

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](mailto: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](mailto: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]

**BILLING CODE 4164-01-P**

## **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.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled “Application of the “Solely Engaged” Exemptions in Parts 117 and 507; Draft Guidance for Industry.” The draft guidance, when finalized, will help establishments and facilities subject to certain FDA regulations determine whether they are “solely engaged” in certain activities. Establishments and facilities “solely engaged” in certain activities are exempt from some or all requirements of the regulations.

**DATES:** Submit either electronic or written comments on the draft guidance by April 18, 2018, to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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-2017-D-6133 for “Application of the “Solely Engaged” Exemptions in Parts 117 and 507; Guidance for Industry.” 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 office 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.

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 guidance to the Office of Food Safety (HFS-300), Center for

Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** *For questions relating to the guidance as it applies to human food:* Jenny Scott, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166. *For questions relating to the guidance as it applies to animal food:* Jeanette Murphy, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a draft guidance for industry entitled “Application of the “Solely Engaged” Exemptions in Parts 117 and 507.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

This guidance concerns two regulations that we have established in Title 21 of the Code of Federal Regulations as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). These two regulations are part 117 (published in the **Federal Register** on September 17, 2015, 80 FR 55908 and part 507 (published in the **Federal Register** on September 17, 2015, 80 FR 56170). This guidance is intended to help establishments and facilities subject to part 117 or part 507 determine whether they are “solely engaged” in certain activities. Establishments and facilities “solely engaged” in certain activities are exempt from some or all requirements in parts 117 or 507.

Parts 117 and 507 contain exemptions specific to establishments and facilities “solely engaged” in certain activities. The relevant exemptions can be categorized as follows: (1) Exemption from human food current good manufacturing practice (CGMP) requirements, (2) exemption from human food preventive controls

requirements, (3) exemption from animal food CGMP requirements, and (4) exemption from animal food preventive controls requirements.

This draft guidance, when finalized, will clarify that if all of the activities performed by an establishment are exempt under one or more CGMP exemptions, then the establishment is not subject to the part 117 and/or part 507 CGMPs, as applicable. If all the activities performed by a facility are exempt under one or more preventive controls exemptions, then the facility is not subject to the part 117 and/or part 507 preventive controls requirements, as applicable. If all the activities performed by a facility are exempt under one or more CGMP exemptions and one or more preventive controls exemptions, then the facility is not subject to the CGMP or preventive controls requirements in part 117 and/or part 507, as applicable.

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153033.htm> (whichever is applicable) or <https://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: October 16, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017-22731 Filed 10-19-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Program Project: Cell Biology.

*Date:* November 9, 2017.

*Time:* 11:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301-435-1022, [balasundaram@csr.nih.gov](mailto:balasundaram@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Radiation Therapy and Biology.

*Date:* November 14-15, 2017.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301-996-6208, [hongb@csr.nih.gov](mailto:hongb@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; National Swine Resource and Research center review.

*Date:* November 14, 2017.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301-435-0912, [Katherine\\_Malinda@csr.nih.gov](mailto:Katherine_Malinda@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Disease Prevention and Management, Risk Reduction and Health Behavior Change.

*Date:* November 16-17, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Monaco, 2 North Charles Street, Baltimore, MD 21201.

*Contact Person:* Michael John McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, Bethesda, MD 20892, 301-480-1276, [mike.mcquestion@nih.gov](mailto:mike.mcquestion@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Aging and Development, Auditory, Vision and Low Vision Technologies.

*Date:* November 16-17, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Darcy Washington DC, 1515 Rhode Island Ave. NW., Washington, DC 20005.

*Contact Person:* Paek-Gyu Lee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4201, MSC 7812, Bethesda, MD 20892, (301) 613-2064, [leepg@csr.nih.gov](mailto:leepg@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Biotherapeutics Development.

*Date:* November 16-17, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn San Antonio Riverwalk, 217 N St. Mary's, San Antonio, TX 78205.

*Contact Person:* Nicholas J. Donato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040, Bethesda, MD 20817, 301-827-4810, [nick.donato@nih.gov](mailto:nick.donato@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Drug Development and Therapeutics.

*Date:* November 16-17, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn San Antonio Riverwalk, 217 North St. Mary's, San Antonio, TX 78205.

*Contact Person:* Lilia Topol, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301-451-0131, [ltopol@mail.nih.gov](mailto:ltopol@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Medical Imaging.

*Date:* November 16-17, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Alexandria Mark Center, 5000 Seminary Road, Alexandria, VA 22311.

*Contact Person:* Leonid V. Tsap, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7854, Bethesda, MD 20892, (301) 435-2507, [tsapl@csr.nih.gov](mailto:tsapl@csr.nih.gov).

*Name of Committee:* AIDS and Related Research Integrated Review Group; AIDS Discovery and Development of Therapeutics Study Section.

*Date:* November 16, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

*Contact Person:* Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301-443-5779, [prasads@csr.nih.gov](mailto:prasads@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small