

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by January 18, 2018, 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993-0002, 301-796-5661 or email: [Susan.Monahan@fda.hhs.gov](mailto:Susan.Monahan@fda.hhs.gov), no later than January 16, 2018.

#### Requests for Oral Presentations:

During online registration, you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by January 19, 2018. All requests to make oral presentations must be received by the close of registration on January 18, 2018, 4 p.m. If selected for presentation, any presentation materials must be emailed to Maggie Fu at [maggie.fu@fda.hhs.gov](mailto:maggie.fu@fda.hhs.gov) no later than January 25, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

**Streaming Webcast of the Public Workshop:** This public workshop will also be webcast. The webcast link will be available on the registration Web page after January 23, 2018. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar (<https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>) and select this event from the list of items provided. Organizations are

requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the Internet at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>.

#### IV. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**), and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA's Digital Health Innovation Action Plan issued on July 27, 2017 available at: <https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265>.

Dated: December 4, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-26457 Filed 12-7-17; 8:45 am]

**BILLING CODE 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 January 22, 2018.

**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 January 22, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of January 22, 2018. 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](mailto: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) 2018-2022. 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 2018-2022. 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-6294]

#### Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.