4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1010]

Food and Drug Administration Prescription Drug User Fee Act VI Benefit-Risk Implementation Plan; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft 5-year plan describing the Agency's approach to further the implementation of structured benefit-risk assessment, including the incorporation of the patient's voice in drug development and decision-making, in the human drug review program and the opportunity for public comment on the draft plan. This new draft plan is an update to the 5-year plan published in February 2013 on FDA's website. This new draft plan is part of FDA's commitments that were made as part of the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). FDA has published the draft plan on its website.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2018-N-1010 for "Food and Drug Administration Prescription Drug User Fee Act VI Benefit-Risk Implementation Plan; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993-0002, 301-796-5003, Fax: 301-847-8443, Graham.Thompson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 5-year plan describing the Agency's approach to further the implementation of structured benefit-risk assessment into human drug and biologics review. This draft plan is intended to meet a performance goal included in the sixth authorization of PDUFA (PDUFA VI). This reauthorization, part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.

This new draft plan is an update to the 5-year plan published in February 2013 on FDA's website: https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf.

FDA's commitments to meet certain performance goals under PDUFA VI were developed in consultation with patient and consumer advocates, health care professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.2 of the commitment letter, "Enhancing Benefit-Risk Assessment in Regulatory Decision-Making" (https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf) outlines FDA's commitments in this area, including publication of an update to the implementation plan published in 2013 entitled "Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making" (https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf). The update includes a report on the progress made during PDUFA V and a plan for continued implementation during Fiscal Years (FY) 2018--2022. The publication and implementation of this plan are intended to fulfill the commitments described in Section J of the PDUFA VI Commitment Letter.

II. FDA Draft PDUFA VI Benefit-Risk Implementation Plan

Benefit-risk assessment is the foundation for FDA's regulatory review of human drugs and biologics. In PDUFA V, FDA's Center for Drug Evaluation and Research and Center for Biologics and Research committed to further our efforts to enhance benefit-risk assessment and communication in the human drug review process in FY 2013--2017. Enhancing and communicating benefit-risk assessment continues to be an Agency priority in PDUFA VI. The

draft plan describes the progress made on PDUFA V in benefit-risk assessment. This progress includes revision of FDA's review/decision templates and manuals to incorporate FDA's approach to benefit-risk assessment, training review and management of staff on the revised templates and manuals, developing an evaluation plan to ascertain the impact of FDA's implementation of the Benefit-Risk Framework in drug review, holding two public workshops on benefit-risk considerations from the regulator's perspective, and advancing FDA's Patient-Focused Drug Development initiative. This draft plan also summarizes the third-party evaluation of FDA's implementation of the Benefit-Risk Framework into FDA's new drug review.

The plan also includes an overview of FDA's commitments in PDUFA VI for continued implementation of structured benefit-risk assessment during FY 2018--2022. These commitments include participating in a meeting to gather stakeholder input on key topics, publishing a draft guidance on benefit-risk assessment for new drugs and biologics, continuing to revise relevant Manuals for Policies and Procedures and Standard Operating Practices and Procedures to incorporate benefit-risk assessment approaches, and conducting a second evaluation of the implementation of the Benefit-Risk Framework beginning in 2021. In addition to these commitments, FDA also plans to explore additional opportunities to enhance our use and communication of benefit-risk assessments.

III. Electronic Access

FDA has published the draft plan on its website: https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm. The period for public comment on the draft plan will remain open for 60 days following the publication of this notice. After consideration of public comments, FDA will finalize the plan.

Throughout PDUFA VI, the Agency will update the plan as necessary and post all updates on FDA's website.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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