for this collection. The commenter also provided comments that were not PRA-related and are beyond the scope of this document.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th></th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response (in hours)</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Meeting Requests</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combining and sending meeting request letters for manufacturers, importers, and researchers</td>
<td>67</td>
<td>1</td>
<td>67</td>
<td>10</td>
<td>670</td>
</tr>
<tr>
<td><strong>Meeting Information Packages</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combining and submitting meeting information packages for manufacturers, importers, and researchers</td>
<td>67</td>
<td>1</td>
<td>67</td>
<td>18</td>
<td>1,206</td>
</tr>
<tr>
<td><strong>Collection Totals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA’s estimate of the number of respondents for meeting requests in table 1 of this document is based on the number of meeting requests to be received over the next three years. In year 1 of this collection, FDA estimates that 50 preapplication meetings will be requested. In year 2, FDA estimates that 100 meetings will be requested, especially as applications and reports for substantial equivalence, etc., are received and acted upon. Once the public knows more about submitting these applications in year 3 three, the request for meetings is expected to drop back to the year 1 one rate of 50 per year. Thus, FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting requests in table 1 of this document to be 67 (50 year 1 requests + 100 year 2 requests + 50 year 3 requests divided by 3). The hours per response, which is the estimated number of hours that a respondent would spend preparing the information recommended by the guidance to be submitted with a meeting request, is estimated to be approximately 10 hours each, and the total burden hours are 670 hours (10 hours preparation/mailing times 67 average respondents per year). Based on FDA’s experience, the Agency expects it will take respondents 1,206 hours of time (67 respondents times 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development. The total number of burden hours for this collection of information is 1,876 hours (670 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).


Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2012–30057 Filed 12–12–12; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2012–D–1161]

Draft Guidance for Industry and Food and Drug Administration Staff; Design Considerations for Devices Intended for Home Use; 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 “Design Considerations for Devices Intended for Home Use.” This document is intended to assist manufacturers in designing and developing home use medical devices that comply with applicable standards of safety and effectiveness and other regulatory requirements. Home use devices are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This document identifies several factors that manufacturers should consider, especially during device design and development, and provides recommendations for reducing or minimizing these unique risks. 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 March 13, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Design Considerations for Devices Intended for Home Use” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for
The draft guidance, when finalized, will satisfy 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. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov or from CBER at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. To receive “Design Considerations for Devices Intended for Home Use” from CDRH, you may either send an email request to 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 1750 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 801 and 21 CFR part 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0420; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in Form FDA 3500A have been approved under OMB control number 0910–0291.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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: December 5, 2012.
Leslie Kux, Assistant Commissioner for Policy.

[FR Doc. 2012–30033 Filed 12–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1005]

Draft Guidance for Industry on Safety Considerations for Product Design To Minimize Medication Errors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Safety Considerations for Product Design to Minimize Medication Errors.” The draft guidance provides sponsors of investigational new drug applications, new drug applications, abbreviated new drug applications, biologics licensing applications, abbreviated new drug applications, and nonprescription drugs marketed without an approved application (e.g., monograph) with a set of principles for developing drug products using a systems approach to minimize medication errors relating to product design. The draft guidance includes recommendations intended to improve the drug product and container closure design at the earliest stages of product development for all prescription and nonprescription drug products.