assessments provided by applicants in their regulatory submissions.

Recognizing that there are many reasonable approaches for conducting a benefit-risk assessment, M4E(R2) does not specify a particular approach to be used by industry. However, the document does offer specific guidance on the major elements that should be included in the benefit-risk assessment. Furthermore, consistent with the concept paper that laid the groundwork for the Expert Working Group, the revised draft guidance does not dictate an approach used by a regulator in conducting a benefit-risk assessment.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document 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.*

III. Electronic Access

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

Dated: *September 28, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25122 Filed 10–1–15; 8:45 am]

BILLING CODE 4164–01–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 of 2012 (FDASIA). Independent consulting firms conducted two assessments during PDUFA V. This is the second assessment to evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity in the human drug review program and to 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 November 2, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0418 for ''An Evaluation of the Prescription Drug User Fee Act Workload Adjuster; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other

applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alice Tsai, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1149, Silver Spring, MD 20993–0002, 240–402–6069, *Alice.Tsai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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, health care professionals, and other public stakeholders from July 2010 through May 2011. These recommendations included an FDA commitment to contract with an independent accounting or consulting 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 (NDAs) and biologics license applications (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; hereafter referred to as the Complexity Factor) 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 consulting firm. The study, conducted by Deloitte & Touche, LLP, in fiscal year (FY) 2009, found that the adjustment methodology used by FDA reasonably captures changes in the workload complexity for reviewing human drug applications under PDUFA IV. Although the FY 2009 evaluation concluded that the adjustment methodology was reasonable at that 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 of 2007 (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. The first assessment (to examine the performance of the workload adjuster since FY 2009) conducted by IBM in FY 2013, found that the workload adjuster does reasonably represent changes in workload volume associated with the human drug review process. However, the report concluded that methodology was flawed with respect to measuring workload complexity, because it does not represent total amount of work per submission. The report recommended that FDA consider removing the Complexity Factor. In addition, the report found that the workload adjuster's use of 5-year rolling averages to measure changes in workload against the base years was not as sensitive to recent trends as 3-year rolling averages would be. The report is available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM350567.* After reviewing the report and public comments, FDA discontinued the use of the Complexity Factor in the adjustment methodology and adopted 3-year averages to measure changes in workload volume.

The second assessment (to address the recommendations from the first evaluation and assess the continued performance of the workload adjuster) was just completed. The independent consulting firm is required to submit a report based on its assessment. The report will evaluate whether the workload adjuster reasonably represents actual changes in workload volume and will present options to discontinue, retain, or modify any elements of the adjustment. After review of the report and receipt of public comment, FDA, if warranted, may adopt appropriate changes to the methodology.

FDA is seeking public comment now on the second assessment of the PDUFA Workload Adjuster, available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM464878.pdf.*

Dated: *September 29, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25117 Filed 10–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0684]

Identification of Alternative In Vitro Bioequivalence Pathways Which Can Reliably Ensure In Vivo Bioequivalence of Product Performance and Quality of Non-Systemically Absorbed Drug Products for Animals; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the