–25210 Filed 9–29–11; 8:45 am]

BILLING CODE 4184–01–P

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

guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 29, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. 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: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6155, Silver Spring, MD 20993–0002, 301–796–3416.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs.'' Most PET drugs are designed for parenteral administration and are produced by aseptic processing. The goal of aseptic processing is to make a product that is free of micro-organisms and toxic microbial byproducts, most notably bacterial endotoxins. The media fill is the performance of an aseptic manufacturing procedure using a sterile microbiological growth medium in place of the drug solution to test whether the aseptic procedures are adequate to prevent contamination during actual drug production. This draft guidance takes the form of questions and answers written specifically to help manufacturers comply with the Agency's current good manufacturing practices for PET drugs (part 212 (21 CFR part 212)) regarding media fills.

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 media fills and process simulations for PET drugs. 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. 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 of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. 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 part 212 have been approved under OMB control number 0910–0667.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25196 Filed 9–29–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 4, 2011, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave, Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900.

Contact Person: Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6639, *Shanika.Craig@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 4, 2011, the committee will provide advice and recommendations on the following issues: (1) Proposed changes to the Mammography Quality Standard Act (MQSA) policies and inspection procedures; (2) accreditation body review of soft copy mammography images; and (3) reporting breast density on mammography reports and patient lay summaries. The committee will also receive updates on the MQSA program and the status of the Full Field Digital Mammography universal quality control manual.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views,