

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2014-N-0179]

**Training Program for Regulatory Project Managers; Information Available to Industry****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

**DATES:** Pharmaceutical companies may submit proposed agendas to the Agency by April 11, 2016.

**FOR FURTHER INFORMATION CONTACT:** Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993-0002, 301-796-0578, [dan.brum@fda.hhs.gov](mailto:dan.brum@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide firsthand exposure to industry's drug development processes, and a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

**II. The Site Tours Program**

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a

senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

**III. Site Selection**

All travel expenses associated with the Site Tours Program will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms interested in offering a site tour or learning more about this training opportunity should respond by submitting a proposed agenda to Dan Brum directly (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: February 3, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2010-D-0395]

**Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays; Guidance for Industry and Food and Drug Administration Staff; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays." This guidance document discusses information to be included in premarket notifications for zonisamide or lamotrigine assays.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2010-D-0395 for “Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays; Guidance for Industry and Food and Drug Administration Staff; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://>

[www.regulations.gov](http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:**

Courtney Lias, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 4626, Silver Spring, MD 20993-0002, 301-796-5458.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is issuing this guidance document to describe its current thinking concerning issues that should be addressed in premarket notifications for assays intended to quantitate the anti-seizure drugs lamotrigine and zonisamide in serum. Some of the general concepts in this guidance may also be helpful in preparing 510(k) submissions for other therapeutic drug assays previously cleared by FDA, and classified within 21 CFR 862, subpart D. The draft guidance was available for comment on August 6, 2010. The comment period closed on November 4, 2010. No comments relating to the specific recommendation in the guidance were received. Minor revisions to the guidance have been made for clarifications and updates.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on Premarket Notifications for Lamotrigine and Zonisamide Assays. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the

requirements of the applicable statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of “Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays,” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1654 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control No. 0910-0120). The labeling provisions addressed in the guidance have been approved by OMB Control No. 0910-0485.

**V. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 4, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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