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; Specifications for the Electronic Common Technical Document Validation Criteria

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are announcing the date that FDA will begin rejecting submissions which fail Electronic Common Technical Document (eCTD) validations 1306 or 1323 that have been raised to high validation errors as described in the "Specifications for eCTD Validation Criteria."

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 to announce that eCTD validations 1306 and 1323, described in "Specifications for eCTD Validation Criteria," have been raised to high validation errors. Beginning March 1, 2022, FDA will reject submissions that fail either of these validations.

According to the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications," submissions subject to section 745A(a) of the Federal Food, Drug, and Cosmetic Act 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 Data Standards Catalog. eCTD submissions must follow FDA eCTD technical specification entitled "The Comprehensive Table of Contents Headings and Hierarchy." Documents which are not properly referenced in the eCTD backbone as described in the "M2 eCTD: Electronic Common Technical Document Specification" and "The eCTD Backbone Files Specification for Module 1," result in content that is not accessible within FDA eCTD technical specification "The Comprehensive Table of Contents Headings and Hierarchy." eCTD validations 1306 ("No leaf element for file") and 1323 ("No file for leaf element"), within the "Specifications for eCTD Validation Criteria," describe parts of the eCTD specifications which were not followed correctly. Rejection for failing to pass either eCTD validations 1306 or 1323 will begin on March 1, 2022.

Dated: August 18, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy

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