

of automated collection techniques, when appropriate, and other forms of information technology.

State Petitions for Exemption From Preemption—21 CFR 100.1(d) (OMB Control Number 0910-0277)—Extension

Under Section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the

FD&C Act) (21 U.S.C. 343-1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under section 100.1(d) enables FDA to

determine whether the State food labeling or standard of identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.1(d)	1	1	1	40	40

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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.
[FR Doc. 2011-14412 Filed 6-9-11; 8:45 am]
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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.

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,
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.
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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

comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, Juanmanuel.vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance

of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Data To Support Communications Usability Testing, as Used by the Food and Drug Administration—(OMB Control Number 0910-NEW)

FDA plans to use the data collected under this generic clearance to inform its communications campaigns on a variety of topics related to products that the FDA regulates. FDA expects the data to help staff message developers achieve FDA communication objectives. FDA also plans to use the data to help tailor print, broadcast, and electronic media communications in order for them to have powerful and desired impacts on target audiences. The data will not be used for the purposes of making policy or regulatory decisions.

The information collected will serve two major purposes. First, as formative research it will provide the critical knowledge needed about target

audiences. FDA must explore audiences' beliefs, perceptions, and decision-making processes on specific topics in order to meet the basic objectives of its risk communication campaigns. Such knowledge will provide the needed target audience understanding to design effective communication strategies, messages, and product labels. These communications will aim to improve public understanding of the risks and benefits of using various FDA-regulated products by providing users with a better context in which to place risk information more completely.

Second, as pretesting, it will give FDA some information about the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents may be asked to give their reaction to the messages in person or online.

FDA's Centers and Offices will use this mechanism to test the usability of 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 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
In-Person Surveys	7,500	1	7,500	1	7,500
Remote Online Surveys	67,000	1	67,000	30/60	33,500
Screener Only ¹	500	1	500	5/60	42
Total					41,042

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.

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 studies using the variety of test methods listed above. FDA is requesting this burden so as not to restrict the Agency's

ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: June 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0418]

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, Elizabeth.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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

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 20993-0002, 301-796-9001, FAX 301-847-8533, *e-mail:* EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 19, 2011, the committee will discuss new drug application (NDA) 202293 dapagliflozin, manufactured by Bristol-Myers Squibb and AstraZeneca. Dapagliflozin is the first drug in the class of sodium-glucose co-transporter 2 (SGLT2) inhibitors, developed as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

FDA intends to make background material available to the public no later

than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or 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 a 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> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).