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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's Web site at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on July 14, 2017 (82 FR 32556). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Azelastine hydrochloride.
Azithromycin.
Barium sulfate.
Betamethasone dipropionate.
Budesonide.
Canagliflozin; Metformin hydrochloride.
Dantrolene sodium.
Dapsone.
Deflazacort (multiple Reference Listed Drugs).
Docosanol.
Empagliflozin; Metformin hydrochloride.
Epinephrine.
Erythromycin.
Everolimus.
Fluorometholone.
Hydrocortisone acetate.
Ivermectin.
Levorphanol tartrate.
Lisdexamfetamine dimesylate.
Mometasone furoate.
Nitisinone.
Olaparib.
Osimertinib mesylate.
Permethrin.
Pirfenidone.
Telotristat etiprate.
Terbutaline sulfate.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Brimonidine tartrate (multiple Reference Listed Drugs).
Bromfenac sodium.
Ciprofloxacin hydrochloride.
Cobicistat; Elvitegravir; Emtricitabine; Tenofovir alafenamide fumarate.
Dapsone.
Diclofenac sodium.
Emtricitabine; Rilpivirine hydrochloride; Tenofovir alafenamide fumarate.
Emtricitabine; Tenofovir alafenamide fumarate.
Esomeprazole magnesium.
Lisdexamfetamine dimesylate.
Mesalamine.
Mycophenolate mofetil.
Ofloxacin.
Olopatadine hydrochloride (multiple Reference Listed Drugs).
Ropinirole hydrochloride.
Sucralfate.
Tadalafil.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidances at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 16, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22736 Filed 10–19–17; 8:45 am]

BILLING CODE 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.

[FR Doc. 2017–22768 Filed 10–19–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6133]

Application of the ''Solely Engaged'' Exemptions in Parts 117 and 507; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.