4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1216]

Technical Specifications for Electronic Submissions; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to receive information, recommendations, and comments on matters related to the Agency's publication of technical specifications, which explain, clarify, and define the specific use of data standards in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and certain investigational new drug applications (INDs) to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). This docket is intended for general comments related to technical specifications that are not specific to documents or issues that are the subject of other dockets, or for comments specific to electronic submission guidances.

DATES: The announcement of this establishment of a public docket is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments to this docket 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-2018-D-1216 for "Technical Specifications for Electronic Submissions; Establishment of a Public Docket."

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.

- 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: 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, ronald.fitzmartin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 745A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1) requires that submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the Public Health Service Act (42 U.S.C. 262(a) or (k)) be submitted in the electronic format specified by FDA, beginning no earlier than 24 months after FDA issues a final guidance specifying an electronic submission format.

The Agency has concluded it is not feasible to describe and implement the electronic format or formats that would apply to all the submissions covered by section 745A(a) in one guidance document. Therefore, FDA issued the guidance for industry "Providing Regulatory Submissions in Electronic Format--Submissions under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act," which describes how FDA interprets the electronic submission requirements of section 745A(a) of the FD&C Act (see https://www.fda.gov/downloads/drugs/guidances/ucm384686.pdf).

To assist sponsors in the submission of data in standardized electronic format in NDAs, ANDAs, BLAs, and certain INDs, CBER and CDER have developed technical specifications guidances which provide useful technical specifications, recommendations, and general

considerations for submitting standardized data and related information in electronic format. Technical specifications guidances are guidances that explain, clarify, and define the specific use of data standards in regulatory submissions. Technical specifications guidances are available at: https://www.fda.gov/ForIndustry/DataStandards/default.htm.

II. Establishment of a Docket

FDA is establishing a public docket so that anyone can share information, comments, and ideas on any matters related to the use of technical specifications that are not specific to the documents or issues addressed in other dockets. This information will give the Agency insight into stakeholders' experiences and views regarding the use of technical specifications guidances and the data standards they contain. The docket also permits anyone to share information, comments, or ideas that are specific to one or more technical specifications guidances. Instructions regarding how to submit comments to specific technical specifications documents have been posted within the docket.

This docket will be open for comment simultaneously with several other dockets that are specific to particular electronic common technical document (eCTD) submissions and FDA data standards documents. (For more information on eCTD submissions and FDA data standards, see https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm and https://www.fda.gov/ForIndustry/DataStandards/default.htm, respectively). Do not submit comments to this general docket that have already been submitted to other dockets. As FDA finalizes specific documents or requests comments on specific issues for which another docket exists, the Agency will generally consider only those comments that have been submitted to that specific docket. Do not submit comments related to another specific docket to this general

technical specifications docket, as the Agency may not consider them. FDA will not respond directly to questions or requests submitted to this docket but will consider any submitted information in its work to develop and issue technical specifications guidances.

Dated: June 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-12969 Filed: 6/15/2018 8:45 am; Publication Date: 6/18/2018]