simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g. name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available. The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour (52 x 900) totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (e.g. paper). The costs have been updated based on the Bureau of Labor Statistics estimates of inflation.

In the **Federal Register** of May 4, 2010 (75 FR 23781), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

42 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours	Total Operating & Maintenance Costs
42 CFR 493.17	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

Dated: August 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19358 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–N–0394]

Clinical Studies of Safety and Effectiveness of Orphan Products Research Project Grant (R01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of FDA's Office of Orphan Products Development (OPD) grant program. The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these 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.

DATES: Important dates are as follows:

1. The application due dates are February 2, 2011; February 1, 2012. The resubmission due dates are October 14, 2011; October 15, 2012.
2. The anticipated start dates are November 2010; November 2012.
3. The opening date is December 2, 2010.
4. The expiration date is February 2, 2012; October 16, 2012 (resubmission).

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Katherine Needleman, Orphan Products Grants Program, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993–0002, 301–796–8660, e-mail: *katherine.needleman@fda.hhs.gov.*

Vieda Hubbard, Division of Acquisition Support and Grants, Office of Acquisitions & Grant Services, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7177, e-mail: *vieda.hubbard@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://grants.nih.gov/grants/guide* (select the "Request for Applications" link), *http://www.grants.gov* (see "For Applicants" section), and *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/WhomtoContactaboutOrphanProductDevelopment/ucm134580.htm.*[1]

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–11–001
93.103

A. Background

The OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and medical foods that are indicated for a rare disease or condition (that is, one with prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostics and vaccines will qualify for orphan status only if the U.S. population to whom they will be administered is fewer than 200,000 people per year.

B. Research Objectives

The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these

[1] FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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.

[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