eligible to receive a waiver or deferral of their repatriation loan. This form is to be completed by eligible repatriates, authorized legal custodian, or authorized agency/individual. Exemption applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

7. *The HHS Repatriation Program: Temporary Assistance Extension Request Form:* under 45 CFR 211 & 212 temporary assistance may be furnished beyond the 90 days eligibility period if the repatriate meets the qualifications established under Program regulations. This form is to be completed by the eligible repatriate, authorized legal custodian, or the authorized agency/individual. This form should be submitted to ORR or its designated grantee generally 14 days prior to the expiration of the 90 days eligibility period.

8. *The HHS Repatriation Program: State Request for Federal Support Form:* During emergency repatriation activities, States activated by ORR are to use this form to request support and/or assistance from HHS, including but not limited to required pre-approval of expenditures, augmentation of State personnel, funding, reimbursement, among other things.

Respondents: Designated state, federal, and/or non-governmental agencies/individuals and eligible repatriates. Responders are authorized by 42 U.S.C. 1313 and 24 U.S.C. 321–329; Executive Order 12656 (as amended by E.O. 13074, February 9, 1998; E.O. 13228, October 8, 2001; E.O. 13286, February 28, 2003); and regulations found under 45 CFR 211 & 212.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
The HHS Repatriation Program: Emergency and Group Processing Form.	25,000 or more depending on the Emergency.	1	0.30	7,500 or more.
The HHS Repatriation Program: Privacy and Repayment Agreement Form.	1,000 will increase during emergencies	1	0.05	50 or more.
The HHS Repatriation Program: Refusal of Temporary Assistance Form.	15 or more	1	0.05	0.75 or more.
The HHS Repatriation Program: Emergency and Group Repatriation Financial Form.	15 or more	1	0.30	4.5 or more.
The HHS Repatriation Program: Non-emergency Monthly Financial Statement Form.	52 or more	12	0.30	187 or more.
The HHS Repatriation Program: Repatriation Loan Waiver and Referral Request Form.	800 or more	1	0.30	240 or more.
The HHS Repatriation Program: State Request for Federal Support.	20 or more	1	0.30	6 or more.
The HHS Repatriation Program: Temporary Assistance Extension Request Form.	50 or more	1 or more	0.30	15 or more.

Estimated Total Annual Burden Hours: 8,003.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email 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, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–26467 Filed 10–16–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Office of Women's Health General Update on Strategic Priorities and Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Office of Women's Health General Update on Strategic Priorities and Initiatives. FDA staff will provide updates on strategic priorities, educational outreach, and research initiatives of interest to national organizations focused on the health of women.

DATES: The meeting will be held on November 30, 2015, 9 a.m. to 11 a.m.

ADDRESSES: The meeting will be held at the AARP Cy Brickfield Center, 601 East St. NW., Washington, DC 20049.

FOR FURTHER INFORMATION CONTACT: Deborah Kallgren, Office of Women's Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9440, FAX: 301–847–8604, *deborah.kallgren@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: There is no fee, but pre-registration is required. Send registration information (including name, title, firm or organization name, address, telephone, and fax number) to Deborah Kallgren. Seating is limited to 25 participants (1 person per organization).

If you need special accommodations due to a disability, please contact Deborah Kallgren (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: October 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26439 Filed 10–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0471]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 November 18, 2015.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0297. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

User Fee Cover Sheet; Form FDA 3397 (OMB Control Number 0910–0297)—Extension

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications (BLAs) and supplements to those applications. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications (NDAs), BLAs, or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs, BLAs, and/or, supplemental applications to those applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2014, there are an estimated 290 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105–115). The total number of annual responses is based on the number of submissions received by FDA in FY 2014. CDER received 3,005 annual responses that include the following submissions: 128 NDAs; 7 BLAs; 1,586 manufacturing supplements; 1,081 labeling supplements; and 203 efficacy supplements. CBER received 705 annual responses that include the following submissions: 11 BLAs; 611 manufacturing supplements; 64 labeling supplements; and 19 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions.

In the **Federal Register** of April 15, 2015 (80 FR 20232), 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 [1]

FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3397	290	12.79	3,710	0.5 (30 min.)	1,855

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26435 Filed 10–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0776]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reclassification Petitions for Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver