This document is scheduled to be published in the
Federal Register on 2026-10-16 and available online at
https://www.federalregister.gov/d/2026-21195, and on
https://govinfo.gov

BILLING CODE 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; Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Supporting Electronic Common Technical Document Version 3.2.2 and Version 4.0

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 FDA will begin rejecting electronic submissions that fail new Electronic Common Technical Document (eCTD) Version 3.22 (v3.22) and Version 4.0 (v4.0) based validations. The new eCTD v3.2.2 validations are 2024 and 2025, which are high-severity validation errors as described in the Specifications for eCTD Validation Criteria. The new eCTD v4.0 validations are eCTD4-084, eCTD4-085, US-eCTD4-561, US-eCTD4-562, US-eCTD4-563, and US-eCTD4-564, which are high-severity validation errors as described in the Specifications for eCTD v4.0 Validation Criteria.

DATES: Rejection for failing to pass the new high-severity eCTD v3.22 and v4.0 validations will begin January 16, 2027. Submit either electronic or written comments at any time.

ADDRESSES: You may submit comments 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 "Instruction."

Instructions: All submissions received must include the Docket No. FDA-2018-D-1216 for "Electronic Common Technical Document; Data Standards; Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Supporting Electronic Common Technical Document Version 3.2.2 and Version 4.0." 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 Chris McCormick, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7266, Silver Spring, MD 20993-0002, 301-651-7158, Chris.McCormick@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is issuing this *Federal Register* notice to announce that eCTD v3.2.2 validations 2024 and 2025 and the eCTD v4.0 validations eCTD4-084, eCTD4-085, US-eCTD4-561, US-eCTD4-562, US-eCTD4-563, and US-eCTD4-564 (described in Specifications for eCTD Validation Criteria and Specifications

for eCTD v4.0 Validation Criteria, respectively) will become effective. Beginning January 16, 2027, FDA will reject electronic submissions that fail these validations.

According to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications), submissions subject to section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k-1(a)) must be submitted in eCTD format using the version of eCTD currently supported by FDA unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver. The version of eCTD currently supported by FDA is specified in the FDA Data Standards Catalog (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog). FDA plans to update the Specifications for eCTD Validation Criteria and the Specifications for eCTD v4.0 Validation Criteria to add the effective dates for the above-referenced high-severity validations after publication of this notice. Specifications and validation criteria for eCTD are available on FDA's eCTD web page (available at https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-21195 Filed: 10/15/2026 8:45 am; Publication Date: 10/16/2026]