Experimental Study of Cigarette Warnings

0910-NEW

FDA SUPPORTING STATEMENT PART A

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)."

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. Various phases of research have been underway since 2013. The current phase of the research includes the study proposed here, which is an effort by FDA to collect data and explore the potential impact of new cigarette graphic health warnings (GHW) on public understanding of the negative health consequences of cigarette smoking. The study is not designed, nor is it the intent of the study, to investigate the effect of these warnings on behavior, behavioral intentions, or emotional reactions. In this study, we define "public understanding" as outcomes among the targeted study population of adolescents and adults as described further in Section 2, below.

FDA's Center for Tobacco Products requires data on how the warnings tested may improve understanding of the negative health consequences of cigarette smoking in order to implement the mandatory graphic warning label statements as required by section 4(d) of FCLAA. For warnings to be considered for future regulatory action, individual warnings must demonstrate statistically significant improvements, as compared to the control condition, on both the two outcomes of New Information and Self-Reported Learning (knowledge gain). The warnings will then be evaluated not only on the presence of a statistically significant effect on both outcomes, but also on the magnitude of the effect as an indicator of the conceptual significance of the findings. Future regulatory action will be informed by the results of this study, additional scientific information, and other legal and policy considerations as appropriate.

2. Purpose and Use of the Information Collection

FDA's Center for Tobacco Products will conduct this experimental study to inform its implementation of section 201 of the Tobacco Control Act to issue a rule directing the use of textual warning statements accompanied by color graphics depicting the negative health consequences of cigarette smoking. The purpose of this experimental study is twofold: (1) it builds upon previous research that informed the selection of textual warning statement and image pairings that are designed to be the most effective in increasing public understanding of the negative health consequences of cigarette smoking; and (2) it eventually will support a proposed rule in fulfilment of the Agency's statutory obligation under section 201 of the Tobacco Control Act.

FDA has undertaken a rigorous science-based research approach to develop the GHW being tested in this study. 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 previous 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 previous set of focus groups was conducted with adult smokers, adolescent smokers, and adolescents susceptible to cigarette smoking to gain a better understanding of consumers' knowledge and beliefs about the harms of cigarette smoking, general impressions about cigarette package warnings, and reactions to draft warning statements. Findings from that study informed revisions to the textual warning statements, which FDA tested in another previous experimental study, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings* (OMB Control Number 0910-0848, approved by OMB on January 29, 2018). The image component of the new GHW has also been informed by previous studies, including testing of image concepts in 54 in-depth individual interviews, *Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions* (OMB Control Number 0910-0796, approved by OMB on October 15, 2015) and testing of revised image concepts, tested alone as well as paired with textual warning statements in a set of 20 focus groups with more than 160 participants, *Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images* (OMB Control Number 0910-0796, approved by OMB on January 29, 2018). Both studies testing the image component of the new GHW included adult smokers, adolescent smokers, and adolescents susceptible to cigarette smoking.

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 multiple experts to inform areas of research to support implementation of section 201 of the Tobacco Control Act.

FDA proposes to conduct an experimental study to explore reactions to new cigarette GHW to assess whether those warnings increase understanding of the negative health consequences of cigarette smoking in a large sample of adolescent smokers, adolescents susceptible to smoking, and current adult smokers and non-smokers. The study sample will provide insight into the potential for such warnings to increase public understanding of the negative health consequences of cigarette smoking. The study sample will be recruited from an online consumer panel. The study is not designed to be nationally representative, nor will nationally representative estimates be produced. An experimental design does not require a

nationally representative sample of these subgroups to demonstrate an effect. The panel choice is driven by the large and diverse membership to allow for targeting of adequate numbers of those in the specified tobacco use status groups and to obtain a reasonable degree of demographic diversity in each of the targeted groups and the overall sample (see Part B).

Participants will complete a screening questionnaire through an email invitation. After screening for inclusion (see Study Screener), participants who qualify for the study will complete Session 1, comprising three consecutive components: (1) a baseline assessment of beliefs about the negative health consequences of cigarette smoking; (2) assignment to study condition and exposure to cigarette warning stimuli according to condition assignment; and (3) assessment of new information, self-reported learning, and other reactions to the stimuli (see Session 1 Survey Instrument). These three components are described below.

- *Component (1):* First, participants will be asked questions about their beliefs about the health consequences of cigarette smoking.
- *Component (2):* Following the baseline assessment of beliefs about the health consequences of cigarette smoking, participants will be randomized to one of 16 treatment conditions or a control condition with variation in exposure to cigarette warnings. Participants in each experimental condition will be exposed to one graphic health warning, with each condition corresponding to a unique warning from a set of 16. Participants in the control condition will be exposed to a random selection of one of four Surgeon General's warnings. All stimuli will be presented sequentially on a mock cigarette package and a mock cigarette advertisement, with the stimuli formats presented in a random order. When viewing the mock cigarette packages, participants will be able to manipulate the package electronically to rotate it 360 degrees to ensure they are able to view all sides of the package and zoom in on specific areas. The warnings on the mock packages will be placed either on the upper portion of the front and rear panels of the mock package comprising the top 50 percent of the front and rear panels of the package (for GHW) or on the side of the package (for Surgeon General's Warnings), and all warning language will appear as black text on a white background. The mock advertisements will be full-page magazine-style advertisements, and the warnings will appear on the top 20 percent of the advertisement (for GHW) or the bottom of the advertisement as per current warning placement practice in accordance with FCLAA and FTC formatting specifications (for Surgeon General's Warnings). The stimuli for all conditions can be found in the Stimuli document.
- *Component (3):* After viewing the warning stimuli in both package and advertisement formats, participants will complete a brief set of measures to assess (a) if the information presented in the warning was new; (b) self-reported learning from the warning; (c) if the warning was easy to understand; (d) if the warning was perceived to be a fact or an opinion; (e) if the warning was informative; (f) if the warning grabbed their attention; and (g) if the warning made them think about the health risks of smoking.

One to two days following completion of the baseline assessment (Session 1), participants will receive an email invitation to complete a follow-up (Session 2). In this follow-up session, participants will first be re-exposed to the warning stimuli they were shown in Session 1. This exposure will follow the same protocol described in Component 2, above. Following stimuli exposure, participants will complete a set of immediate post-test measures assessing beliefs about the negative health consequences of cigarette smoking (see Session 2 Survey Instrument). These measures will facilitate an assessment of change in beliefs related to smoking-related health consequences following exposure to the cigarette warning stimuli.

Approximately 14 days later, at the delayed post-test (Session 3), participants will receive an email invitation to complete a questionnaire assessing measures of belief about the negative health consequences of cigarette smoking, as well as recall of the warning (see Session 3 Survey Instrument).

3. Use of Improved Information Technology and Burden Reduction

Because this is a web-based study, 100 percent of the respondents will submit the information in an electronic format. Respondents will be shown a cigarette warning and will respond to questions using a web-based survey on their 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

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 cigarette GHW focus on different outcomes, such as 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,

[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 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. Tob 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.

even among studies conducted in English, examining similar outcomes, no prior or other ongoing study tests the specific new GHW that are the focus of this study.

This study is designed to obtain specific information about the particular warnings to be used for the Agency's implementation of section 201 of the Tobacco Control Act.

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 across three separate sessions. 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

FDA has consulted with multiple experts to inform various aspects of the study design and implementation of research to support implementation of section 201 of the Tobacco Control Act. The feedback from these experts informed the content of warnings as well as issues surrounding study design and methodological approaches.

In the *Federal Register* of September 26, 2018 (83 FR 48625), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six unique comment submissions. Four submissions were PRA related, and some included multiple comments.

(Comment) One commenter stated that it's important to educate and reinforce the facts surrounding the dangers of smoking.

(Response) FDA agrees that it is important to provide the public with accurate information about the risks associated with the use of tobacco products. The purpose of this study is to assess whether new cigarette warnings increase understanding of the negative health consequences of smoking among the sample included in the study.

(Comment) One comment urged FDA to move forward to complete the proposed consumer research study as soon as possible to facilitate the prompt promulgation of a rule to require new warnings on cigarette packages and in cigarette advertisements. The comment also

(2002). Responses to tobacco control policies among youth. Tob Control. 11(1):14–19.

stated that FDA must take every available opportunity to minimize delays that may be attributable to the Paperwork Reduction Act.

(Response) FDA agrees that it is important to complete this study and promulgate a rule in accordance with the statutory mandate laid out by Congress. FDA is following the requirements of the Paperwork Reduction Act and its associated timelines.

(Comment) One comment stated that, as designed, the proposed study does not help FDA satisfy the requirements of the First Amendment because FDA has failed to consider less-burdensome alternatives and because FDA has not identified a "substantial" interest that this current iteration of a cigarette health warnings rule serves.

(Response) As stated previously, the purpose of the proposed study is to assess whether new cigarette health warnings increase understanding of the negative health consequences of smoking among the sample included in the study. FDA further notes that this notice is respecting a proposed study, the results of which, if used in a future rulemaking, would be provided along with other evidence in a future notice of proposed rulemaking and subject to public comment at that time.

(Comment) FDA received two comments that asked FDA to provide more detail about the design of the proposed study to allow for meaningful public comments. One commenter also stated that FDA must provide additional information for public comment, including details of the protocol, inclusion criteria for screening study participants, questionnaire, and the text and color graphics the agency proposes to test.

(Response) FDA notes in response to this comment that the proposed study and copies of the instruments used to collect this information are described in detail as part of the overall information collection request submitted to OMB for review.

(Comment) One comment provided a published scientific study and suggested that focusing on the presence of certain features of the warnings might provide more robust evidence about the effectiveness of warning labels rather than a comparison of a single pictorial message to a text-only message.

(Response) FDA appreciates the submission of the published study; however, it focuses on outcomes (e.g., negative emotional engagement, behavioral intentions) not relevant to the study FDA proposes, as described in Section 1 of this document. The proposed study examines how new cigarette health warnings provide new information, increase self-reported learning, change beliefs about the negative health consequences of cigarette smoking, and increase thinking about the risks of smoking, among other outcomes. In addition, the choice of control condition to which the cigarette health warnings will be compared was informed by a number of factors discussed in the response to the next comment below.

(Comment) One comment stated that the cigarette health warnings should be compared relative to the new text-only warning statements rather than the current, familiar text-only Surgeon General's warnings.

(Response) FDA disagrees. First, Section 201 of the Tobacco Control Act amends section 4 of FCLAA to require FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the textual label statements. Second,

FDA believes that the comparison to the current Surgeon General's warnings is the most appropriate comparison for the purposes of this proposed study. This comparison will allow for investigation of the potential effect of implementing new cigarette health warnings compared to the current state of warnings for cigarette packages and advertisements, which the commenter noted are "familiar."

(Comment) One comment recommended that certain demographic (e.g., age, socioeconomic status) and other (e.g., nicotine dependence among smokers) factors should be evaluated during the course of this study.

(Response) FDA disagrees. The purpose of this proposed study is to assess whether new cigarette health warnings increase understanding of the negative health consequences of smoking, not the mechanisms for such changes. Some basic sub-group analyses will be performed by age group and, while effects on the outcomes of interest in specific demographic or other sub-groups may be useful as context for better understanding the results and for future agency regulatory actions, the primary analyses will focus on whether new cigarette health warnings increase understanding of the negative health consequences of smoking in the overall sample.

(Comment) One comment urged FDA to consider previous research that has shown that use of "graphical" warnings can produce an opposite effect to the desired outcome.

(Response) The purpose and design of the proposed study includes identifying unintended consequences (i.e., if the control warnings showed greater gains on outcomes compared to the warnings in the treatment conditions).

(Comment) One comment recommended that the study design include pre/post measures of risk perceptions to evaluate whether the cigarette health warnings meaningfully increase likely pre-existing high levels of incoming risk perceptions.

(Response) FDA declines to make such a change. The purpose of this proposed study is to assess whether new cigarette warnings increase understanding of the negative health consequences of smoking, not whether such warnings increase risk perceptions. The focus of the study is on the specific health conditions that are the focus of the warning statements and their accompanying color graphics depicting the negative health consequences of smoking, not on the perception of overall risks of smoking.

(Comment) One comment indicated that the sample size for each condition appears to be small.

(Response) The sample size for this study is based upon a comprehensive statistical power analysis, taking into account the study design, planned analyses to be conducted, and potential study attrition. Based on its statistical power analysis, FDA is confident that the study will have sufficient sample sizes to detect a small to medium effect size on an item assessing beliefs about the health effects of smoking.

(Comment) One comment stated that the proposed study's methodology suffers from selection bias. Specifically, the commenter stated that the proposed study is a voluntary online experiment, uses sampling methodology that may limit generalizability of outcomes to the

broader U.S. population, and appears to lack corrective measures such as the ability to identify factors that contribute to participant drop out.

(Response) Even though an experimental design does not require a nationally representative sample of these subgroups to demonstrate an effect, FDA has made efforts to ensure that the demographics of participants in the study population are diverse. The results of this study will provide insight into the potential for such warnings to increase public understanding of the negative health consequences of cigarette smoking.

Additionally, the Statistical Analysis Plan describes how the study's sample size calculation and study analysis account for the potential of attrition over the multiple time points (i.e., study sessions). FDA does not anticipate significant item non-response as described in Section 3 of Supporting Statement B.

(Comment) One comment asserted that the study questions create a serious risk of bias. Specifically, the commenter stated that FDA's broad description of the questions to be asked in the study suggests that they are deliberately crafted to support a "pre-ordained" result, namely, that the warnings would increase understanding of the negative health consequences of cigarette smoking.

(Response) There is no pre-ordained result to the study, but there are specific research questions that this study intends to address (see Supporting Statement Part B and Statistical Analysis Plan). The questions used in this study were selected based on the results of prior studies on similar topics, including cigarette warnings, and follow item design best practices. The items included are well-established and/or pulled from validated instruments in communication and social science research focusing on warnings in general or cigarette warnings specifically. The findings of a comprehensive literature review on studies assessing warnings to consumer products (including tobacco and cigarette warnings) informed the selection of the items in the proposed study. Once identified, we extracted those items and evaluated them, considering the study's purpose and the items' reliability and validity. Some questions have been slightly edited to fit the specific content of the warnings to be tested, but the question instructions and question stems have not changed. The study questions are face valid (i.e., it is clear they measure what they are intended to measure) and specific. Additionally, the study questions have previously been shown to produce a range of responses, indicating that they do not produce demand characteristics (i.e., study participants do not respond to the items with what they think the researchers want to hear).

(Comment) One comment stated that FDA will need to avoid question-order bias.

(Response) FDA agrees that it is important to avoid question-order bias in this proposed study. In many sections of the study instrument, the order of questions is randomized specifically to avoid question-order bias. In other sections of the study instrument, the order was determined by starting with more general and then moving on to more specific items to avoid bias. In designing the survey, FDA ensured that the item order follows established models of information processing and attention.

(Comment) One comment raised a number of concerns that the study protocols do not appear to adequately mimic real-world conditions because cigarette smokers would not be

exposed to only a single warning (but rather they would be exposed to all of them over time); the study asks participants to specifically focus on the warnings, which will likely overestimate their effects; in the real world, consumers would rarely view both cigarette packaging and advertisements at the same time; the study does not measure whether consumers would get used to the warnings after viewing them repeatedly over a long period of time; and the study's 14-day gap between Sessions 2 and 3 gives participants time to do their own research about the risks of cigarettes, which could overstate any effects that cigarette health warnings might have.

(Response) The proposed study is not a naturalistic field experiment, however it is designed to increase the external validity of the study where possible in the context using the online panel to obtain the large sample needed. For example, the procedures proposed for the current study provide a greater number of exposures (and thus closer to real-world conditions) and use a longer follow-up time than many similar studies (Ref. 6).

Additionally, the Tobacco Control Act requires that the cigarette health warning label statements with accompanying color graphics be displayed both on cigarette packages (with the ability to rotate them to inspect all sides, rather than using a static image, to better approximate real-world conditions) and in cigarette advertisements; therefore, exposure to the warnings on both formats (i.e., on packs and advertisements) provides an appropriate assessment of the potential real-world impact of the warnings, as smokers and non-smokers will be exposed to the warnings in both formats once they are implemented.

The comment correctly indicates that study participants are only exposed to one warning, and not all warnings. However, this is necessary in the context of the experimental study to differentiate the effects of each individual warning on the outcomes measured. Once implemented the warnings would appear on cigarette packs and advertisements and would rotate to assure exposure to all the warnings over the course of a given year. FDA disagrees that such standard procedures for experimental testing of visual stimuli would likely overestimate the effects. In the case that an overestimation occurred, it would be non-differential for all conditions, including the control condition. The main analyses focus on the individual comparisons of the 16 experimental conditions to the control condition. If anything, the absolute (but not the relative) levels of the outcomes would be affected, therefore not biasing the overall results or interpretation of the results.

Finally, if warnings in certain conditions prompt study participants to seek health information in the 14-day follow-up period, thus resulting in greater understanding of the negative health consequences of cigarette smoking, such an effect could be viewed as strengthen findings that the warnings are working as intended and provide further evidence that the study mimics real world conditions in which consumers could seek additional information about the negative health consequences of smoking. Participants' health beliefs will be assessed at all three study sessions, thus allowing for comparison of the effect both immediately after exposure as well as after a delay.

FDA believes the proposed study design is appropriate to maximize internal validity to ensure that the conclusions drawn from it are valid and to maximize external validity where possible through the methods described above.

(Comment) One comment recommended that FDA consider assessing comprehension of the new warnings objectively (i.e., evaluating recall of specific content, evaluating comprehension of disease risk) rather than participants indicating only that they learned (i.e., "self-reported learning from the warning").

(Response) FDA agrees that it is important to assess comprehension of the new warnings objectively. The proposed study contains these items, in addition to other measures. Please refer to Section 2 in Supporting Statement Part B ("Procedures for the Collection of Information"), which outlines the specific constructs and measures used, as well as when they are assessed during the study. Those include both the self-reported outcomes, as well as beliefs about the negative health consequences of cigarette smoking and recall of the warnings assessed objectively in line with this comment.

(Comment) One comment stated that FDA should prioritize measuring the impact of the warnings on behavior (e.g., quit intentions among cigarette smokers, initiation intentions among non-users) over concepts such as whether the warning is informative or grabs attention.

(Response) As described in Section 1 of this document, the purpose of the proposed study is to assess whether new cigarette health warnings increase understanding of the negative health consequences of cigarette smoking to provide the scientific support necessary to inform future rulemaking consistent with section 201 of the Tobacco Control Act. The study is not designed to, nor is it the intent of the study, to investigate the effect of these warnings on behavior, behavioral intentions, or emotional reactions.

(Comment) One comment stated that the study does not appear to include meaningful pretesting.

(Response) FDA did not pretest the questionnaire items. As described in the response to a previous comment, the items are well-established and/or pulled from validated instruments in communication and social science research focusing on warnings in general or cigarette warnings specifically. The findings of a comprehensive literature review on studies assessing warnings to consumer products (including tobacco and cigarette warnings) informed the selection of the items in the proposed study. Once identified, we extracted those items and evaluated them, considering the study's purpose and the item's reliability and validity.

Additionally, health belief items assess knowledge of the specific content in the warning statements. The language and wording used in these items were derived from the specific language used in the warning statements, which underwent formative testing with adult current smokers, adolescent current smokers, and adolescents susceptible to cigarette smoking. One focus group study conducted by FDA, *Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions* (OMB Control Number 0910-0674) assessed reactions and understanding of the draft warning statements which informed revisions to the warning statements. A follow-up focus group study, *Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images* (OMB Control Number 0910-0796) assessed reactions and understanding of the draft warning statements that were paired with images. In addition, FDA evaluated the performance of questionnaire items and draft warning statements in a large quantitative study, *Experimental Study on Warning Statements for Cigarette Graphic Health*

Warnings (OMB Control Number 0910-0848). The findings informed the selection of the proposed study's measures. The findings from the aforementioned studies informed the development of warning statements, revisions to those statements, and the questions used to assess participant reactions (e.g., beliefs) about the warnings.

In addition, the proposed study will pretest the programmed questionnaire to ensure no programming issues affect the quality of the data (see Section 2 in Supporting Statement Part B).

9. Explanation of Any Payment or Gift to Respondents

Lightspeed (formerly GMI), the subcontracting organization that manages the web-based research panel to be used in this study, will provide "Lifepoints" valued at approximately $10 to panel members who complete each session for a total of $30 for a participant who completes all three sessions of the study. Lifepoints 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 Lifepoints 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 targeted population. Among young adults (aged 18-24 years), 19.6% report current cigarette smoking, and among older adults (aged 25 years and older), 17.9% report current smoking. Among youth (aged 12-17 years), the numbers are substantially lower: 4.6% report past 30-day smoking[4] 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 age 18 and sales to adolescents under age 18 is illegal in every state (and under age 21 in some jurisdictions). Additionally, previous research has shown that recruiting and retaining adolescents into studies about tobacco use is challenging.[6]

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), reviewed and approved the protocol. 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.

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[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. 376(4):342–53.

[5] Trinidad DR et al. (2017). Susceptibility to tobacco product use among youth in Wave 1 of the Population Assessment of Tobacco and Health (PATH) study. Prev Med. 101:8-14.

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

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).

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

- Lightspeed will invite adolescent children of adult panel participants to participate in the study through an email invitation (with links to the screener) to their parents asking for their consent to have their child participate, 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 (with links to the screener). 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. The research organization contracted to manage data collection will receive no personally identifiable information (PII) about participants.
- Respondents will be informed before they encounter the first questionnaire 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 questionnaire.
- Respondents will have the option to decline to respond to any item in the questionnaire for any reason.
- Redirect links embedded in the questionnaire will direct adolescents back to Lightspeed to report having completed the questionnaire and receive non-monetary compensation. All those who handle or analyze data will be required to adhere to the standard data security policies of the research organization contracted to manage data collection.

To ensure data security, all project staff from the research organization contracted to manage data collection are required to adhere to strict standards and to sign a nondisclosure agreement as a condition of employment on this project. They maintain 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 study 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 are 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 and then collected and stored on a protected network share on the network. Only authorized 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 questionnaires will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

Privacy Analysis

In developing this study, FDA consulted the Agency's Privacy Officer to identify potential risks to the privacy of study participants and other individuals whose information may be handled by or on behalf of FDA in the performance of this study. FDA designed the study to minimize privacy risks in keeping with the Fair Information Practice Principles and to apply controls selected from the National Institute of Standards and Technology (NIST) Special Publication 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations*. FDA also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in FDA satisfy all such requirements in accordance with law and policy. FDA submitted a privacy impact assessment which was approved by the FDA and HHS Privacy Offices.

Privacy Act Applicability

The information collection is not subject to the Privacy Act of 1974. Hence, no Privacy Act Statement is required to be displayed on the form, website, mobile application, or other point at which individuals submit their information. The PII collected or used for this study is limited to the minimum necessary to achieve the authorized purpose and produce a valid study. The study is authorized under the FD&C Act. The PII is necessary because it is the manner in which potential participants are being contacted to participate in the study and to ensure there is no duplication of respondents (i.e., IP addresses).

PII Collection

As part of this study, a subcontractor that operates an online panel, acting on behalf of FDA, will maintain PII about potential participants. The PII about potential participants consists of names, email addresses, IP addresses, and other contact information and is collected as a routine part of maintenance of their online panel from which the potential participants will be

drawn. However, that PII will never be shared with the main contractor or with FDA. Contractors and subcontractors that collect data on behalf of FDA never pass along any PII, and at the most we receive ID numbers. For these collections, we don't have any systems where we maintain or retrieve PII.

FDA has minimized the risk of unnecessary access, disclosure, use, or proliferation of PII about respondents. FDA and other parties involved in this study maintain study records containing PII only as long as required. PII is removed prior to being sent to the main contractor and FDA.

Notice and Transparency

All subjects are provided notice regarding the collection and use of the information they submit from the online panel when enrolling. Additionally, information regarding potential data breaches is noted in the consent, assent, and permission forms that all participants must complete prior to study enrollment. The panel provider may collect IP addresses when participants register for the panel, but FDA does not receive IP addresses. FDA and its contractor will notify participants if their IP address is collected.

Individual Participation and Control

Participants and responses are voluntary. Consent is obtained prior to study participation by clicking a button at the bottom of the consent form. While anonymity of respondents generally cannot be assured unless there is a statutory requirement associated with the information collection, information provided by respondents will be kept private to the extent allowable by law. This will be communicated to respondents by means of consent forms. Respondents also will be advised of the following: the nature of the activity; the purpose and use of the data collected; FDA sponsorship; and the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions.

Data Security

Contractors are required to maintain appropriate administrative, technical, and physical safeguards to ensure the security and confidentiality of records. User roles and responsibilities will determine the type and content data and information necessary for job function (both PII and non-PII). Role-based access will determine and control who will have access to PII on an as needed basis. Access to the system is restricted on the business need to ensure minimum extent necessary. All electronic and hard copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers and hard copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals.

Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access

authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from NIST's Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

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 beliefs about the negative health consequences of cigarette smoking. Asking such questions is critical to the objectives of this information collection, namely to ensure that that appropriate sample is included in terms of tobacco use status and to determine if the GHW in the study increase understanding of the negative health consequences of cigarette smoking. Assessing tobacco use is important to understand how such GHW increase understanding among different populations for whom the content of the warnings may be most relevant, namely, adult smokers and non-smokers, young adult smokers and non-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 every state (and under age 21 in some jurisdictions). These questions are essential to the objectives of this information collection. Questions about demographic information (e.g., race, ethnicity, and sexual orientation) 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 study. 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-based 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 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 866 respondents will complete a screener to determine eligibility for participation in the study pretest (identical to the screener for the main data

collection), estimated to take approximately 2 minutes (0.03 hours) per respondent, for a total of 26 hours (14 adults and 12 adolescents) for screening activities. One hundred respondents will complete the pretest (identical to Session 1 of the main data collection), estimated to last 12 minutes (0.20 hours) per respondent, for a total of 20 hours for completion of both adult (14 hours) and adolescent (6 hours) samples in the pretest.

For the main data collection, approximately 80,541 respondents will complete a screener to determine eligibility for participation, estimated to take approximately 2 minutes (0.03 hours) per respondent, for a total of 2,416 hours for screening activities. FDA estimates that 9,760 respondents will complete the main data collection, estimated to last 25 minutes (0.42 hours) per respondent across all three sessions (12 minutes (0.20 hours) for Session 1, 8 minutes (0.13 hours) for Session 2, and 5 minutes (0.08 hours) for Session 3), for a total of 4,099 hours for completion of both adult and adolescent samples. The total estimated burden for this information collection is 6,561 hours.

Table 1. Estimated Annual Reporting Burden

Activity	**No. of Respondents**	**Annual Frequency per Response**	**Total Annual Responses**	**Average Burden per Response**[1]	**Total Hours**
Adult - Screener for pretest	456	1	456	0.03 hours (2 minutes)	14
Adult - Pretest	68	1	68	0.20 hours (12 minutes)	14
Adult - Screener for main data collection	51,054	1	51,054	0.03 hours (2 minutes)	1,532
Adult - Main data collection (3 sessions)	7,460	1	7,460	0.42 hours (25 minutes)	3,133
Total Adult Hours					***4,693***
Adolescent - Screener for pretest	410	1	410	0.03 hours (2 minutes)	12
Adolescent - Pretest	32	1	32	0.20 hours (12 minutes)	6
Adolescent - Screener for main data collection	29,487	1	29,487	0.03 hours (2 minutes)	885
Adolescent - Main data collection (3	2,300	1	2,300	0.42 hours (25 minutes)	966

sessions)	
Total Adolescent Hours	***1,869***
Total Burden Hours	**6,562**

[1] The hours per response are rounded to two decimal places.

12b. ***Annualized Cost Burden Estimate***

The annualized cost to all respondents for the hour burden for the collection of information is $125,501.37 (Table 2). This is calculated by multiplying the burden hours for adults (4,692) by the May 2016 mean hourly wage as reported by the U.S. Department of Labor, Bureau of Labor Statistics[7] ($23.86) for a total of $111,951.12; multiplying the burden hours for adolescents (1,869) by the federal hourly minimum wage ($7.25)[8] for a total of $13,550.25.

Table 2. Estimated Annualized Cost

Portion of Study	**Total Hours**	**Cost per Hour**	**Total Cost**
Total Adults	4,692	$23.86	$111,951.12
Total Adolescents	1,869	$7.25	$13,550.25
Total	**6,561**		**$125,501.37**

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 $898,363. The cost of data collection including programming and hosting the questionnaires, managing the data collection, and delivering the data is estimated at $643,907 (included in total cost). In addition to the costs from programming, hosting, and managing the data collection, $254,456 in 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 (mock cigarette packages and advertisements).

15. Explanation for Program Changes or Adjustments

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

[7] Available at https://www.bls.gov/oes/current/oes_nat.htm#00-0000.
[8] Available at https://www.dol.gov/whd/minimumwage.htm.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 3. Project Schedule

Activity	Date
Conduct pretests and finalize questionnaires	Within 2 months following OMB approval
Conduct experimental study (Complete main data collection)	Within 4 months following OMB approval
Receive data files	Within 5 month following OMB approval
Receive final methodology report and data analysis	Within 6 months following OMB approval

Data collection is planned to begin in early 2019.

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.