

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-17566 Filed 8-18-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2363]

Electronic Study Data Submission; Data Standards; Support for Standard for Exchange of Nonclinical Data Implementation Guide Version 3.1

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) is announcing support for the 3.1 version of Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data (SEND IG 3.1), the end of support for the 3.0 version of SEND IG, and an update to the FDA Data Standards Catalog (Catalog). (See <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>.) SEND IG 3.1 has been available from CDISC (www.cdisc.org) since July 2016. FDA is encouraging sponsors and applicants to use SEND IG 3.1 in investigational study data provided in regulatory submissions to CDER.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993-0002, 301-796-5333, email: CDERDataStandards@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" (eStudy Data), posted on FDA's Study Data Standards Resources Web page at <https://www.fda.gov/forindustry/datastandards/studydatastandards/>

[default.htm](https://www.fda.gov/forindustry/datastandards/default.htm). The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Food, Drug and Cosmetic Act (21 U.S.C. 379k-1(a)) for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to FDA's Center for Biologics Evaluation and Research or CDER by specifying the format for electronic submissions. The initial timetable for implementing electronic submission requirements for study data was December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

The transition date for support of version 3.1 of CDISC SEND IG is March 15, 2018. Although SEND IG version 3.1 is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the new version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.

The transition date for the end of FDA support for SEND IG 3.0 is March 15, 2018. Therefore, FDA support for SEND IG 3.0 will end for studies that start after March 15, 2019. The Catalog will be updated to list March 15, 2019, as the "date support ends."

II. Electronic Access

Persons with access to the Internet may obtain the referenced material at <https://www.fda.gov/ectd>.

Dated: August 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-1956]

Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Identifying Trading Partners Under the Drug Supply Chain Security Act" (draft trading partner guidance). FDA is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA). This guidance explains how to determine when certain statutory requirements will apply to entities that may be considered trading partners in the drug supply chain. FDA is also soliciting public input specific to the activities of "private-label distributors" of drug products and whether those activities fall within the definitions under DSCSA of the various trading partners.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 20, 2017.

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").