4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Electronic Common Technical Document; Data Standards; Support Ends for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 2.01 and Requirement Begins for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 3.3

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research are announcing the date that FDA will no longer support electronic submissions using the Electronic Common Technical Document (eCTD) Backbone Files Specification for Module 1 Version 1.3, Comprehensive Table of Contents Headings and Hierarchy Version 1.2.2, U.S. Regional Document Type Definition (DTD) Version 2.01, and U.S. Regional Stylesheet Version 1.1, and will require electronic submissions to be submitted using eCTD Module 1 U.S. Regional DTD Version 3.3. The Agency will update the eCTD Submission Standards document to reflect these changes.

DATES: The requirement for electronic submissions to be submitted using eCTD Module 1 U.S. Regional DTD Version 3.3 will begin on March 1, 2022.

ADDRESSES: You may submit either electronic or written comments 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 "Electronic Common Technical Document; Data Standards; Support Ends for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 2.01 and Requirement Begins for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 3.3." 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.

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993-0002, 301-796-7997, jonathan.resnick@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: FDA is issuing this *Federal Register* notice pursuant to the guidelines described in the FDA guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act" (December 2014, available at https://www.fda.gov/media/88120/download), section III.F "When will revisions or updates to existing formats take effect?" to announce the end of support for electronic submissions using eCTD Module 1 U.S. Regional DTD Version 2.01 and the date the requirement begins to submit using eCTD Module 1 U.S. Regional DTD Version 3.3 as described in this notice.

On June 15, 2015, FDA began accepting electronic submissions using eCTD Module 1 U.S. Regional DTD Version 3.3 as described in "The eCTD Backbone Files Specification for Module 1" Version 2.3. This upgrade of eCTD Module 1 includes functionality for promotional

material and risk evaluation and mitigation strategies submissions, the ability to dynamically update certain heading elements (e.g., FDA forms), and the ability to submit grouped submissions. FDA has continued to accept electronic submissions using the previous version of the eCTD Module 1, using U.S. Regional DTD Version 2.01 as described in "The eCTD Backbone Files Specification for Module 1" Version 1.3.

Due to the limitations of eCTD Module 1 U.S. Regional DTD Version 2.01, FDA support for electronic submissions using eCTD Backbone Files Specification for Module 1 Version 1.3, Comprehensive Table of Contents Headings and Hierarchy Version 1.2.2, U.S. Regional DTD Version 2.01, and U.S. Regional Stylesheet Version 1.1 will end on March 1, 2022. The requirement for electronic submissions to be submitted using eCTD Module 1 U.S. Regional DTD Version 3.3 will begin on March 1, 2022. The Agency will update the eCTD Submission Standards document to reflect these changes.

Dated: October 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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