

Experimental Study on Warning Statements for Cigarette Graphic Health Warnings

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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. Section 201 of the Tobacco Control Act amends section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require 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).” Section 202(b) of the Tobacco Control Act further amends section 4 the FCLAA by adding that the Secretary, through notice and comment rulemaking, may adjust the “text of any of the label requirements . . . if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.”

In the Federal Register of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled “Required Warnings for Cigarette Packages and Advertisements,” which specified 9 images to accompany the new textual warning statements 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 violated the First Amendment. In a letter to Congress on March 15, 2013, the Attorney General reported FDA’s intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act. Preliminary research has been underway since 2013. The next phase of the research includes the study proposed here, which is an effort by FDA to collect data concerning revised textual warning statements for use with new images as part of cigarette graphic health warnings (GHW), and to explore their potential impact on public understanding of the risks associated with the use of cigarettes.

FDA’s Center for Tobacco Products requires data on how the public may respond to various textual warning statements related to the negative health consequences of cigarette smoking in order to determine the appropriate final set of textual warning statements to be further tested and evaluated in support of a future rulemaking. The results will inform the Agency’s broader efforts to finalize the development of cigarette GHW to be tested in future studies and ultimately to implement the mandatory graphic warning label statement as required by section 201 of the Tobacco Control Act.

2. Purpose and Use of the Information Collection

FDA’s Center for Tobacco Products will conduct this experimental study to help inform its implementation of section 201 of the Tobacco Control Act to issue a rule directing the use of

warning statements accompanied by color graphics depicting the negative health consequences of cigarette smoking. More specifically, FDA intends to evaluate revisions to the warning statements in section 201(a) of the Tobacco Control Act and is conducting this study to explore consumer perception of warning statements. Section 202(b) states that the Secretary may revise the warning statements if “such a change would promote greater public understanding of the risks associated with the use of tobacco products.” Results from this study will be used to determine which textual warning statements will be paired with color graphics depicting the negative health consequences of cigarette smoking to be tested in a future study.

The purpose of this experimental study is twofold: (1) it aims to build upon the work of previous research and efforts to help inform the selection of textual warning statements that will be the most effective in improving public understanding of the health consequences of cigarette smoking; and (2) it will inform future research efforts to test a new set of cigarette GHW (textual warning statements plus graphics) in fulfillment of the Agency’s statutory obligation under section 201 of the Tobacco Control Act.

FDA has undertaken a rigorous science-based research approach to help with the development of the textual warning statements to ensure that the content of the statements is based on accurate and reliable science. In order to identify gaps in consumer knowledge and misperceptions about the health effects of cigarette smoking, FDA conducted systematic literature reviews on cigarette smoking beliefs among consumers as well as analyses using multiple datasets from national surveys. In addition to the existing literature, this study is informed by the following focus group research conducted by FDA: *Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions* (OMB Control Number 0910-0674, approved by OMB on April 6, 2015). This set of focus groups was conducted with adult smokers, adolescent smokers, and adolescents susceptible to tobacco use to gain a better understanding of consumers’ knowledge and beliefs about the harms of cigarette smoking, general impressions about cigarette pack warnings, and reactions to draft cigarette pack warning statements. Findings from this study informed the current experimental study, including qualitative feedback that was used to revise the warning statements that will be tested in the current study.

To inform the design of the current study, FDA reviewed the existing scientific literature on methods, design issues, and outcome measures used in other studies seeking to improve consumer knowledge and to correct misperceptions about the health risks of cigarette smoking. In addition, FDA consulted with experts who were Special Government Employees to inform areas of research to support implementation of section 201 of the Tobacco Control Act. Recommendations from these experts informed the content of the revised textual warning statements as well as issues surrounding study design and methodological approaches.

FDA proposes to conduct an experimental study in order to explore consumer reactions to textual warning statements (original statements found in section 201(a) of the Tobacco Control Act and new revised warning statements). In the study, participants from an online consumer panel will be randomized to one of 17 conditions. In all conditions, participants will view a set of 9 textual warning statements presented in a sequential order as black text on a white background in 17-point font in the center of the screen. After viewing each statement, participants will respond to a small set of questions about their prior knowledge about the health condition mentioned in each statement and beliefs about the statement. Following exposure to

all 9 statements, participants will respond to a larger set of questions focused on knowledge and beliefs about the health consequences of cigarette smoking.

Participants randomized to the control condition will view the 9 statements listed in section 201(a) of the Tobacco Control Act:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

In each of the 16 experimental conditions, participants will view 8 of the 9 statements listed in section 201 of the Tobacco Control Act with the other statement replaced by the revised version of that statement that focuses on the same or a similar health consequence. The revised warning statements are as follows:

- WARNING: Smoking causes mouth and throat cancer.
- WARNING: Smoking causes head and neck cancer.
- WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- WARNING: Smoking during pregnancy causes premature birth.
- WARNING: Smoking during pregnancy stunts fetal growth.
- WARNING: Smoking during pregnancy causes premature birth and low birth weight.
- WARNING: Secondhand smoke causes respiratory illnesses in children, like pneumonia.
- WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- WARNING: Smoking causes COPD, a lung disease that can be fatal.
- WARNING: Smoking causes serious lung diseases like emphysema and chronic bronchitis.
- WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
- WARNING: Smoking causes cataracts, which can lead to blindness.

Following their responses to the larger set of questions, participants will be presented with another set of 9 warning statements in which all 9 are comprised of the revised warning statements. Participants will then complete a second set of questions focused on knowledge and beliefs about the health consequences of cigarette smoking.

3. Use of Improved Information Technology and Burden Reduction

Because this is a web-based study, 100% of the respondents will submit the information in an electronic format. Respondents will be shown a textual warning statement and respond to questions using a web-based survey on their personal computers or tablets. 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

There is no duplicative collection of this information. No comparable data have been collected by any other entities. FDA has developed a database of U.S. and international studies about various aspects of GHW; that database now includes more than 500 articles. FDA is aware of past and ongoing research with similar general goals of examining the effects of warnings about tobacco products; however, those studies are not comparable, nor do they supplant the need for this study. Specifically, those studies differ from the proposed collection in important ways making this collection necessary. First, studies that have examined warning statements as part of cigarette GHW focus on different outcomes, such as attention or behavior.¹ Second, other studies were not conducted using warning text in English and/or in the United States.² Third, studies were conducted using qualitative (i.e., focus groups) rather than quantitative methods.³ Fourth, and most importantly, even among studies conducted in English, testing revised warnings examining similar outcomes, no prior or other ongoing study tests the specific revised textual warning statements that are the focus of this study.

This study is designed to gain specific information about the textual warning statements that can be used for the Agency's implementation of section 201 of the Tobacco Control Act and section 202(b), for which the existing scientific literature on warnings is not directly relevant.

5. Impact on Small Businesses or Other Small Entities

¹ E.g., Brown KG et al. (2013). Graphic imagery is not sufficient for increased attention to cigarette warnings: the role of text captions. *Addiction*. 108(4):820–25; Kees J, Burton S, Andrews JC, et al. (2010). Understanding how graphic pictorial warnings work on cigarette packaging. *J Public Policy Marketing*. 29:265–76.

² E.g., Ngan TT et al. (2016) Changes in Vietnamese male smokers' reactions towards new pictorial cigarette pack warnings over time. *Asian Pac J Cancer Prev*. 17 Suppl, 71–78; Alaouie, H et al. (2015). Effectiveness of pictorial health warnings on cigarette packs among Lebanese school and university students. *Tobacco Control*. 24:e72–e80; Sychareun V et al. (2015). Perceptions and acceptability of pictorial health warning labels vs text only--a cross-sectional study in Lao PDR. *BMC Public Health*. 15:1094. doi: 10.1186/s12889-015-2415-9.

³ E.g., Levis DM et al. (2014). Women's perspectives on smoking and pregnancy and graphic warning labels. *Am J Health Behav*. 38(5):755–64; Hoek J et al. (2013). A qualitative exploration of young adult smokers' responses to novel tobacco warnings. *BMC Public Health*. 13(1): 609. doi: 10.1186/1471-2458-13-609; Crawford MA et al. (2002). Responses to tobacco control policies among youth. *Tobacco Control*. 11(1):14–19.

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 important data needed for FDA to implement section 201 of the Tobacco Control Act, which amends section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333).

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 March 28, 2017 (82 FR 15359), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 13 comment submissions. Eight submissions were PRA related, and some included multiple comments.

(Comment) Three comments suggested that the textual warning statements should be evaluated together with accompanying images because the impact of the final cigarette graphic warning labels will be a combination of the effects of both the text and images.

(Response) FDA declines to make this change at this time. This current phase of the research, which includes the study proposed here, is an effort by FDA to collect data concerning revised textual warning statements that may later be used with new images as part of cigarette graphic health warnings. In the future, FDA will conduct research pairing warning statements with images.

(Comment) One comment suggested using a longitudinal study design to understand the long-term effects of the warning statements.

(Response) FDA declines to make this change. A longitudinal study, while providing useful data, is beyond the scope of the research questions being addressed in the present study.

(Comment) One comment recommended FDA use a baseline assessment of understanding of risks associated with cigarette smoking in the form of a pre-exposure assessment of current awareness of negative health outcomes associated with cigarette smoking to evaluate respondents' baseline knowledge.

(Response) FDA declines to make this change. The measurement of baseline level of understanding of risk should be evenly distributed throughout the conditions due to the randomized nature of the experiment.

(Comment) One comment suggested that FDA implement prescreening measures and collect information about the study respondents.

(Response) Prior to randomization to condition, FDA will implement a screener to collect information about potential study participants to confirm eligibility. A copy of the screener is part of the overall package submitted to OMB for review through the public Web site <https://www.reginfo.gov>. Participant demographics will be assessed in the questionnaire and additional demographics will be provided by the Internet panel for all participants.

(Comment) Two comments suggested that FDA change the control group of warning statements to which the revised textual warning statements would be compared in this study.

(Response) FDA declines to make this change. The purpose of the proposed study is to test if the revised textual warning statements promote greater public understanding of the negative health consequences of cigarette smoking compared to the warnings enumerated in the TCA. Therefore, the TCA warning statements are the appropriate comparison group.

(Comment) One comment questioned whether the use of an Internet panel is the most appropriate method for obtaining the desired information in this study, as compared to in-person interviews.

(Response) With respect to the sample, the large heterogeneous sample that can be obtained through the Internet panel will allow FDA to test outcomes across a range of individuals, thus strengthening the conclusions and generalizability of the study.

(Comment) Two comments suggested that the timing of the administration of Section B of the questionnaire (administered after viewing eight TCA warnings with one revised warning, but before viewing a second set of nine revised warnings) could introduce bias. One of those comments also suggested FDA remove Section B.

(Response) FDA declines to make such a change at this time. Section B includes the primary outcome measures necessary to assess participants' understanding of the negative health consequences of cigarette smoking as described in the revised warning statements compared to the TCA statements. Further, knowledge gained from exposure to questions in Section B is expected to be minimal and consistent across conditions. Therefore, any such knowledge gained from exposure to Section B would suggest that any differences found between conditions are robust.

(Comment) One comment recommended that FDA conduct a power analysis to ensure the sample size is adequate for detecting the expected effect size.

(Response) FDA agrees that it is important to conduct a power analysis; the Agency did conduct a power analysis to ensure the sample size is appropriate for the proposed study.

(Comment) One comment expressed a desire to see the questionnaire to be used in the study as well as an explanation of the study design.

(Response) FDA notes that the questionnaire and supporting statements outlining the study design and methods were available as supporting documents in the docket for public review during the public comment period. Additionally, the study is described in detail as part of the overall package submitted to OMB for review through the public Web site <https://www.reginfo.gov>, and copies of the instrument used to collect this information are also included in that package.

(Comment) Many comments focused on the content of the revised textual warning statements in the proposed study, and provided suggestions for changes to the wording of the warning statements and additional topics on which they should focus.

(Response) The topics being tested in this proposed study include a wide range of health conditions caused by cigarette smoking and are presented with as much information as practicable. The revised warning statements were developed based on opportunities to promote greater public understanding about the negative health consequences of cigarette smoking. In addition, prior to the proposed study, the warning statements have been tested with consumers; vetted by medical and other scientific experts; and revised to ensure that they clearly and understandably convey factual information about the negative health consequences associated with the use of cigarettes. Based on comments about the content of the revised textual warning statements and FDA's ongoing preparation for the proposed study, FDA is changing the warning statement "WARNING: Smoking raises blood sugar, which can cause type 2 diabetes" to "WARNING: Smoking causes type 2 diabetes, which raises blood sugar." This change was made to better reflect the causal link between cigarette smoking and diabetes and to clarify that higher blood sugar is a result, not a cause, of diabetes. FDA has updated the questionnaire accordingly.

(Comment) One comment suggested that FDA conduct a "meaningful pretest" for the questionnaire.

(Response) As explained in the draft supporting statements included in the docket, the purpose of the pretests is to help ensure understandability of the questionnaire, to reduce participant burden, and to enhance interview administration. The questionnaire uses slightly modified versions of scales and instruments that have already been thoroughly tested and used in previous research.

(Comment) Many comments suggested changes to or addition of specific constructs as study outcomes or suggested how FDA should use the outcomes already included in the study. Measures suggested for FDA consideration included the following: how much the warning statements attract attention; how novel they are; personal identification with the statements; levels of emotion evoked/emotional appeal or emotional reaction; perceived risk or likelihood of the outcome occurring; and perceived effectiveness of the revised warning statements.

(Response) FDA declines to make such changes to the outcome measures, although FDA notes that the questionnaire already includes items assessing perceived effectiveness of the warnings. The purpose of this study is to assess whether potential textual warning statements, which have been revised from those enumerated in 201 of the Tobacco Control Act, promote greater understanding of the negative health consequences of cigarette smoking, and the proposed outcome measures focus on just such an evaluation. Therefore, the suggested outcome measures do not contribute to the evaluation of whether the revised warning statements improve public understanding of the negative health consequences of cigarette smoking.

(Comment) One comment noted that the study does not include information that would assist in the design of the graphic images.

(Response) FDA agrees that the proposed study does not include these outcomes, and the Agency declines to make such a change. The focus of this study is on the textual warning statements only to assess whether they promote greater understanding of the negative health consequences of cigarette smoking and not the design of the graphic images.

(Comment) Two comments stated that FDA was including measures of risk perception and suggested that FDA include additional risk perception measures, such as likelihood of the outcome; measures of absolute and comparative perceived risk; and perceptions of these risks over and above any “background” risk and other similar outcomes.

(Response) FDA declines to make such changes because this study does not aim to measure risk perceptions. The measures included in this proposed study assess knowledge and understanding of a negative health outcome caused by cigarette smoking. The goal of these measures is not to assess the absolute or relative level of perception of such risks, but rather to investigate the effect that viewing the warning statements has on increasing the understanding of the negative health consequences of cigarette smoking.

(Comment) Two comments suggested that, in order to minimize the burden of the proposed collection, FDA should use best practice methods for survey and focus group research, including developing a statistical analysis plan and involving a private consultant with experience in conducting such research efficiently.

(Response) As stated in the supporting statements included in the docket, FDA is working with a skilled and experienced research contractor to conduct the proposed study. In addition, FDA scientific experts possess skill and expertise in conducting such research. Survey and focus group best practices will be used, including avoiding bias in questions due to wording and question order and developing a statistical analysis plan.

9. Explanation of Any Payment or Gift to Respondents

Lightspeed will provide “MarketPoints” valued at approximately \$5 to panel members who complete the study. MarketPoints are a routine part of Lightspeed’s panel maintenance strategy, and can be traded for material items with Lightspeed partner vendors (e.g., Amazon.com, Starbucks) or for cash. Panel members customarily receive MarketPoints for each

survey completed in recognition of time spent and to encourage cooperation in future panel surveys.

The population of respondents needed to complete the data collection represents a special population, for which incentives are necessary to recruit them. Among young adults (aged 18-24) 19.6% report current cigarette smoking, among older adults (aged 25 and older) 17.9% report current smoking. Among youth the numbers are substantially lower, among 12-17 year olds, 4.6% report past 30 day smoking⁴ and 28.6% are susceptible to smoking.⁵ Thus, respondents needed for this study represent a minority of the general population. In addition, identifying adolescent smokers is difficult as use of tobacco is illegal in a few states for those under 18 and sales to adolescents under age 18 is illegal in nearly every state. Additionally, previous research has shown that recruiting and retaining adolescents into studies about tobacco is challenging.⁶

In general, empirical studies show that incentives can increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys within some respondent populations.⁷ Although the vast majority of published research on this topic is based on mail, telephone, or in-person surveys, there are now several studies on the effects of incentives within the context of a web-based survey. For example, a 2006 meta-analysis of 32 studies indicates that incentives increase the odds that potential respondents will begin a web survey, and a second meta-analysis of 26 studies shows that, having begun a web survey, incentives increase the odds of completing it.⁸

The majority of studies identified in the literature offered an incentive, although the incentive amount, type, and timing varied. Most often, researchers included cash incentives in the initial survey mailing and ranged from \$1 to \$20. Numerous experimental studies were conducted to identify how the use of incentives affects response rates. The findings presented below focus on studies that used address-based sampling for paper or web-based surveys.

One objective of a study of alcohol use among young adults in Wisconsin (N = 7,200) was to determine if small cash incentives affect response rates differently in web-based surveys compared to mail surveys.⁹ Respondents were randomly assigned to be in the “push to mail”

⁴ Kasza KA et al. (2017). Tobacco-product use by adults and youths in the United States in 2013 and 2014. *N England J Med.* 2017 Jan 26;376(4):342–53.

⁵ Trinidad DR et al. (2016). Susceptibility to tobacco product use among youth in Wave 1 of the Population Assessment of Tobacco and Health (PATH) study. Poster at Society for Research on Nicotine and Tobacco Conference (publication pending).

⁶ Diviak KR et al. (2006). Recruitment and retention of adolescents in a smoking trajectory study: Who participates and lessons learned. *Substance Use and Misuse.* 41, 175-182; McCormick LK et al. (1999). Recruiting adolescents into qualitative tobacco research studies: experiences and lessons learned. *J Sch Health,* 69, pp. 95–99.

⁷ Singer E & Ye C. (2013). The use and effects of incentives in surveys. *The ANNALS of the American Academy of Political and Social Science.* 645(1), 112-141; LeClere F et al. (2012). Household early bird incentives: leveraging family influence to improve household response rates. In *American Statistical Association Joint Statistical Meetings, Section on Survey Research*; Cantor D et al. (2003). Comparing promised and pre-paid incentives for an extended interview on a random digit dial survey. In *Presentation for the Annual Meeting of the American Association for Public Opinion Research,* Nashville, TN; Singer E. (2002). The use of incentives to reduce nonresponse in household surveys. In *Survey Nonresponse,* eds. Groves RM et al. 163–78. New York, NY: Wiley; Singer E et al. (1998.) Does the payment of incentives create expectation effects? *Public Opinion Quarterly.* 62:152–64.

⁸ Göritz AS. (2006). Incentives in web studies: methodological issues and a review. *Int J Internet Science.* 1(1): 58–70.

⁹ Stevenson J et al. (2011). Effects of mode and incentives on response rates, costs and response quality in a mixed mode survey of alcohol use among young adults. Accessed online at https://uwsc.wisc.edu/documents/UWSC_StevensonEtAl2011.pdf.

group or “push to web” group and either received a \$1 or \$2 cash incentive in the initial mailing. Before the alternative survey mode was offered, the response rate for the “push to mail” group with a \$1 incentive was 39.2% and 42.7% for the \$2 incentive group. Similarly, the \$2 “push to web” group had a higher response rate than the \$1 incentive group (29.7% and 25.8%, respectively). The final response rate for the “push to mail” group was 3.1% higher in the \$2 incentive group and 5.1% higher in the \$2 “push to web” incentive group. These results are statistically significant.

In a two-phase sampling study for the 2011 National Household Education Surveys (NHES) field test, both \$2 and \$5 cash incentives were used at the screening stage.¹⁰ The \$5 incentive resulted in a significantly higher response rate than the \$2 incentive (71.0% and 66.5%, respectively), but this did not carry over to the topical survey response rate (73.9% and 71.9%, respectively). However, the higher response rate to the initial screening (42.8% for the \$5 incentive group compared to 36.3% for the \$2 incentive group) resulted in saved costs associated with nonresponse follow-up mailings. A separate experiment was also conducted with the 2011 NHES field test for the topical survey incentives, including \$5, \$10, \$15, and \$20 cash incentives.¹¹ Findings from the study indicate that incentives greater than \$10 did not increase the response rate compared to the \$5 level (\$5: 79.3%; \$10: 75.6%; \$15: 78.8%; \$20: 78.3%).

The National Immunization Survey (NIS) previously described also conducted an experiment to determine how incentives affect response rates.¹² This study included three incentive groups: (1) no incentive; (2) prepaid \$1 cash incentive; and (3) \$10 Amazon.com gift code if the survey was completed within ten days. In addition, households either received only a survey URL or a survey URL and a QR code, as previously described. Households that received an incentive (either the cash or Amazon.com gift code) were significantly more likely to login to the survey compared to households that did not receive an incentive ($p < 0.001$). Furthermore, households that received a QR code and an incentive were more likely to login to the survey than respondents who received a QR but not an incentive. Finally, households that received the QR code and an incentive had a higher rate of eligibility compared to respondents in the landline control group ($p < 0.01$).

10. Assurance of Confidentiality Provided to Respondents

Concern for privacy and protection of respondents’ rights will play a central role in the study implementation; storage and handling of data; and data analysis and reporting. The Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection, as well as FDA’s IRB, the Research Involving Human Subjects Committee (RIHSC), will review and approve the protocols for the surveys prior to any data collection. The primary concern of both IRBs is protecting respondents’ rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law. FDA received RTI and FDA IRB approvals in April 2017.

¹⁰ Han D et al. (2013). An evaluation of incentive experiments in a two-phase address-based sample mail survey. *Survey Research Methods*. Vol. 7, No. 3, pp. 207–18.

¹¹ Montaquila JM et al. (2013). A study of two-phase mail survey data collection methods. *Journal of Survey Statistics and Methodology*. 1:66–87.

¹² Ward C et al. (2014). Evaluating the effectiveness of early bird incentives in a web survey. Accessed online at http://www.census.gov/fedcas/cfc2014/ppt/02_ward.pdf.

All data will be collected with an assurance that the respondents' answers will remain private to the fullest extent allowed by law. The study instrument will contain a statement that responses will be kept private. Private information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the Agency's regulations (21 CFR part 20). CTP consulted with FDA's Privacy Office, which conducted a Privacy Threshold Analysis and concluded that the Privacy Act does not apply to this information collection.

Security for survey respondents will be assured in a number of ways:

- Lightspeed (formerly GMI), the subcontracting organization that manages the web-based research panel, will invite adolescent children of adult panel participants to complete the survey through an email invitation to their parents asking for their consent to have their child's opinions, which is fully compliant with the Children's Online Privacy Protection Act's (COPPA) revised standards. Lightspeed will invite adult panel participants directly through an email invitation. Each respondent will be known only by a unique alphanumeric variable.
- Participants will log onto Lightspeed's secure server using a link provided by Lightspeed. RTI will receive no personally identifiable information about participants.
- Respondents will be informed before they encounter the first survey item that their data will be kept private consistent with laws governing privacy.
- Respondents will be required to provide their assent to freely participate before they encounter the first survey item.
- Respondents will have the option to decline to respond to any item in the survey for any reason.
- Redirect links embedded in the survey will direct adolescents back to Lightspeed to report having completed the survey and receive non-monetary compensation. All those who handle or analyze data will be required to adhere to the standard data security policies of RTI.

To ensure data security, all RTI project staff are required to adhere to strict standards and to sign a nondisclosure agreement as a condition of employment on this project. RTI maintains restricted access to all data preparation areas (i.e., receipt, 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. No respondent identifiers will be contained in reports to FDA, and results will only be presented in aggregate form.

Implementation of data security systems and processes will occur as part of the survey data collection. Data security provisions will involve the following:

- All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as provided in its regulations. Respondents will receive information about privacy protections as part of the informed consent process.
- All project employees will sign a non-disclosure agreement.

- All data are secured on Lightspeed’s database servers that only reside on private, backend servers that are behind layered firewall architecture. Data is never stored on a public network or outside the data tier. Relational database management systems (RDBMS) access is strictly controlled and limited to only a few authorized users whose access is limited to the minimum necessary to accomplish administrative tasks. Web and application servers communicate with the RDBMS only via a private network segment with a multi-layer firewall architecture in place. Access control is provided to secure data directories. All client specific data are stored in restricted access data directories controlled by access control lists.
- All data transmission will be encrypted as the responses will be on a Web site with an SSL certificate applied. Data will be passed through a firewall at RTI and then collected and stored on a protected network share on the RTI network. Only authorized RTI project staff members will have access to the data on the secure network.

All respondents will be assured that the information they provide will be maintained in a secure manner and will be used only for the purpose of this research. Respondents will be assured that their names will not be reported with responses provided. Respondents will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent’s social security number. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors, such as cigarette smoking and knowledge about the potential negative health consequences of cigarette smoking. Asking such questions is critical to the objectives to this information collection, namely to determine if revised warning statements about the negative health consequences of smoking promote greater public understanding of the risks associated with the use of tobacco products. Assessing tobacco use is important to understand how such revised warning statements work among different populations of those for whom the content of the warnings may be most relevant, namely, adult smokers, young adult smokers, adolescent smokers, and those youth who are susceptible to initiating smoking. Some questions about tobacco use are potentially sensitive because tobacco use among adolescents under age 18 is illegal in a few states and sales to adolescents under age 18 are illegal in nearly every state (and under 21 in some jurisdictions). These questions are essential to the objectives of this information collection. Questions about demographic information, such as race and ethnicity, could be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise respondents that these topics will be covered during the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with a specific toll-free phone number (linking directly to the RTI IRB Office) to call in case they have a question or concern about the sensitive issue.

Finally, as with all information collected, these data will be presented with all identifiers removed.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA’s burden estimate is based on prior experience with research that is similar to this proposed study. Approximately 762 respondents will complete a screener to determine eligibility for participation in the study pretest, estimated to take approximately 2 minutes (0.033 hours) per response, for a total of 25 hours for screening activities. One hundred respondents will complete the pretest, estimated to last 15 minutes (0.25 hours) per response, for a total of 25 hours for completion of both adult and adolescent samples in the pretest.

For the main data collection, approximately 19,082 respondents will complete a screener to determine eligibility for participation, estimated to take approximately 2 minutes (0.033 hours) per response, for a total of 630 hours for screening activities. Two thousand five hundred respondents will complete the full study, estimated to last 15 minutes (0.25 hours) per response, for a total of 625 hours for completion of both adult and adolescent samples. We estimate a total of 2,500 respondents will complete the main data collection. The total estimated burden is 1,305 hours.

Table 1. Estimated Annual Reporting Burden

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Adult - Screener for pretest	487	1	487	0.033	16
Adult -Pretest	68	1	68	0.25	17
Adult - Screener for main data collection	11,925	1	11,925	0.033	394
Adult - Main data collection	1,667	1	1,667	0.25	417
Total Adult Hours					844
Adolescent -	275	1	275	0.033	9

Screener for pretest					
Adolescent - Pretest	32	1	32	0.25	8
Adolescent - Screener for main data collection	7,157	1	7,157	0.033	236
Adolescent - Main data collection	833	1	833	0.25	208
Total Adolescent Hours					461
Total Burden Hours					1,305

12b. Annualized Cost Burden Estimate

Table 2. Estimated Annualized Cost

Portion of Study	Total Hours	Cost per Hour	Total Cost
Total Adults	844	\$22.33	\$18,846.52
Total Adolescents	461	\$7.25	\$3,342.25
Total	1,305		\$22,188.77

The annualized cost to all respondents for the hour burden for the collection of information is \$22,188.77 (Table 2). This is calculated by multiplying the burden hours for adults (844) by the 2015 mean hourly wage as reported by the U.S. Department of Labor, Bureau of Labor Statistics ([\\$22.23](#)) for a total of \$18,846.52; multiplying the burden hours for adolescents (462) by the federal hourly minimum wage ([\\$7.25](#)) for a total of \$3,342.25.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no additional capital costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal Government for this information collection is \$177,632. The cost of data collection including programming and hosting the survey, managing the data collection and delivering the data to RTI is estimated at \$65,000 (included in total cost). In addition to the costs from programming, hosting, and managing the data collection, the costs arise from the time spent by the contractor to assist in the development and conduct of the

collection of information, analysis of the data, and the development of the study stimuli depicting the textual warning statements.

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

Table 3. Project Schedule

Activity	Date
Conduct pretests and finalize questionnaire	Within 2 months following OMB approval
Conduct experimental study (Complete main data collection)	Within 3 months following OMB approval
Receive data files	Within 4 month following OMB approval
Receive final methodology report and data analysis	Within 5 months following OMB approval

Data collection is planned to begin by October 6, 2017, in order for FDA to meet its timeline. Future development and research activities are dependent on the timely completion of the present study.

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

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection. 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

There are no exceptions to the certification.