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 Electronic Common Technical Document Validation Criteria

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing the date that FDA will begin rejecting submissions that fail either Electronic Common Technical Document (eCTD) validation 1551 or 1553, which are high severity validation errors as described in the Specifications for eCTD Validation Criteria. Validation errors 1551 and 1553 have been added to the Specifications for eCTD Validation Criteria.

DATES: Rejection for failing to pass either eCTD validation 1551 or 1553 under a submission to CDER will begin on October 18, 2021.

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.

SUPPLEMENTARY INFORMATION: FDA's CDER is issuing this *Federal Register* notice to announce that eCTD validations 1551 and 1553 have been added to the Specifications for eCTD Validation Criteria (available at https://www.fda.gov/media/87056/download) as high validation errors. Beginning October 18, 2021, FDA will reject submissions that fail either of these validations.

Under section 745A(a) (21 U.S.C. 379k-1(a)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 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. According to the guidance for industry "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (available at https://www.fda.gov/media/135373/download), submissions subject to section 745A(a) of the FD&C 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 (available at https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources).

As described in the guidance for industry "Providing Regulatory Submissions in Electronic and Non-Electronic Format--Promotional Labeling and Advertising Materials for Human Prescription Drugs" (The Promotional Labeling Guidance) (available at https://www.fda.gov/media/128163/download), certain types of promotional-material-related submissions, including postmarketing submissions of promotional materials using Form FDA 2253 (required by § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i)) and 21 CFR 601.12(f)(4)) (called 2253 submissions), fall within the scope of section 745A(a) of the FD&C Act and are, therefore, subject to the mandatory electronic submission requirements (unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver). The Promotional Labeling Guidance provides that 2253 submissions are required to be accompanied by a completed fillable Form FDA 2253. When submitting Form FDA 2253, firms must submit the most current product labeling, as required in § 314.81(b)(3)(i), under eCTD section 1.14.6, as described in the Promotional Labeling Guidance. Electronic Common Technical Document validations 1551 ("2253 submission does not include Product Labeling") and 1553 ("The only valid FDA Form to include in a 2253 submission is FDA Form 2253") describe parts of the eCTD specifications that were not followed correctly (see the Specifications for eCTD

Validation Criteria, pp. 29 and 30, respectively). Submissions to CDER that are subject to section 745A(a) of the FD&C Act and fail to pass either eCTD validation 1551 or 1553 will begin being rejected on October 18, 2021.

Dated: August 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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