The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions for exemption from preemption; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions for exemption from preemption in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A) of the FD&C Act.

Dated: June 6, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 15, 2010 (75 FR 78249) the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0679. The approval expires on April 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: June 1, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2009–D–0008]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions for exemption from preemption; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions for exemption from preemption in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A) of the FD&C Act.

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SUPPLEMENTARY INFORMATION: In the Federal Register of December 15, 2010 (75 FR 78249) the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0679. The approval expires on April 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: June 1, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2011–N–0401]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Communications Usability Testing, as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a generic clearance to collect information that will provide tools to test the usability of FDA communications on specific topics and to assist in the development and modification of communication messages to promote public health and compliance with regulations.

DATES: Submit either electronic or written comments on the collection of information by August 9, 2011.

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All
There will be two lengths of surveys conducted, depending on whether the survey is in person or remote and online. An in-person survey will last an average of 60 minutes and take place at an FDA computer or at a nongovernmental location; a remote survey will last approximately 30 minutes and take place at the participant’s computer. These estimates were determined through analysis of times from previous usability surveys using similar questions, survey of usability professionals to ascertain average times for users to perform tasks, and a pilot survey of 10 internal users comprised of staff from the Centers for Disease Control and Prevention (CDC) and CDC contractors. Some remote surveys will take much less time. The majority of usability surveys conducted at CDC were done remotely; thus FDA estimates that in the future more surveys will be done remotely rather than in person.

Estimate of survey respondents was based on an estimate of the ideal number of usability surveys that FDA would conduct over a 3-year period. Factored in were initial surveys and subsequent followup surveys utilizing a satisfactory level of participants.

Because FDA has not conducted these types of surveys at the level needed previously, it is anticipated that most of FDA’s communications will require some sort of usability survey. Additionally, FDA anticipates conducting a number of important baseline surveys for its home Web page and other highly trafficked subsites in order to redesign these pages as part of FDA’s priority to more effectively utilize its Web site.

Annually, FDA projects about 125 usability surveys as a baseline for messages about FDA-regulated products for consumers, patients, industry representatives, or health care professionals. The data will not be used for the purposes of making policy or regulatory decisions.

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

<table>
<thead>
<tr>
<th>Survey type</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>In-Person Surveys</td>
<td>7,500</td>
<td>1</td>
<td>7,500</td>
<td>1</td>
<td>7,500</td>
</tr>
<tr>
<td>Remote Online Surveys</td>
<td>67,000</td>
<td>1</td>
<td>67,000</td>
<td>30/60</td>
<td>33,500</td>
</tr>
<tr>
<td>Screener Only</td>
<td>500</td>
<td>1</td>
<td>500</td>
<td>5/60</td>
<td>42</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>41,0412</td>
</tr>
</tbody>
</table>

1 These participants take the screener (which will be comprised of Demographic and/or Introductory Question, Attachments 5 and 6) but are not selected for the full survey.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Institutional Review Boards” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, Elizabet.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 15, 2010 (75 FR 78252), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0130. The approval expires on April 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: June 1, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14410 Filed 6–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FR Doc. 2011–14409 Filed 6–9–11; 8:45 am]

ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE; NOTICE OF MEETING

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 19, 2011, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel’s telephone number is 301–589–5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20903–0002, 301–796–9001, FAX 301–847–8533, e-mail: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–546–8871 and 1–888–346–1350.

Interested persons may submit to the person listed above, before the meeting, written data, information, and views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 5, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 24, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 27, 2011.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm. Scroll down to the appropriate advisory committee link.

Food and Drug Administration

[FR Doc. 2011–14409 Filed 6–9–11; 8:45 am]

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