

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.

**Tobacco Product Reporting Violation Form (OMB Control Number 0910-NEW)**

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321 *et seq.*) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

FDA is requesting OMB approval for a new collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

As part of its enforcement strategy, FDA created a Tobacco Call Center (with a toll-free number: 1-877-CTP-1373) to accept information from the public about violations of the Tobacco

Control Act. Callers are able to report potential violations of the Tobacco Control Act and FDA will conduct targeted followup investigation based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation happened, the product type (*e.g.*, cigarette, smokeless, roll-your-own, *etc.*), tobacco brand, type of potentially violative promotional materials, potential violation type, who potentially violated, and the name, address, phone number, and e-mail address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation. FDA has developed a form that will be used to solicit this information from the caller (FDA Form 3779, Tobacco Product Violations Reporting), which is expected to

eventually replace current form FDA Form 3734 for Cigarette Flavor Ban Violations. This new form will be posted on FDA's Web site, and information may be submitted by filling out the form online (or the public can request a copy of Form 3779 by contacting the Center for Tobacco Products (CTP)). In addition, FDA has developed a smartphone application for use with iPhones, Android, *etc.* to allow consumers to report potential violations to FDA via their smartphone. Others may simply choose to send a letter to FDA with their information. In summary, the public will be able to report information regarding possible violations of the Tobacco Control Act through the following methods: calling the Tobacco Call Center using CTP's toll-free number; using a fill-able form found on FDA's Web site; using FDA's tobacco violation reporting smartphone application, and sending a letter to FDA's Center for Tobacco Products.

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

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Activity and FDA Form 3779	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act by telephone, Internet form, smartphone application, or mail .....	1,000	1	1,000	0.167	167

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

FDA estimates that submitting the information (by phone, Internet form, smartphone application, or mail) will take 10 minutes. Since a similar type of reporting went into effect for the cigarette flavor ban, FDA has received several reports via the Internet or e-mail. Judging from the rate of reporting for the cigarette flavor ban, FDA estimates the number of respondents will be 1,000 who will submit 1 report each annually by phone, Internet form, smartphone application, or mail. Because of the variety of products regulated by FDA under the authority of the FD&C Act, as amended by the Tobacco Control Act, FDA expects the rate of calls and reports received to remain steady over the next 3 years.

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-0002]

**Arthritis Advisory Committee; Notice of Postponement of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the Arthritis Advisory Committee meeting scheduled for September 13, 2011. This meeting was announced in the **Federal Register** of July 19, 2011 (76 FR 42715). The postponement is due to the fact that the Agency recently received submissions from some of the investigational new drug (IND) application holders for anti-nerve growth factor (Anti-NGF) antibody drug products that contain large quantities of new information that will require additional time for Agency review prior to the advisory committee meeting.

**FOR FURTHER INFORMATION CONTACT:**

Philip A. Bautista, 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 301-827-8533, *e-mail:* AAC@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.

Dated: August 17, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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