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]

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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

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–D–6854 for ''Good ANDA Submission Practices.'' Received comments 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 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.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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mindy Ehrenfried, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993–0002, 301–796–4515.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Good ANDA Submission Practices.'' This guidance is intended to assist applicants preparing to submit ANDAs to FDA. It highlights common, recurring deficiencies that may lead to a delay in the approval of an ANDA. This guidance also makes recommendations to applicants on how to avoid these deficiencies so that applicants can submit ANDAs that may be approved in the first review cycle. This guidance has been developed as part of FDA's ''Drug Competition Action Plan'' (*https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan*), which, in coordination with the Generic Drug User Fee Amendments (GDUFA I and II) (Pub. L. 112–144 and Pub. L. 115–52, respectively) and other FDA activities, is expected to increase competition in the market for drugs, facilitate entry of high-quality and affordable generic drugs, and improve public health.

This guidance finalizes the draft guidance of the same title issued on January 4, 2018 (83 FR 532). FDA considered comments received on the draft guidance as the guidance was finalized and made minor edits and other editorial changes to improve clarity. Revisions include clarification of the recommendations pertaining to patent and exclusivity deficiencies, as well as those pertaining to product quality deficiencies relating to the drug substance. We have also clarified the recommendations relating to ANDAs that propose to use bioequivalence methods that differ from recommendations in a relevant product-specific guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Good ANDA Submission Practices.'' 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 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the 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. 2022–01580 Filed 1–26–22; 8:45 am]

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