proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

**Mary Jones,**

*Reports Clearance Officer.*

[FR Doc. 2017–21960 Filed 10–11–17; 8:45 am]

**BILLING CODE 4184–41–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–5568]**

### Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards; Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting.

**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.'' The topics to be discussed will include the current status of electronic submissions and data standards initiatives to improve the predictability and consistency of the electronic submissions process in support of the human drug review program. FDA is seeking input from a variety of stakeholders—industry, academia, patient advocates, professional societies and other interested parties—as it fulfills its commitment under the Prescription Drug User Fee Act of 2017 (PDUFA) to hold annual public meetings to seek stakeholder input related to enhancing the transparency and accountability of the electronic submission and data standards activities. FDA will use the information from the public meeting to inform the development of the FDA Information Technology (FDA IT) Strategic Plan and electronic submissions gateway target timeframes.

**DATES:** The public meeting will be held March 21, 2018, from 9 a.m. to 4 p.m. Submit either electronic or written comments regarding this public meeting prior to the meeting through April 18, 2018. 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., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the 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/default.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 18, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 18, 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.

*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–5568 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 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:** Ron Fitzmartin, Center for Drug Evaluation

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993–0002, 301–796–5333, email: *cderdatastandards@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., 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. FDA agreed in the PDUFA VI commitment letter 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 2018–2022. The commitment letter can be found at *https://www.fda.gov/forindustry/userfees/prescriptiondrug userfee/ucm446608.htm.*

## II. Topics for Discussion at the Public Meeting

FDA strives to achieve a fully automated standards-based IT environment that enhances the regulatory review processes for human drugs and biologics. The purpose of the March 21, 2018, public meeting is to obtain input from industry and other interested stakeholders on enhancing the transparency and accountability of the electronic submission and data standards activities. To help fulfill its commitment, FDA is particularly interested in receiving input on the following topics:

- Electronic Submissions
  - Electronic submission process, including key electronic submission milestones and associated sponsor notifications from the completion of the upload of the submission to the Electronic Submissions Gateway (ESG) through the time the submission is made available to the review team.
  - Electronic submission system past performance, emerging industry needs, and technology initiatives.
  - Published and future targets for the ESG and related electronic submission systems.
  - Implementation of electronic Common Technical Document (eCTD) v4.0.
- Data Standards Initiatives
  - International Organization for Standards (ISO) Identification of Medicinal Products (IDMP): ISO IDMP standards implementation will support a variety of regulatory activities related to development, registration, and life cycle management of medicinal products, as well as pharmacovigilance and risk management. There are five standards that describe the substance (ISO 11238), dosage form and routes of administration (ISO 11239), units of measure (ISO 11240), medicinal product identifier (ISO 11615), and pharmaceutical product identifier (ISO 11616).
  - Individual Case Safety Reports (ICSRs): ICSRs provide a consistent approach to the creation and review of drug and biologics safety information and pharmacovigilance activities.

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

## III. Participating in the Public Meeting

*Registration:* To register to attend ''Prescription Drug User Fee Act VI; Electronic Submissions and Data Standards; Public Meeting; Request for Comments'' please send an email to *cderdatastandards@fda.hhs.gov* by February 19, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by February 19, 2018, midnight 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 you need special accommodations due to a disability, please contact Chenoa Conley, 301–796–0035, email *Chenoa.Conley@fda.hhs.gov* at least 7 days before the meeting.

*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 wish 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 6, 2018. All requests to make oral presentations must be received by the close of registration on February 19, 2018, midnight Eastern Time. If selected for presentation, any presentation materials must be emailed to *cderdatastandards@fda.hhs.gov* no later than March 14, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

*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/prescriptiondrug userfee/ucm446608.htm.*

Dated: October 5, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–21981 Filed 10–11–17; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0461]**

### Format and Content of a Risk Evaluation and Mitigation Strategy Document; Revised Draft Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Format and Content of a REMS Document.'' A Risk Evaluation and Mitigation Strategy (REMS) document, which is part of a REMS that is required by FDA, establishes the goals and requirements of the REMS. This revised draft guidance describes a new recommended format for a REMS document. The new format was developed based on extensive stakeholder feedback. This guidance revises and supersedes the draft guidance entitled ''Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications,'' that was published by FDA on October 1, 2009.

**DATES:** Submit either electronic or written comments on the draft guidance