4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1349]

Extension of the Timetable Requirement to Submit Study Data in Logical Observation Identifiers Names and Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the extension of the deadline to provide Logical Observation Identifiers Names and Codes (LOINC) for clinical laboratory test results in investigational study data provided in regulatory submissions submitted to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. FDA has determined, in response to industry comments and internal review, that it is appropriate to extend the date required to submit LOINC codes in new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs), and for certain investigational new drugs (INDs). LOINC codes will be required in NDAs, ANDAs, and BLAs for studies that start after March 15, 2020 (March 15, 2021, for certain INDs).

ADDRESSES: You may submit either electronic or written comments at any time 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-2015-N-1349 for "Extension of the Timetable Requirement to Submit Study Data in Logical Observation Identifiers Names and Codes." 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. 7268, Silver Spring, MD 20993-0002, 240-402-7911, stephen.ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On May 14, 2015, FDA announced in the *Federal Register* (80 FR 27690) its adoption of LOINC for lab test results. FDA supports LOINC-coded laboratory test results because: (1) LOINC is widely used among clinical laboratories; (2) LOINC-coded lab data make the information easier to understand and analyze; and (3) the currently supported exchange standard for laboratory test results in clinical trials, the Study Data Tabulation Model (available at http://www.cdisc.org/sdtm), already supports the exchange of LOINC codes (available at https://loinc.org/). FDA's decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives. The FDA Data Standards Catalog was updated to indicate FDA support for LOINC and a requirement date of March 15, 2018, for NDAs, ANDAs, and BLAs, and March 15, 2019, for certain INDs (see https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm). FDA has determined, in response to industry comments and internal review, that it is appropriate to extend the date required to submit LOINC codes. LOINC codes will be required in NDAs, ANDAs, and BLAs for studies that start after March 15, 2020 (March 15, 2021, for certain INDs). Although use of LOINC codes are not required at this time, FDA continues to support and encourages the use of LOINC codes for clinical laboratory test results used in investigational study data.

Dated: October 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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