4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6313]

Prescription Drug User Fee Act VI Commitment to Assess Current Practices of the Food and Drug Administration and Sponsors in Communicating During Investigational New Drug Development; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the statement of work to assess current practices of FDA and sponsors in communicating during investigational new drug (IND) development and identify best practices and areas of improvement. The independent assessment is part of FDA performance commitments under the recent reauthorization of the Prescription Drug User Fee Act (PDUFA). The independent assessment of current practices of FDA and sponsors in communicating during drug development is described in detail in the document entitled "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022" available at https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf. As part of FDA performance commitments described in this document, the assessment will be conducted by an independent contractor. FDA is providing for public comment on the statement of work before revising and requesting contractor proposals.

DATES: Submit either electronic or written comments by [INSERT DATE 45 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 45 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 45 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.

You may submit comments as follows:

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-2017-N-6313 for "Prescription Drug User Fee Act VI Commitment to Assess Current Practices of the Food and Drug Administration and Sponsors in Communicating During Investigational New Drug Development." 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: Yoni Tyberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1151, Silver Spring, MD 20993, 301-348-1718, Fax: 301-847-8443, Yonatan.Tyberg@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The IND phase of drug development is the time during which human trials of investigational drugs are conducted. During the IND phase, sponsors and FDA engage in many types of communications. To ensure the effectiveness of human drug review programs, it is critical that these communications be conducted in a timely and efficient manner.

The timely review of the safety and effectiveness of new drugs and biologics is central to FDA's mission to protect and promote the public health. Prior to enactment of PDUFA in 1992, FDA's drug review process was relatively slow and not very predictable compared to that of other countries. Due to concerns expressed by both industry and patients at the time, Congress enacted PDUFA, which provided the added funds through user fees that enabled FDA to hire additional reviewers and support staff and upgrade its information technology systems. In return for additional resources, FDA agreed to certain review performance goals, such as completing reviews of new drug applications and biologics license applications and taking regulatory actions on them in predictable timeframes. These changes revolutionized the drug approval process in the United States and enabled FDA to speed the application review process for new drugs and biologics without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of new drugs and biologics prior to approval.

PDUFA provides FDA with a source of stable, consistent funding that has made it possible for it to focus on promoting innovative therapies and help bring to market critical products for patients. When PDUFA was originally authorized in 1992, it had a 5-year term. The program has been subsequently reauthorized every 5 years with the most recent reauthorization occurring in 2017 for fiscal years (FYs) 20182022. To prepare for the 2017 reauthorization of PDUFA, FDA conducted negotiations with the regulated industry and held regular consultations with public stakeholders including patient advocates, consumer advocates,

and health care professionals between September 2015 and February 2016. Following these discussions, related public meetings, and Agency requests for public comment, FDA published proposed recommendations for PDUFA VI for FYs 20182022. FDA committed under PDUFA VI to contract with an independent third party to assess current practices of FDA and sponsors in communicating during IND development and to identify best practices and areas of improvement.

The statement of work can be accessed at https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM577087.pdf.

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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