

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden
Title Amendments .....	18	1	3	54
State TANF plan .....	18	1	30	540

Estimated Total Annual Burden Hours: 594.

#### Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

#### OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget,  
Paperwork Reduction Project. Fax: 202-395-7285. E-mail:  
[OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV).  
Attn: Desk Officer for the  
Administration for Children and  
Families.

Robert Sargis,

Reports Clearance Officer.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2011-N-0591]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 21, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title: "Data to Support Communications Usability Testing, as Used by the Food and Drug Administration." Also include the FDA 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](mailto:Juanmanuel.vilela@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### 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 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 decisionmaking 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 on-line.

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.

In the **Federal Register** of June 10, 2011 (76 FR 34083), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

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 <sup>2</sup> .....	500	1	500	5/60	42
Total .....					41,042

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

<sup>2</sup> These participants take the screener (which will be comprised of *Demographic* and/or *Introductory Questions*, 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, a 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 previously. 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: August 17, 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-0553]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form

**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 the collection of information contained in FDA's Tobacco Product Reporting Violation Form.

**DATES:** Submit either electronic or written comments on the collection of information by October 21, 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:

Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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.