

products. Applicants must include in the application's Background and Significance section documentation to support the estimated prevalence of the orphan disease or condition (or in the case of a vaccine or diagnostic, information to support the estimates of how many people will be administered the diagnostic or vaccine annually) and an explanation of how the proposed study will either help support product approval or provide essential data needed for product development.

### C. Eligibility Information

The grants are available to any foreign or domestic, public or private, for-profit or nonprofit entity (including State and local units of government). Federal agencies that are not part of the Department of Health and Human Services (HHS) may apply. Agencies that are part of HHS may not apply. For-profit entities must commit to excluding fees or profit in their request for support to receive grant awards. Organizations that engage in lobbying activities, as described in section 501(c)(4) of the Internal Revenue Code of 1968, are not eligible to receive grant awards.

## II. Award Information/Funds Available

### A. Award Amount

Of the estimated fiscal year (FY) 2012 funding (\$14.1 million), approximately \$10 million will fund noncompeting continuation awards, and approximately \$4.1 million will fund 5 to 10 new awards, subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2013 will be similar to FY 2012. Phase 1 studies are eligible for grants of up to \$200,000 per year for up to 3 years. Phase 2 and 3 studies are eligible for grants of up to \$400,000 per year for up to 4 years. Please note that the dollar limitation will apply to total costs (direct plus indirect). Budgets for each year of requested support may not exceed the \$200,000 or \$400,000 total cost limit, whichever is applicable.

### B. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of more than 1 year, a second, third, or fourth year of noncompetitive continuation of support will depend on the following factors: (1) Performance during the preceding year; (2) compliance with regulatory requirements of IND/investigational device exemption (IDE); and (3) availability of Federal funds.

## III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at <http://grants.nih.gov/grants/guide>. For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Obtain Username and Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: July 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-19354 Filed 8-5-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

### Draft Guidance for Industry and Food and Drug Administration Staff; Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance for Industry and FDA Staff; Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays." This draft guidance document discusses information to be included in premarket notifications for lamotrigine or zonisamide assays. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR

10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 4, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Avis Danishefsky, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5620, Silver Spring, MD 20993-0002, 301-796-6142.

### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is issuing this draft 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. The Therapeutic Drug Monitoring (TDM) Roundtable of the American Association of Clinical Chemists (AACC) submitted to FDA recommendations for lamotrigine assays. Many of the recommendations in this draft guidance document are consistent with the AACC TDM Roundtable recommendations. 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 part 862, subpart D.

#### II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on therapeutic drug assays that measure lamotrigine or zonisamide. 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 draft guidance may do so by using the Internet. To receive "Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1654 to identify the guidance you are requesting. A search capability for all CDHR guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

### IV. Paperwork Reduction Act of 1995

This draft 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 in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910-0485.

### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: August 2, 2010.

**Nancy Stade,**

*Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.*

[FR Doc. 2010-19419 Filed 8-5-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0495]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices; Neurological and Physical Medicine Device Guidance Document; Reopening of Comment Period; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 28, 2010 (75 FR 44267). The document reopened the comment period for a notice of availability of draft guidance documents for 11 neurological and physical medicine devices. The document was published with an inadvertent error. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993, 301-796-9148.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2010-18406, appearing on page 44267, in the **Federal Register** of Wednesday, July 28, 2010, the following correction is made:

1. On page 44267, in the first column, the heading "[Docket No. FDA-2009-N-0495]" is corrected to read "[Docket No. FDA-2009-D-0495]".

Dated: July 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2003-D-0243] (formerly 2003D-0571)

#### **Guidance for Industry on Drug Substance Chemistry, Manufacturing, and Controls Information; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #169 entitled "Drug Substance Chemistry, Manufacturing, and Controls Information." This guidance provides recommendations on the chemistry, manufacturing, and controls (CMC) information for drug substances that should be submitted to support original new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs). The guidance is structured to facilitate the preparation of applications submitted in Common Technical Document (CTD) format.

**DATES:** Submit either electronic or written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Alem Ghiorghis, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8266, email: [alem.ghiorghis@fda.hhs.gov](mailto:alem.ghiorghis@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of June 1, 2006 (71 FR 31194), FDA published the notice of withdrawal and revision of seven guidances. CVM made Level II revisions to draft guidance entitled "Drug Substance Chemistry, Manufacturing, and Controls