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

<table>
<thead>
<tr>
<th>42 CFR Section</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Responses</th>
<th>Total Hours</th>
<th>Total Operating &amp; Maintenance Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 CFR 493.17</td>
<td>60</td>
<td>15</td>
<td>900</td>
<td>1</td>
<td>900</td>
<td>$46,800</td>
</tr>
</tbody>
</table>

1 There are no capital costs associated with this collection of information.
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://appsobilize.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at https://commons.era.nih.gov/commons/registrationRegistrationInstructions.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 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 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. 3620, Silver Spring, MD 20993–0002, 301–750–6142.

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