



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4337]

Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards;

Announcement of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the following public meeting entitled “Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.” FDA is also requesting public comments on the subject. The purpose of the meeting and the request for comments is to fulfill FDA’s commitment to seek stakeholder input related to data standards and the electronic submission system’s past performance, future targets, emerging industry needs, and technology initiatives. FDA will use the information from the public meeting as well as from comments submitted to the docket to provide input into data standards initiatives, the FDA Information Technology (IT) Strategic Plan, and electronic submissions gateway target timeframes.

DATES: The public meeting will be held on April 10, 2019, from 9 a.m. to 4 p.m. Submit either electronic or written comments by April 10, 2019. See the SUPPLEMENTARY

INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993-0002. Entrance for public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and

security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

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 April 10, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 10, 2019. 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-4337 for “Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.” 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 laws. 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: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 301-796-0035, chenoa.conley@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to achieve the long-term goal of improving the predictability and consistency of the electronic submission process and enhancing transparency and accountability of FDA information technology-related activities. In the PDUFA VI commitment letter, FDA agreed to hold annual public meetings to seek stakeholder input related to electronic submissions and data standards to inform the FDA IT Strategic Plan and published targets. The commitment letter outlines FDA's performance goals and procedures under the PDUFA program for the years 2018 through 2022. The commitment letter can be found at <https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm>.

FDA will consider all comments made at this meeting or received through the docket (see ADDRESSES).

II. Participating in the Public Meeting

Registration: To register to attend "Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards," please register at <https://www.eventbrite.com/e/pdufa-vi-public-meeting-on-electronic-submissions-and-data-standards-tickets-49895060469>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. A draft agenda will be posted approximately 1 month prior to the meeting.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting on April 10, 2019, must register by 11:59 p.m. on March 22, 2019, 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.

Request for Oral Presentations: During online registration, you may indicate if you wish to present during the public comment session and which topic(s) you would like to address. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. Following the close of registration, FDA 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 March 27, 2019. All requests to make oral presentations must be received by the close of registration at 11:59 on March 22, 2019, Eastern Time. If selected for presentation, any presentation materials must be emailed to cderdatastandards@fda.hhs.gov no later than April 3, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

If you need special accommodations due to a disability, please contact Chenoa Conley, 301-796-0035, email Chenoa.Conley@fda.hhs.gov, no later than April 3, 2019.

Transcripts: Please be advised that as soon as a transcript of the public meeting 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/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm>.

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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