TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total	.....	.....	.....	.....	240

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

Dated: November 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29327 Filed 12–4–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2012–N–0273]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Review; Experimental Study of Graphic Cigarette Warning Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a reinstatement 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 (the PRA).

DATES: Fax written comments on the collection of information by January 4, 2013.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0668. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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.

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

The purpose of this submission is to request OMB approval to conduct Web-based surveys to evaluate the relative effectiveness of various graphic health warnings on cigarette packs, which will inform the Agency's efforts to implement the mandatory graphic warnings required by the Tobacco Control Act.

Experimental Study of Graphic Cigarette Warning Labels (OMB Control Number 0910–0668—Reinstatement)

The current approval for this information collection expired October 31, 2012. FDA seeks to reinstate the collection and to reflect that there is no change in the reporting burden. At this time, the Agency is not collecting the information, but awaits OMB review and approval, and therefore believes that we are not in violation of the PRA.

Tobacco products are responsible for more than 400,000 deaths each year. The Centers for Disease Control and Prevention report that approximately 46 million U.S. adults smoke cigarettes in the United States, even though this behavior will result in death or disability for half of all regular users. Paralleling this enormous health burden is the economic burden of tobacco use, which is estimated to total $193 billion annually in medical expenditures and lost productivity. Curbing the significant adverse consequences of tobacco use is one of the most important public health goals of our time.

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act, which amends section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), requires FDA to issue ''regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1).'' The study proposed here is an effort by FDA to collect data concerning graphic warnings on cigarette packages and their impact on consumer perceptions, attitudes, and behavior with respect to smoking.

On June 22, 2011, FDA issued a final rule in the **Federal Register** of June 22, 2011 (76 FR 36628), entitled ''Required Warnings for Cigarette Packages and Advertisements,'' which specified nine graphic images to accompany the new textual warnings for cigarettes. Although the rule was scheduled to become effective 15 months after it issued, a panel of the U.S. Court of Appeals of the District of Columbia held, on August 24, 2012, that the rule in its current form violates the First Amendment. FDA expects that the information that FDA proposes to collect will be relevant to FDA's regulation of cigarette warnings no matter the final outcome of the current litigation.

This study, the Experimental Study of Graphic Cigarette Warning Labels, is a voluntary annual experimental survey of consumers. The purpose of the study is to assess the effectiveness of various graphic warnings on cigarette packs for achieving three communication goals: (1) Conveying information about various health risks of smoking; (2) encouraging cessation of smoking among current smokers; and (3) discouraging initiation of smoking among youth and former smokers. The study will collect data from various groups of consumers, including current smokers aged 13 years and older, former smokers aged 13 years and older, and non-smokers aged between 13 and 25 years who may be susceptible to initiation of smoking. The study goals are to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to graphic warning labels; (2) determine whether consumer responses to graphic warning labels differ across various groups based on smoking status, age, or other demographic variables; and (3) evaluate the relative effectiveness of various graphic images associated with each of the nine warning statements specified in

the Tobacco Control Act for achieving each of the communication goals. The information collected from the study will help inform the Agency's efforts to implement the mandatory graphic health warnings required by the Tobacco Control Act.

The experimental study data will be collected from participants of an Internet panel of approximately 43,000 people. Participation in the experimental study is voluntary.

In the **Federal Register** of March 27, 2012 (77 FR 18250), FDA published a 60-day notice requesting public comment on its proposed collection of information. FDA received eight comments that were not PRA-related and that were outside the scope of this collection of information. FDA also received a comment that asked FDA to provide more detail about the design of the proposed consumer research study to allow for meaningful public comments. The commenter also encouraged FDA to provide additional information for public comment, including details of the protocol, screen, questionnaire, and actual graphic warnings images to be used with study participants to enhance the quality, utility, and clarity of the information to be collected and further the goals of the PRA to ensure the greatest possible public benefit from and maximize the utility of the information. FDA notes in response to this comment that the study and copies of the instruments used to collect this information are described in detail as part of the overall package submitted to OMB for review. The study and copies of the instrument were made available to the public during the original information collection period. They will also be available to the public at *www.reginfo.gov* once OMB receives the package for review.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	60	1	60	0.5 (30 minutes) ..	30
Screener	15,000	1	15,000	0.016 (1 minute) ..	240
Experimental Survey	5,400	1	5,400	0.5 (30 minutes) ..	2,700
Total					2,970

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

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 15,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.016 hours), for a total of 240 hours. Fifty-four hundred respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 2,700 hours. The total estimated burden is 2,970 hours (30 hours plus 240 hours plus 2,700 hours).

Dated: November 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29321 Filed 12–4–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0656]

Animal Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following meeting: Animal Drug User Fee Act. The topic to be discussed is proposed recommendations for the reauthorization of the Animal Drug User Fee Act (ADUFA III).

Date and Time: The meeting will be held on December 18, 2012, from 9 a.m. to 12 p.m.

Location: The meeting will be held at FDA's Metro Park North Campus, 7519 Standish Pl., third floor, Meeting Room A, Rockville, MD 20855. There is parking near the building.

Contact: Jacqueline Farmer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8695, FAX: 240–276–9744, email: *ADUFAReauthorization@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by December 11, 2012.

If you need special accommodations due to a disability, please contact Jacqueline Farmer at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Comments: Interested persons may submit either written comments regarding this meeting to the Division of Dockets Management (see Transcripts) 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*. So that FDA can consider comments and revise the recommendations as necessary, we request that comments be submitted to the docket by January 4, 2013.

SUPPLEMENTARY INFORMATION: