DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0092]

Electronic Study Data Submission; Data Standards; Availability of Validation Rules for Standard for Exchange of Nonclinical Data Formatted Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), is announcing the availability of the Validation Rules for Standard for Exchange of Nonclinical Data (SEND) Formatted Studies document. CDER is making this document available to improve the standardization and quality of nonclinical data that are submitted to CDER as well as to improve the predictability of data quality and usefulness.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1183, Silver Spring, MD 20993, email: edata@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On February 6, 2014, FDA issued a Federal Register notice (79 FR 7201) announcing the availability of a revised draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data". The revised draft guidance incorporates by reference a technical specifications document entitled "Study Data Technical Conformance Guide." On February 6, 2014, FDA issued a Federal Register notice (79 FR 7204) announcing the availability of the Guide and an update to the Data Standards Catalog. The Guide is available at http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pd

f. Section 8.2.3 of the Guide, "Support on Data Validation Rules," states that "[t]he Standards Web page provides links to the validation rules needed to ensure data compliance with CDISC standards, such as SDTM, SEND, ADaM, and define.xml." In this notice, we are announcing the availability of the SEND validation rules.

The Validation Rules for SEND Formatted Studies is an Excel file that provides human readable description of a rule set for validation (Nonclinical Validator Specifications (XLS)).Submitters of nonclinical study data can use this information to identify how FDA validates the data. It is available from the FDA Study Data Standards Resources Web page: http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm. The file contains a combination of conformance rules (i.e., how well the data conform to the standard) and business rules (i.e., quality checks; how well the data may support meaningful analysis). The file may be updated periodically as new or updated validation rules are developed. The Change History tab will provide a descriptive change history of the document.

The validation rules in the Nonclinical Validator Specifications document were created following the suggested human readable validation rule syntax published by a Computational Science Symposium workgroup. This document is available at: http://www.phusewiki.org/wiki/index.php?title=Guidelines_for_Validation_Rule_Developers.

Dated: May 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

4160-01-P

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