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. 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.

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 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 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.
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 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.

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...