ANNUAL RESPONSE BURDEN ESTIMATES

[This information collection request is for a two-year period.]

Instrument	Total number of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Previously Approved Instruments					
PRS	32	4	31.2	3,994	1,997
HPOG-Impact Baseline Survey(s) (Supplemental baseline questions; study sample members)	10,500	1	0.25	2,625	1,313
HPOG-Impact Baseline Survey(s) (Supplemental baseline questions; grantees)	20	525	0.25	2,625	1,313
Current Request for Approval					
HPOG–NIE Sampling Questionnaire for the HPOG surveys	54	1	2	108	54
HPOG–NIE Follow-Up Phone Call Protocol for the Stakholder/Network survey	162	1	0.17	28	14
HPOG–NIE Grantee survey	54	1	4	216	108
HPOG-Impact Implementation interview guide for partnering employers	60	1	0.50	30	15
HPOG-Impact Implementation interview guide for instructors	60	1	0.75	45	22
HPOG-Impact Implementation interview guide for HPOG program mangement	20	1	1.50	30	15
HPOG-Impact Implementation interview guide for HPOG program staff	80	1	1	80	40
HPOG–NIE Management and Staff survey	540	1	0.5	270	135
HPOG–NIE Stakeholder/Network survey	500	1	0.5	250	125
HPOG–NIE Employer survey	200	1	0.5	100	50
HPOG-Impact 15-month Participant Follow-Up survey	5,600	1	0.7	3,920	1,960
HPOG-Impact 15-month Control Group Member Follow-Up survey	2,800	1	0.6	1,680	840
HPOG–NIE 15-month Participant Follow-Up survey	600	1	0.7	420	210

Estimated Annual Response Burden Hours: 8,211.

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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of the 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 collections should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_ OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2013–10577 Filed 5–3–13; 8:45 am]

BILLING CODE 4184–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0485]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission Process for Voluntary Complaints to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use.

DATES: Submit either electronic or written comments on the collection of information by July 5, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Electronic Submission Process for Voluntary Complaints to the Center for Devices and Radiological Health—(OMB Control Number 0910–NEW)

This ICR collects information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because there has been no established guidelines or instructions on how to submit a compliant to CDRH, complaints often contain minimal information and are received via phone calls, emails, or conversationally from any CDRH staff. CDRH seeks to establish a consistent format and process for the submission of device complaints that will enhance our timeliness in receiving, assessing and evaluating voluntary complaints. The information provided in the complaints received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
	700	1	700	.25 (15 minutes)	125

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

Dated: April 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10597 Filed 5–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0418]

An Evaluation of the Prescription Drug User Fee Act Workload Adjuster; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on an assessment of the Prescription Drug User Fee Act (PDUFA) Workload Adjuster conducted by an independent consulting firm. This assessment was conducted to fulfill FDA performance commitments made as part of the fifth authorization of PDUFA in section XV, ''Improving FDA Performance Management,'' subsection B, which was reauthorized by the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. The assessment will be conducted by an independent consultant in two phases. This is the first assessment of two during PDUFA V to evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity in the human drug review program and present options to discontinue, retain, or modify any elements of the adjustment. After review of the report and receipt of public comment, FDA can adopt appropriate change to the workload adjustment methodology, if warranted.

DATES: Submit electronic or written comments by June 5, 2013.

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Giles Mills, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3288, Silver Spring, MD 20993–0002, 301–796–4707, *Giles.Mills@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law FDASIA. This new law includes the reauthorization of PDUFA that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products.

Title I of FDASIA is the fifth authorization of PDUFA and includes by reference the performance goals and procedures for PDUFA V transmitted by the Secretary of Health and Human Services to Congress in a commitment letter. FDA developed recommendations for PDUFA V in consultation with drug industry representatives, patient and consumer advocates, healthcare professionals, and other public stakeholders from July 2010 through May 2011. These recommendations included an FDA commitment to contract with an independent