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 Adjustor 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, 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 complaint 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>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>700</td>
<td>1</td>
<td>700</td>
<td>25 (15 minutes)</td>
<td>125</td>
</tr>
</tbody>
</table>

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

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 Adjustor; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

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


Leslie Kux,
Assistant Commissioner for Policy.
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achieve its intended role of adjusting the workload adjuster in PDUFA V to ensure that it is periodic reassessments of the workload complexity (known as 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.

Leslie Kux,
Assistant Commissioner for Policy.

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.


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