Experimental Study of Graphic Cigarette Warning Labels

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.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Tobacco products are responsible for more than 440,000 deaths each year. The Centers for Disease Control and Prevention (CDC) reports 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 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. One way to do this is through cigarette label warning statements that describe and graphically depict the harm associated with tobacco use causing individuals to think harder about the choice to use tobacco.

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111-31) into law, granting the Food and Drug Administration (FDA) 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. 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 an experimental study to evaluate the relative efficacy of various graphic images depicting the risks of cigarette smoking for

influencing consumers' attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking. The information collected from the study will inform the Agency's efforts to implement the mandatory graphic warnings required by the Tobacco Control Act.

2. Purpose and Use of the Information Collection

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 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.

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 a one-time 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 the FEDERAL REGISTER of February 22, 2010 (75 FR 7604), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received five comments in response to the notice.

All five comments supported FDA's proposal to sponsor consumer research to provide a scientific basis for regulations requiring color graphics to accompany the new statutory health warnings set forth in the Federal Cigarette Labeling and Advertising Act, as amended by the Tobacco Control Act.

One comment recommended that the FDA consider conducting follow-up assessments to determine whether the warnings are having their intended effects and, if not, to determine what revisions are needed.

FDA agrees that appropriate surveillance is important, and that the comment makes an excellent suggestion for future research.

Two comments recommended that FDA include information about cessation resources in the tested graphic warnings.

FDA will be testing a variety of different graphics that will vary in style and intensity. Some of the tested images will include information about cessation resources. Decisions about whether to include specific graphics containing cessation information in final regulations will be made after the results of the experimental study are available and these data will be a primary factor in the selection of images for final regulations.

One comment recommended that FDA use images that are medically accurate to avert claims that the graphics are deceptive to consumers and ensure that smokers are confident in the accuracy of the health information provided.

FDA agrees that it is important to ensure that the graphic health warnings convey accurate information about smoking risks to consumers. The data collected from the proposed research will provide important information to ensure that the graphic health warnings being tested do not elicit unintended responses from consumers.

One comment urged that FDA ensure that the questionnaire ask questions in an objective and unbiased manner.

FDA agrees with this recommendation and has designed a survey instrument that includes validated measures used in other research. Thus the questions are objective, unbiased, and reliably understood by respondents. In addition, FDA plans to conduct cognitive interviews

prior to the experimental survey. These interviews will help identify any unanticipated problems consumers may have in understanding or responding to the questions in the survey.

One comment questioned the basic premise of requiring graphic health warnings, stating that international experience shows that graphic health warnings have not reduced smoking rates.

The purpose of this study is not to determine whether FDA should require graphic health warnings. Congress has already made that determination. Similarly, the purpose of this study is not to determine the absolute effectiveness of graphic health warnings in terms of changing smoking behavior. Instead, the purpose of this study is to determine the relative efficacy of various graphic health warnings for conveying risk information to consumers and provide a scientific basis for FDA's regulations for graphic health warnings as required by the Federal Cigarette Labeling and Advertising Act, as amended by the Tobacco Control Act.

One comment sought assurance that FDA will obtain appropriate parental consent and IRB approvals, especially with respect to the collection of information from adolescents.

FDA strongly agrees that appropriate parental consent and IRB approval is important and necessary. Such consent and approval will be obtained as part of the standard regulatory research process and before any collection of information.

One comment questioned FDA's decision to use an Internet survey, especially with respect to the collection of information from adolescents, and recommended that FDA sponsor an in-person survey instead.

As indicated above, the purpose of this study is to assess the relative efficacy of various graphic health warnings. The use of an Internet-based panel to collect our experimental data is appropriate for this purpose. FDA believes that the Internet-based panel will provide the most efficient and practical methodology for collecting the data.

One comment also indicated that an Internet-based survey is not well-suited to analyzing health warnings because the health warnings under real world conditions appear on three-dimensional packages rather than on two-dimensional images on a computer screen. The comment recommended that FDA consider a prior mailing of realistic mock-ups of cigarette packages, which the participants could examine while taking the survey.

FDA agrees that it is important that survey participants view realistic images of the tested graphic health warnings on product packaging. The study is designed so that participants will view a three-dimensional animation of mock-ups of various graphic warnings on product packaging. Participants will be able to manipulate the animation during the survey to see the front, back, and sides of the package. We believe that this animation is sufficient to ensure that study participants view the tested graphic warnings under realistic conditions.

One comment recommended that FDA include a meaningful pretesting of the survey instrument, including the use of cognitive interviews.

FDA agrees that meaningful pretesting of the survey instrument is important, and plans both cognitive interviews and pretests. The cognitive interviews will help FDA evaluate and refine the draft questionnaire, and help to identify areas where the instrument is ambiguous, burdensome, or confusing. FDA will also conduct pretests of the algorithms and programs for respondent sampling, survey administration and data collection.

One comment raised a number of individual concerns that the planned cross-sectional design of the proposed survey is not capable of providing information from which causal conclusions about the relationship between exposure to the graphic images and smoking behavior can be based. The comment also raised the concern that questions regarding intended actions about smoking cessation or smoking initiation are inadequate to demonstrate actual

behavioral changes. To address these concerns, the comment recommended the use of a longitudinal design that monitors actual behavior over time.

The purpose of this study is not to determine the absolute effectiveness of graphic health warnings in terms of changing smoking behavior. Instead, as indicated above, the purpose of the study is to determine the relative efficacy of various graphic health warnings for purposes of providing a scientific basis for FDA's regulations for graphic health warnings as required by the Federal Cigarette Labeling and Advertising Act, as amended by the Tobacco Control Act. A cross-sectional design is appropriate for this purpose.

In addition, FDA disagrees that questions concerning intentions to quit smoking or to not begin smoking are inappropriate. The more recent scientific literature shows that statements by smokers concerning their intentions to quit smoking are predictive of their making subsequent quit attempts.[1] Similarly, the scientific literature demonstrates that statements by children and adolescents concerning their intentions to smoke or not smoke are reliable predictors of subsequent smoking and precedes smoking initiation.[2]

One comment noted that it is important that the study be conducted in a manner that avoids question order bias.

FDA agrees that efforts must be taken to avoid any potential bias, and is confident that the study will be conducted in a manner that yields objective and reliable results. The planned cognitive interviews and pretests should help identify potential problems with question order and allow FDA to address those concerns prior to the experimental survey.

One comment recommended that FDA use a research design that tests across subjects, rather than within subjects. The comment states that failure to use an across-subjects design will lead to an overestimate of the effects of bolder warnings.

FDA's proposed study employs a between-subjects design that will test across subjects.

One comment recommends that care be taken to avoid information overload, given the number of warning statements and images.

FDA agrees with the comment. The between-subjects design of the study will reduce the potential for information overload. Each treatment group of respondents will view and respond to one graphic warning label.

One comment also included comments on a separate Federal Register notice seeking public comment on a proposed FDA collection of information concerning the pretesting of tobacco communications, Docket No. FDA-2010-N-0084. That notice is not related to the information collection concerning graphic health warnings. Accordingly, those comments are not addressed in this document.

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[1] Zhou, X et al. "Attempts to quit smoking and relapse: Factors associated with success or failure from the ATTEMPT cohort study," *Addictive Behaviors*, 2009; 34: 365-373; Hyland A et al. (2006), "Individual-level predictors of cessation behaviours among participants in the International Tobacco Control (ITC) Four Country Survey, *Tobacco Control*, 15: iii83-iii94.

[2] Hampson SE et al., "Predictors of the Development of Elementary-School Children's Intentions to Smoke Cigarettes: Hostility, Prototypes, and Subjective Norms," *Nicotine and Tobacco Research* 2007 July; 9(7): 751-760; Wakefield, M. et al., "The role of smoking intentions in predicting future smoking among youth: findings from the Monitoring the Future data," *Addiction* 2004 Jul; 99(7): 914-22; Pierce J, et al., "Validation of susceptibility as a predictor of which adolescents take up smoking in the United States," *Health Psychology*, 1996(Sept): 355-61.

FDA agrees with the comment. The between-subjects design of the study will reduce the potential for information overload. Each treatment group of respondents will view and respond to one graphic warning label.

One comment also included comments on a separate Federal Register notice seeking public comment on a proposed FDA collection of information concerning the pretesting of tobacco communications, Docket No. FDA-2010-N-0084. That notice is not related to the information collection concerning graphic health warnings. Accordingly, those comments are not addressed in this document.

9. Explanation of Any Payment or Gift to Respondents

The study respondents will be drawn from a panel maintained by E-rewards. E-rewards provides 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 or 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 takes 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 has 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 nor 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 6,645 hours (Table 1). To test the programming of the survey before administration, if time allows, we will conduct a pretest with a total of 60 individuals selected from E-Rewards Internet panel. The pretest instrument will take no more than 15 minutes to complete. The total hour burden for the pretests is 15 hours. Approximately 600 hours of burden results from the completion of a screener to determine eligibility for participation in the study by individuals that do not qualify for the study. This estimate is calculated using the desired sample size for each group and the qualifying rate. For example, we estimate that 70% of the adults that receive an invitation to participate in the study will qualify. Thus, to obtain 2 adult samples of 4,500 each, we will screen approximately 13,000 e-rewards panel members and 4,000 individuals will not qualify. Assuming a qualifying rate of 20% for the young adult sample we will screen approximately 22,500 panel members to achieve the final sample and 18,000 will not qualify. Assuming a qualifying rate of 15% for youth, we must screen approximately 30,000 panel members to achieve the final target sample size and 25,500 will not qualify. We assume that the screener for adults and young adults will take 1/120 hour to complete and that the screener for youth will take 1/60 hour. We obtain a combined burden estimate for the screener by taking the total number of adults that do not qualify for the study and multiply by 1/120, which is approximately 183 hours, and by taking the total number of youth that do not qualify and multiply by 1/60, which is approximately 425 hours. The combined burden is equivalent to approximately 36,000 respondents completing a screener in 1/60 hour, or 600 hours. Eighteen thousand (18,000) respondents will complete the full study, estimated to last 15 minutes (15/60 hours) and approximately 5,400 of those respondents will complete an additional survey one to two weeks following the original survey, estimated to last 15 minutes (15/60 hours), for a total of 5,850 hours. The total estimated burden is 6,465 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

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	15/60	15
Screener	36,000	1	36,000	1/60	600
Experimental Survey	23,400	1	23,400	15/60	5,850
Total					6,465

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $103,440 [6,465 hrs. x $16/hr (the 2008 median wage rate in the U.S.) [3]].

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

All respondent 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

This is a new data collection. There are no program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

The period of performance is 12 months and assumes that OMB approval is received by September 2010. 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

[3] http://www.bls.gov/oes/2008/may/oes_nat.htm#b00-0000.

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.