Experimental Study of Graphic Cigarette Warning Labels

0910-0668

SUPPORTING STATEMENT (PART A)

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

On June 22, 2011, FDA issued a final rule, "Required Warnings for Cigarette Packages and Advertisements," which specified nine graphic images to accompany the new textual warnings for cigarettes, 76 Fed. Reg. 36627 (June 22, 2011). Although the rule was scheduled to become effective 15 months after it was 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.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Tobacco products are responsible for more than 400,000 deaths each year. The Centers for Disease Control and Prevention (CDC) reports 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 at $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 (Public Law 111-31) into law, granting the 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.

This act 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)." These label statements include:

1. WARNING: Cigarettes are addictive.
2. WARNING: Tobacco smoke can harm your children.
3. WARNING: Cigarettes cause fatal lung disease.
4. WARNING: Cigarettes cause cancer.
5. WARNING: Cigarettes cause strokes and heart disease.
6. WARNING: Smoking during pregnancy can harm your baby.
7. WARNING: Smoking can kill you.
8. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
9. WARNING: Quitting smoking now greatly reduces serious risks to your health.

The bill also gives the Secretary discretion to "adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area."

FDA's Center for Tobacco Products will conduct one experimental study annually to evaluate the relative efficacy of various graphic images depicting the risks of cigarette smoking - including elements such as type size, text and format - for promoting greater public understanding of the risks associated with cigarette smoking. The study, the Experimental Study of Graphic Cigarette Warning Labels, is a voluntary annual experimental survey of consumers.

2. Purpose and Use of the Information Collection

The study, the Experimental Study of Graphic Warning Cigarette Labels, is a voluntary annual experimental survey of consumers. The objectives of the experimental study are to (1) measure consumers' attitudes, beliefs, and intended behaviors related to cigarette smoking in response to graphic warning labels; (2) determine whether consumers' 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 for achieving three communication goals:

- conveying information about various health risks of smoking;
- encouraging cessation of smoking among current smokers; and
- discouraging initiation of smoking among youth and former smokers.

This experimental study will be conducted using an Internet panel. Selected panel members will view graphic warning images in conjunction with the warning statements and respond to a questionnaire designed to collect participants' responses to the images and demographic information. The target audiences for the study include: (1) current smokers aged 25 years old or older, (2) young adult smokers aged 18 to 25 years old, and (3) youth aged 13 to

17 years old who smoke or may be susceptible to initiation of smoking. The information collected from the study will help inform the Agency's efforts to implement the mandatory graphic warnings required by the Tobacco Control Act.

3. Use of Improved Information Technology and Burden Reduction

The study will use a web-based survey, which will be self-administered on personal computers. Web-based surveys reduce respondent burden; minimize possible administration errors; and expedite the timeliness of data processing. Furthermore, web-based surveys are less intrusive and less costly compared to face-to-face interviews and mail and telephone surveys. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias. Use of electronic means to submit data is expected to be 100%.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection focuses on "regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)" of the Tobacco Control Act. There is no duplicative collection of this information. No comparable data have been collected by any other entities. The information collected from the study will inform the Agency's efforts to implement the mandatory graphic warnings required by the Tobacco Control Act, in particular by providing data that will assist in the selection of images for inclusion in the final regulations.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection of information.

6. Consequences of Collecting the Information Less Frequently

This is an annual data collection. The collection of information will provide the primary data needed for federal policy makers to make science-based decisions concerning the selection of images that will be associated with each of the nine warning statements outlined in the Tobacco Control Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection that would be inconsistent with the regulation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of March 27, 2012 (77 FR 18250) FDA received eight comments, that were not related to the Paperwork Reduction Act and were therefore outside the scope of this collection of information. FDA also received a comment which noted that the 60 Day Federal Register notice did not provide sufficient detail regarding the design or methodology of the proposed consumer research study to allow for meaningful public comments. The commenter also encouraged FDA to provide additional detail about the design of the proposed consumer research study to allow for meaningful public comments, 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 Paperwork Reduction Act. The goals ensure the greatest possible public benefit from and maximize the utility of the information. The commenter indicated that meaningful public comments might assist FDA in refining the study protocols and enhance the quality, utility, and clarity of the information to be collected to further the goals of the Paperwork Reduction Act. 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 information collection package submitted to OMB for review and posting on their public Web site once the 30 Day Federal Register Notice is published. 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.

9. Explanation of Any Payment or Gift to Respondents

The study respondents will be drawn from a panel maintained by e-Rewards. E-Rewards provide its Internet panel members with a token incentive as part of their continuous participation in the Internet panel. Panel members earn e-Rewards currency for the time they spend answering market research surveys. The appropriate incentive that panel members receive for participation is based on an approximate length of the survey. Members can redeem their earned currency for a variety of valuable rewards that are of interest to them. Some examples of incentive partners include Pizza Hut, Best Buy, JCPenney's, Macy's, American Airlines, Hertz, Target, iTunes, and various publication companies for magazine subscriptions, among others. There is no additional payment or gift associated with participation in the study proposed here.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain private to the extent provided by the law. The study instrument will contain a statement that no one will be able to link the respondent's identity to their responses. Identifying information will not be included in the data files delivered by contractors to the agency.

Neither independent contractor, e-Rewards nor RTI, will share personal information regarding panel members with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in the data files delivered to the agency. FDA and RTI will receive data for analysis in aggregate form. Although e-Rewards retains contact information on participants for honoraria purposes, individually identifiable information is not shared with anyone, including FDA and RTI; it is stored separately from the survey data file and is not linked in any way to participant responses.

RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. E-Rewards take the following security measures to ensure separation between respondents' identity and their survey data. First, the survey instrument has no personally identifying information (PII) on it. No respondent name, address, email address, phone number or any other kind of PII appears on the survey. The only

way a survey is identified is with a digital identification number. Second, while the invitation method, whether email, mail or direct mail will inherently have PII information included, this will not be combined with survey responses, so the responses from the survey are not linked to the PII. Third, screener data shall be considered part of the survey data. E-rewards will provide the results of the screener questions for all panelists, regardless of whether they qualify for the study. However, e-Rewards will not retain responses to screening questions for those who are deemed ineligible for any other purpose outside the scope of this project. Fourth, e-Rewards will retain study records for the duration of the study. Upon final delivery of data files to RTI and completion of the project, e-Rewards will destroy all study records including data files upon request. E-rewards will not be able to supply or access this information for any reason, even at the request of RTI, once destroyed. Finally, data coming directly from the survey engine are stored in a proprietary database. While this data is not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to RTI by e-Rewards will be sent via encrypted files.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

One of the communication goals for the warning labels is to prevent smoking initiation among youth. Thus, it is important to understand youth responses to the warning labels. In particular, we are interested in responses to the warning labels among those youth who are susceptible to smoking or have already started experimenting with smoking. In order to identify those youth at risk of smoking or already smoking we need to ask the youth potentially sensitive questions about tobacco use. These questions are potentially sensitive since tobacco use among youth under 18 years of age is illegal in a few states and sales to youth under 18 years of age is illegal in all states.

To alleviate any potential concern for the youth we will take all necessary measures to ensure privacy of their responses. Also, no personal identifying information will be attached to the data used for analysis – e-Rewards keeps personal identifying information to invite youth to participate in surveys but this information will not be shared with RTI (this restriction is stated in the sub-contract between RTI and e-Rewards).

E-Rewards have a standing panel of youth ages 13-17 form which our sample will be recruited. The u.talk.back® panel was created specifically to reach children aged 13-17 years old directly, without parental involvement. The Federal law protecting children, Children's Online Privacy Protection Act (COPPA), does not restrict this type of activity for children aged 13 years old and older. No personally identifying information will be released, per the u.talk.back® member and privacy agreements (http://www.utalkback.com/privacypolicy.do). In summary, e-Rewards' activities for this study will be fully compliant not only with the Federal Law, but with the Council of American Survey Research Organizations® (CASRO) Code of Standards and

Ethics for Survey Research, a tough, internationally-cited set of standards, which has long been the benchmark for the industry."

E-Rewards invitation to youth does encourage parents to know about and approve of youth involvement in the panel and surveys. However, no active parental consent is required or requested. For this study, when the youth are invited to join our specific survey, both parental consent and youth assent will be requested and required. In the invitation for our specific study it will be emphasized that youth responses are strictly private and that youth will be instructed to NOT take the survey under their parents' supervision or to share their answers or opinions with their parents. We will emphasize to the youth and parents that will want to encourage honest responses to the questions so that we can measure a valid youth response to the warning statements and images in the hopes of choosing warning labels and statements which will help prevent youth smoking.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The estimated total hour burden of the collection of information is 2,970 hours (Table 1). FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members from an e-Rewards Internet panel will take part in a pretest to test the programming of the survey before administration. The pretest instrument will take no more than 30 minutes (0.5 hours) to complete, 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 one minute (0.016 hours), for a total of 240 hours. Fifty-four hundred respondents will complete the full study, estimated to last for 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.)

Table 1. Estimated Annual Reporting Burden

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Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pre-test	60	1	60	0.5	30
Screener	15,000	1	15,000	0.016	240
Experimental Survey	5,400	1	5,400	0.5	2,700
Total					2,970

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $47,520 [2,970 hrs. x $16/hr (the 2010 median wage rate in the U.S.) http://www.bls.gov/oes/2010/may/oes_nat.htm#b00-0000.].

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

All respondents' burden is reflected in A12. There are no capital, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to Federal Government

The estimated total cost to the Federal Government for this information collection $975,331. The costs arise from the time spent by the contractor to develop and conduct the collection of information and analyze the data as well as the development of the various graphic images depicting the risks of cigarette smoking.

15. Explanation for Program Changes or Adjustments

The burden for this collection of information has decreased by 3,495 hours, from 6,465 to 2,970 hours. The reason for this decrease was adjustments to the number of surveys taken due to external factors, such as pending litigation regarding graphic health warning labels. The number of minutes to complete the pretest for this collection has been estimated to increase from 15 to 30 minutes, for an increase of 15 hours. The number of respondents to be screened for this collection has decreased by 21,000, from 36,000 to 15,000 respondents, resulting in the total number of burden hours decreasing by 360, from 600 to 240 hours. Finally, the number of respondents who will take the full experimental survey is expected to decrease by 18,000 respondents, from 23,400 to 5,400, while the average burden to respond to the full experimental survey is expected to increase from 15 to 30 minutes. Total burden hours, therefore, have decreased by 3.495 hours (15 hours -360 hours – 3,150 hours).The reason for these adjustments to this collection of information are due primarily to the ruling that 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.

16. Plans for Tabulation and Publication and Project Time Schedule

The period of performance for each annual collection of information is 12 months. The project will not extend beyond the 80th working day after receiving approval of final questionnaire by the Project Officer. The planned schedule for project activities is shown in Table 2.

The Agency will use the study results to inform the Agency's efforts to implement the mandatory graphic warnings required by the Tobacco Control Act. The purpose of tabulation is to qualitatively analyze the data and summarize findings to meet informational needs. The data analysis will include basic summary statistics, including means and frequencies of variables of interest. In addition, commonly accepted statistical techniques, such as descriptive analysis, analysis-of-variance (ANOVA), and regression will be used to analyze the experimental data.

Table 2. Project Schedule

Activity	Date
Conduct pretests and finalize questionnaire	Within 20 working days following OMB approval
Conduct Internet Experimental Survey	Within 5 working days of approval of final questionnaire
Receive data files and syntax files	Within 45 working days of approval of final questionnaire
Receive methodology report	Within 45 working days of end of data collection

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." The dissemination may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site. In describing the information collection, FDA will clearly acknowledge that the data does not provide nationally representative estimates, such as consumer attitudes, knowledge, or behaviors.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.