updates, information describing the type of submission that should be made to FDA, as well as other considerations for submitting a labeling update to FDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA.

- The collections of information in part 314 for the submission of ANDAs (including the content and format of ANDAs and supplements and amendments) have been approved under OMB control number 0910–0001 and in part 314 (included under the 21 CFR parts 10 through 16 hearing regulations) for OMB control number 0910–0191.
- The collections of information pertaining to the electronic submission of labeling changes have been approved under OMB control number 0910–0045.
- The collections of information pertaining to the content and format requirements for human prescription drugs and biological products and the submission of such labeling have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01577 Filed 1–26–22; 8:45 am]

BILLING CODE 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; 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, Agency, or we) is announcing the following virtual public meeting entitled ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' The purpose of the virtual public 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 and electronic submissions initiatives.

DATES: The public meeting will be held on April 12, 2022, from 9 a.m. to 1 p.m. Eastern Time, and will take place virtually, held by webcast only. Submit either electronic or written comments on this public meeting by March 22, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Registration to attend the meeting and other information can be found at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-information-technology-goals-and-progress.*

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 March 22, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 22, 2022. 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Bryan Spells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, *Bryan.Spells@fda.hhs.gov,* 240–402–6511; 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, *Stephen.Ripley@fda.hhs.gov.*

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 document containing the performance goals and procedures for the Prescription Drug User Fee Act (PDUFA) reauthorization for fiscal years 2018 through 2022 (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 Information Technology Strategic Plan and published targets. The PDUFA VI commitment letter outlines FDA's performance goals and procedures under the PDUFA program for the years 2018 through 2022. The PDUFA VI commitment letter can be found at *https://www.fda.gov/media/99140/download.*

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 visit the following website: *https://www.eventbrite.com/e/pdufa-vi-data-standards-public-meeting-2022-tickets-215684276477?ref=estw.* 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.

Opportunity for Public Comment: Those who register online by March 22, 2022, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by March 22, 2022, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter and the approximate time each comment is to begin, and we will select and notify participants by April 1, 2022. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will be held via Zoom (*https://fda.zoomgov.com/j/1606221249*).

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: January 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01570 Filed 1–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6854]

Good Abbreviated New Drug Applications Submission Practices; 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 final guidance for industry entitled ''Good ANDA Submission Practices.'' This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs). This guidance highlights common, recurring deficiencies that may lead to a delay in the approval of an ANDA. It also makes recommendations to applicants on how to avoid these deficiencies with the goal of minimizing the number of review cycles necessary for approval. This guidance finalizes the draft guidance entitled ''Good ANDA Submission Practices'' issued on January 4, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on January 27, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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