



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Electronic Study Data Submission; Data Standards; Technical Rejection Criteria for Study Data Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing the effective date for Electronic Common Technical Document (eCTD) validations referenced in FDA's "Technical Rejection Criteria for Study Data" (TRC).

DATES: The eCTD validations will become applicable on September 15, 2021.

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 Study Data Submission; Data Standards; Technical Rejection Criteria for Study Data Effective Date.” 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 (CDER), 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 (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, Stephen.Ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In accordance with the guidance¹ for industry “Providing Regulatory Submissions in Electronic Format--Standardized Study Data,” submissions that are not submitted electronically and electronic submissions that are not in a format that FDA can process, review, and archive will not be filed or received, unless they have

¹ Under section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(a)), at least 24 months after the issuance of a final guidance document in which FDA has specified the electronic format for submitting certain submission types to the Agency, such content must be submitted electronically and in the format specified by FDA.

an exemption or waiver from the electronic submission requirements. The Agency can process, review, and archive electronic submissions of study data that use the standards specified in the Data Standards Catalog posted to FDA's Study Data Standards Resources web page (<https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>).

The technical rejection criteria are automated validations by the CDER or CBER inbound processing system using the specifications set forth in FDA's "Specifications for eCTD Validation Criteria" to determine compliance with the requirement to submit electronic standardized study data. The eCTD validations referenced in FDA's TRC will become effective on September 15, 2021. Starting September 15, 2021, FDA will reject submissions that contain any high validation errors included in the TRC. The latest version of the TRC is available on FDA's web page on Study Data for Submission to CDER and CBER (<https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber>).

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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