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

accounting firm to review the adequacy of the PDUFA adjustment for changes in workload (hereafter referred to as the workload adjuster).

The workload adjuster was introduced in PDUFA III to allow for FDA to augment the total user fee revenue amount each fiscal year (after adjusting for inflation) to account for changes in workload volume in the human drug application review process. Workload volume is measured by the changes in the number of new drug applications and biologics license applications (NDAs/BLAs), active commercial investigational new drugs (INDs), efficacy supplements, and manufacturing supplements submitted to the human drug review program during the most recent 5-year period.

In PDUFA IV, the workload adjuster was expanded to account for the workload complexity (known as the adjustment for changes in review activities) associated with the review of NDAs/BLAs and active commercial INDs. The NDA/BLA complexity is measured by changes in the number of labeling supplements, annual report reviews, and NDA/BLA meetings per NDA/BLA. IND complexity is measured by changes in the number of special protocol assessments and IND meetings per active commercial IND.

As part of the PDUFA IV recommendations, FDA committed to an evaluation of the adjustment for changes in review activities by an independent accounting firm. The study, conducted by Deloitte & Touche, LLP, found that the adjustment methodology used by FDA reasonably captures changes in the workload complexity for reviewing human drug applications under PDUFA IV. While the FY 2009 evaluation concluded that the adjustment methodology was reasonable at that point in time, the complexity of new drug applications and FDA's regulatory responsibilities are constantly evolving. Moreover, the complexity component of the PDUFA IV workload adjuster was formulated before the enactment of the Food and Drug Administration Amendments Act (FDAAA). Thus, the workload adjuster does not account for new and significant review activities required by FDAAA, such as risk evaluation and mitigation strategies, safety labeling changes, advisory committee meetings, and post-market safety requirements, among others.

Given the dynamic nature of drug products and FDA's regulatory responsibilities, FDA committed to periodic reassessments of the workload adjuster in PDUFA V to ensure that it is achieving its intended role of adjusting the user fee revenues to reflect actual changes in FDA's workload volume and complexity.

The PDUFA V commitment letter instructs FDA to contract with an independent accounting or consulting firm to conduct two assessments of the workload adjuster. This first assessment (to examine the performance of the workload adjuster since FY 2009) was just completed. The independent accounting or consulting firm is required to submit reports based on their assessments. The reports will evaluate whether the workload adjuster reasonably represents actual changes in workload volume and complexity and will present recommendations to discontinue, retain, or modify any elements of the adjustment. After review of the reports and receipt of public comments, FDA, if warranted, may implement appropriate changes to the methodology. If FDA adopts changes to the methodology based on the first report, the changes are effective the fiscal year after FDA adopts the changes and each subsequent fiscal year.

FDA is seeking public comment now on the first assessment of the PDUFA Workload Adjuster, available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee.*

II. Comments

Interested persons may submit either electronic comments regarding the Analysis to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: April 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10626 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–0001]

Food and Drug Administration/International Society for Pharmaceutical Engineering Co-Sponsorship Educational Workshop: Redefining the 'C' in CGMP (Current Good Manufacturing Practices): Creating, Implementing, and Sustaining a Culture of Quality

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), in co-sponsorship with the International Society of Pharmaceutical Engineering (ISPE), is announcing a conference entitled ''Redefining the 'C' in CGMP: Creating, Implementing and Sustaining a Culture of Quality'' Pharmaceutical Quality System (ICH Q10) Conference.

The conference will span 3 days and is dedicated to teaching the principles of CGMP, reaping the benefits that come from establishing and maintaining a state of control, implementing continual improvement, enhancing regulatory compliance, and meeting quality objectives every day. The conference will take place in Baltimore, MD, and will draw on the best industry and regulator contributors on this topic.

Date and Time: The conference will be held on June 11, 2013, from 8:30 a.m. to 5 p.m.; June 12, 2013, from 8 a.m. to 5 p.m.; and June 13, 2013, from 8 a.m. to 4:30 p.m.

Location: The event will be held at the Renaissance Baltimore Harborplace Hotel, 202 East Pratt St., Baltimore, MD 21201, 1–800–535–1201.

Contact Person: Nancy Berg, President, International Society for Pharmaceutical Engineering, 600 North Westshore Blvd., suite 900, Tampa, FL 33609, Web site: *http://www.ISPE.org/CGMP.*

Conference attendees are responsible for their own accommodations.

Registration: You are encouraged to register at your earliest convenience. The ISPE registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted to the conference will receive confirmation. Registration will close after available conference space is filled. Onsite registration will be available on a space available basis on the day of the