4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6879]

Electronic Study Data Submission; Data Standards; Timetable for Updates to the Food and Drug Administration Data Standards Catalog for Study Data Submitted Electronically Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the timetable for updates to the FDA Data Standards Catalog for study data submitted electronically in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and certain investigational new drug applications (INDs) to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). The initial implementation timetable for submitting standardized study data in electronic format was 24 months for NDAs, ANDAs, and applications, and 36 months for certain INDs after publication of the final guidance "Providing Regulatory Submissions in Electronic Format--Standardized Study" in December 2014. When future updates to study data standards listed in the FDA Data Standards Catalog (Catalog) occur, these updated standards will be required in studies with a start date no earlier than 12 months after a *Federal Register* notice announcing such updates is published. When future new study data standards are listed in the Catalog, these new standards will be required in studies with a start date no earlier than 24 months after a *Federal Register* notice announcing such new standards is published.

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").

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-2017-N-6879 for "Electronic Study Data Submission; Data Standards; Timetable for Updates to the FDA Data Standards Catalog for Electronic Submissions of Study Data." 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.

- 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.gpo.gov/fdsys/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.

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, cderdatastandards@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, 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: On December 17, 2014, FDA published final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data" posted on FDA's Study Data Standards Resources webpage at https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm. The guidance implemented the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1) for study data contained in NDAs, ANDAs, applications under subsection (a) or (k) of section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), and certain INDs. The initial implementation date for the electronic submission requirement for standardized study data was 24 months after final guidance for

NDAs, ANDAs, and applications under subsection (a) or (k) of section 351 of the PHS Act (December 17, 2016) and 36 months after final guidance for INDs (December 17, 2017). To provide a consistent timetable for announcing FDA's support and requirement for future version updates and new study data standards, the guidance states that a *Federal Register* notice will specify a transition date with a specific month and day for the transition date. When a *Federal Register* notice is published after March 15 of the current calendar year, the transition date will be March 15 of the next calendar year.

When future version updates to supported study data standards and new study data standards are announced in the *Federal Register*, they will be required in studies that have a start date no earlier than 12 months after the transition date for version updates and no earlier than 24 months after the transition date for new study data standards. Table 1 presents an example of timetables for the requirement to use future version updates and new study data standards after publication of *Federal Register* notices. In the example, a new study data transport format standard and a version update to the Study Data Tabulation Model Implementation Guide (SDTMIG) each have a single date listed when the standard will be required. The new study data transport format is supported as of the date of the *Federal Register* notice, but will only be required in studies that start 24 months after the transition date of March 15, 2019. The SDTMIG version update is supported as of the date of the *Federal Register* notice, but will only be required in studies that start 12 months after the transition date of March 15, 2019.

Table 1.--Example of Timetables for Required Study Data Standards

FDA Data Standards Catalog	Federal Register Notice of FDA Support (yyyy-mm-dd)	Transition Date (yyyy-mm-dd)	Date Requirement Begins (yyyy-mm-dd)
New Study Data Transport	2019-02-20	2019-03-15	2021-03-15

SDTMIG Version Update	2018-09-05	2019-03-15	2020-03-15

Dated: January 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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