

0910-NEW SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food, Drug and Cosmetic Act (FD&C Act) provides FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. The current research will inform the Agency's efforts to implement the provisions of the FD&C Act related to modified-risk tobacco products (MRTPs). MRTPs are defined as tobacco products that are sold or distributed for use to reduce the harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless a modified risk tobacco product application (MRTPA) is submitted and an order issued by FDA pursuant to section 911(g) is effective with respect to such product. Sections 911(g)(1) and (2) of the FD&C Act set forth two bases for FDA to issue an order.

In order for FDA to issue a Risk Modification order under section 911(g)(1) of the FD&C Act, an applicant must demonstrate that, as it is actually used by consumers, the tobacco product will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. In order for FDA to issue an Exposure Modification order under section 911(g)(2) of the FD&C Act, an applicant must demonstrate, among other things, that the magnitude of the overall reductions in exposure to a harmful substance or substances which are the subject of the MRTPA is substantial, issuance of the order would be appropriate to promote the public health, and issuance of the order is expected to benefit the health of the population as a whole taking into account both users and nonusers (including never users and former users) of tobacco products. FDA may issue an order under section 911(g)(2) of the FD&C Act only if scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies, for an application to meet the standards set forth in section 911(g)(1) of the FD&C Act.

Applicants seeking an order under section 911(g)(2) must demonstrate through testing of actual consumer perception that the proposed labeling and marketing of the product does not mislead consumers into believing that the product is or has been demonstrated to be less harmful, or mislead consumers into believing that the product presents less of a risk of disease than one or more other commercially marketed tobacco products according to Section 911(g)(2)(B)(iii) of the FD&C Act.

In addition, Section 911 requires that "any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk

and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products” (FD&C Act § 911(h)(1)). The proposed research will inform the Agency’s efforts to implement the provisions of the FD&C Act related to modified-risk tobacco products.

2. Purpose and Use of the Information Collection

FDA’s Center for Tobacco Products will conduct an experimental study to help inform its implementation of Section 911 of the FD&C Act, wherein they will evaluate information about how consumers understand and perceive tobacco products marketed with modified risk information. Such information could be conveyed in the form of claims, e.g., statements, included in advertising or labeling. There are two broad categories such claims could fall into: One, a risk modification (RM) claim, is one that conveys to the consumer that the product presents a lower—or reduced—level of risk of a tobacco-related disease, relative to other tobacco products in the same class or another class. The other, an exposure modification (EM) claim, conveys to the consumer that the tobacco product presents a reduced exposure to a harmful or potentially harmful constituent relative to another tobacco product (or products) in the same class or a different class. The current experimental study examines modified risk information in the form of both RM and EM claims.

To develop this program of research, FDA assessed the information currently available in the scientific literature related to perceptions, awareness and correlates of interest in products marketed as potentially reduced exposure products (PREPs) (Stratton et al., 2001; Pederson & Nelson, 2007). PREPs included cigarette like products, such as Eclipse, and dissolvable products, such as Arriva, that claimed to reduce exposures to users. A number of these studies employed population-based surveys to examine awareness of and interest in PREPs as well as reported use of, interest in, and beliefs about them (O’Connor et al., 2005; Parascandola et al., 2008; 2009; 2009; 2014; see also Bogen et al., 2009). Findings from these studies suggest that whereas about half of the population reported awareness of PREPs, only a small minority (< 5%) had ever tried them (Parascandola et al. 2009). As might be expected, use of PREPs was more prevalent among current smokers (Parascandola et al., 2008) and among tobacco users, interest in PREPs was associated with greater health concerns, intentions to quit, quit attempts, openness to new products, and nicotine addiction (Parascandola et al., 2008; 2009; 2009; 2014; Shaikh et al., 2014).

A smaller set of studies has examined the impact on consumer beliefs of PREP advertising, which typically contained information about the products’ exposure modification claims. Findings suggest consumers drew conclusions beyond the information that was communicated in the ads, including inferences that the products contained fewer carcinogens and posed fewer health risks than regular cigarettes (Hamilton et al., 2004; Shadel et al., 2006; Shiffman et al., 2004; 2006; Strasser et al. 2008).

More recently, two studies examined consumer reactions to explicit claims of modified risk conveyed in the context of a warning label—namely a statement indicating the product yields “substantially lower risks” compared to other cigarettes (Mays et al., 2015; Popova & Ling, 2014). Findings suggest that such warning label modifications can affect consumer perceptions of the product—e.g., their perceived harm of the product (Mays et al., 2015)—although the effect on perceptions may vary by product type (Popova & Ling, 2014). Finally, one study examined the impact of a modified risk claim when presented in addition to a government warning label. Results presented in that paper suggest the impact of the warning label on risk perceptions was affected by the inclusion of modified risk information among nonsmokers (Capella et al., 2012).

The current experimental study builds on these previous studies by examining the impact of modified risk information on consumer beliefs about and intended use of such tobacco products in several ways, including: employing a more comprehensive host of outcome measures to assess consumers’ reactions to modified risk claims; investigating the impact of product brand (and brand preference) on consumers’ reactions to products with claims; and by experimentally investigating both cigarette and smokeless products among both users and non-users.

In addition to the existing literature, this study is also informed by two sets of focus groups completed August 2012 and February 2014, respectively: Consumer Risk Perceptions of Tobacco Products: Initial Focus Group Study (OMB Control Number 0910-0674) and Consumer Risk Perceptions of Tobacco Products: Second Focus Group Study (OMB Control Number 0910-0497) (see Appendix C). The first set of focus groups was conducted with tobacco users to gain a better understanding of how consumers draw inferences and make judgments about the harmfulness of different products. In the second set of groups, participants discussed and reacted to a set of mock cigarette packs displaying hypothetical RM and EM claims. Findings from the two focus group studies informed the current experimental study in several ways, including highlighting the role of brand on tobacco users’ judgments.

FDA’s Center for Tobacco Products proposes to conduct its “Experimental Study on Consumer Perceptions of Modified Risk Tobacco Products” to develop generalizable scientific knowledge to help inform its implementation of Section 911 of the FD&C Act. Specifically, FDA plans to evaluate information of the type expected to be submitted to the agency in MRTPAs about how consumers understand and perceive tobacco products marketed as MRTPAs.

FDA proposes to conduct an experimental study using an online member panel to better understand: how some consumers may perceive and understand explicit claims; how exposure to information about modified risk or exposure (i.e., claims) influence intentions to try or purchase a tobacco product; and how individual characteristics, such as current tobacco use and/or brand loyalty, might influence these outcomes. Information from the experimental study may also assist FDA in determining what methods and measures are most appropriate for gathering such information from consumers for the evaluation of MRTPAs.

The impact of different claims pertaining to modified risk or exposure on perceptions and potential product adoption will be evaluated by conducting a series of three sub-studies which, in turn, will examine: the impact of claims about cigarettes (Study 1) or smokeless tobacco (SLT) products (Study 2) among young adult and adult current, former or never users of tobacco; and the impact of such claims on adolescents currently using or susceptible to using tobacco (Study 3). All three studies will assess individual-level factors that might influence the impact of claims on consumer responses, including: brand preference, tobacco use history and behavior, concerns about health risks, and openness to new products. Across all studies, participants will be randomized to either see a (modified risk or modified exposure) claim or not (control condition). In Studies 1 and 2, claims will be displayed on mock product packages and ads. For ethical reasons, adolescents (Study 3) will see claims displayed as statements alone, not attached to product packaging or ads. Consumer reactions to claims will be evaluated by measuring constructs such as: understanding of the claim, perceptions of harm and risk, beliefs about the product, quit intentions, and intention to try or purchase the product.

3. Use of Improved Information Technology and Burden Reduction

The study will be administered over the internet. Respondents will be shown an image of a tobacco product 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. Because this is an internet-based study, 100% of the respondents will submit the information in an electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

As reviewed above (Section A.2), there is a related literature of studies examining consumer responses to products that may reduce exposure/harm, including a set of studies examining a specific type of reduced exposure product, which are reduced nicotine cigarettes. Experimental studies have shown that exposure to advertisements for “low nicotine cigarettes” (i.e., Quest cigarettes) led consumers to perceive the product as less addictive and, further, to infer that it is also less harmful, compared to regular cigarettes (Shadel et al., 2006). Further, a subsequent study that experimentally compared digitally-altered versions of the same advertisement for Quest cigarettes concluded that the presence of additional text in the advertisement exacerbated the rate of incorrect beliefs instilled by exposure to the ad (Strasser et al., 2008). The two more recent studies that have examined MRTP claims (Popova & Ling, 2014; Mays et al., 2015) also employed experimental designs. Popova & Ling (2014) conducted an online experimental study with non-smokers wherein participants were randomly assigned to

view one of several labels, including the current Surgeon General’s warnings; one of these labels was an MRTP label that conveyed “lower risk”. In addition, there was a no label condition, and a control group who saw an unrelated ad. These labels were appended to print advertisements for several product types (moist snuff, snus, and e-cigarettes); the order of product type was randomized across participants. A pre-test/post-test design was used to measure perceived harm, positive attitudes towards the product, and openness in trying the product. Results showed that label type influenced consumer responses to the products, although the effects varied by product type. Focusing on the MRTP-relevant label condition (“lower risk”): Results showed the “lower risk” label lowered perceived harm for moist snuff, but not for snus and e-cigarettes; there was no effect (for any product type) on positive attitudes towards the product. Finally, the “lower risk” label increased openness to trying the product, but only for e-cigarettes. In their study, Mays and colleagues (2015) recruited young adult smokers and nonsmokers to participate in an online study in which participants viewed an advertisement for Swedish snus that bore one of several warning labels. Participants were randomly assigned to one of five label conditions. Two of the label conditions conveyed modified risk: a “harm reduction” label (communicating potential-reduced harms of snus compared to cigarettes), and a “harm reduction switch” label (communicating the potential-reduced harm of snus when switching completely to snus from cigarettes). After exposure to the ad, participants completed measures to assess perceived harm and addictiveness of snus, thoughts about not using snus, and intentions to use snus. Results showed that compared to the control condition, participants in the MRTP label conditions were more likely to perceive snus as less harmful than cigarettes. In terms of the effect on thoughts about not using snus, smokers in the MRTP condition reported fewer thoughts about not using snus compared to those in one of the warning label conditions. However, there was no effect of label condition on behavioral intentions.

FDA is also aware of related research efforts currently underway among academic and industry investigators. For instance, some of these projects were presented at the 2016 Society for Research on Nicotine and Tobacco (SRNT) Conference. Thus, we expect the published literature to continue to grow. The current package represents the first in a program of research FDA will undertake to develop knowledge in this area. The FDA-funded longitudinal cohort study, Population Assessment of Tobacco and Health (PATH), is designed to address regulatory science questions facing FDA. The Wave 1 questionnaire included a question about consumers’ interest in “a tobacco product claiming reduced harm”, and a study examining responses to this item was presented via a poster at SRNT (Pearson et al., 2016). Whereas this item, similar to many of the studies in the extant literature on PREPs (reviewed in Section A.2.) assesses interest in the concept of MRTPs, or MRTPs as a product category, the current package will examine consumer responses to specific (hypothetical) products, using experimental methods. Moreover, it is likely that manufacturers wishing to submit MRTPAs will be conducting similar studies to evaluate consumer perceptions of their products. However,

these studies are intended to supplement the current scientific literature regarding consumer perceptions of modified risk tobacco products. Studies by MRTPA applicants will evaluate a particular product. This study is designed to gain information that can be used to inform the Agency's knowledge concerning potential consumer perceptions concerning modified risk tobacco products as FDA evaluates representations of modified risk or exposure on consumers and determines what methods and measures may be appropriate for making such an evaluation.

5. Impact on Small Businesses or Other Small Entities

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

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. The collection of information will provide important data needed for FDA to implement Section 911 of the FD&C Act.

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

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

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of November 19, 2014 (79 FR 68888). FDA received 3 comments 2 of which were related to the PRA. The comments are summarized as follows:

(Comment) One commenter critiqued the inclusion of items assessing brand loyalty, asserting such constructs have “no practical utility” for MRTPA review and is beyond the FDA’s statutory authority because it is not mentioned in the FD&C Act.

(Response) FDA does not agree. Although concepts such as “brand loyalty” are not specifically mentioned in the FD&C Act, FDA seeks understanding of how attitudes toward one’s preferred brand(s) may affect perceptions and understanding of modified risk information (Section 911(h)(1)). The goal of the present experiments is to understand how consumers react to RM and EM claims, in order to inform FDA’s ability to evaluate MRTPAs. Brand loyalty is widely regarded as an important driver of consumer behavior (Keller & Lehman, 2006). Moreover, psychological theory and evidence suggests that the source of information can affect how that information is processed – including whether or not it is perceived as believable, and is persuasive (Eagly & Chaiken, 1993). Thus, consumers’ brand attitudes are highly relevant to

understanding how they interpret and respond to claims made by that brand. To omit this possible influence from our analyses would, in our assessment, limit our ability to fully understand consumer perceptions of MRTPs.

(Comment) One commenter suggested that to assess the variable “purchase interest,” FDA should assign a hypothetical price to the product being studied.

(Response) FDA acknowledges that price plays an important role in consumers’ purchasing decisions. However, examination of the role of price is beyond the scope of the present studies. The experimental design of this study will enable comparisons between experimental conditions on intentions to use the product; thus, rather than evaluating absolute levels of interest, results will examine relative levels of interest across experimental conditions. Thus, the measure of intentions to use the product will assess consumer interest in the product without regard to cost.

(Comment) One commenter noted that Study 1 proposes to focus on conventional cigarettes and asks how FDA proposes to address the issue of novel devices/products when considering consumer perceptions?

(Response) FDA agrees that the current studies are not designed to assess interest in novel devices/products. Addressing questions related to consumer perceptions of novel devices/products, and reactions to claims about those products, is beyond the scope of the current set of studies.

(Comment) One commenter asked for specificity regarding how FDA will define susceptibility to tobacco use among the adolescents in Study 3.

(Response) FDA plans to use items from Pierce and colleagues (1996) to identify adolescents who are susceptible to using tobacco. These items are: (1) Do you think that you will smoke a cigarette soon? (2) Do you think you will smoke a cigarette at any time in the next year? and (3) If one of your best friends were to offer you a cigarette, would you smoke it? Response options are: (1) Definitely yes; (2) Probably yes; (3) Probably not; and (4) Definitely not. A respondent who selects a response of 1, 2, or 3 to any of these items is classified as susceptible.

(Comment) One commenter sought clarification regarding which health warnings will be used (on the study stimuli) alongside the claims and how FDA intends to address the balance between MRTP claims and warnings.

(Response) Study stimuli—images of tobacco product packages and ads—will display the warning labels currently mandated for each product category. The warnings will be rotated (between participants) so that all mandated warnings are used. Because the current studies are not intended to examine the relationship between warnings and claims (including potential interactions between the two), warning label assignment will not be an experimental factor in the study design. Instead, the warnings will be rotated throughout all conditions to control for any differences between them (alone or in combination with a particular claim).

9. Explanation of Any Payment or Gift to Respondents

GMI will provide “MarketPoints” valued at approximately \$10 to panel members who complete the survey. MarketPoints are a routine part of GMIs panel maintenance strategy, and can be traded for material items with GMI partner vendors (e.g., Amazon.com and Starbucks) or for cash. Panel members customarily receive approximately \$10 worth of MarketPoints per survey in recognition of time spent and to encourage cooperation in future panel surveys. Empirical studies show that incentives—particularly pre-paid incentives—can increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys within some respondent populations (Singer & Ye, 2013; LeClare, 2012; Cantor et al, 2003; Singer, 2002; Singer, 1998). 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 (OR 1.19, CI 1.13—1.25), and a second meta-analysis of 26 studies shows that, having begun a web survey, incentives increase the odds of completing it (OR 1.27; CI 1.12—1.44) (Goritz, 2006).

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.

Two statewide studies conducted in Washington by Messer et al. (2011) aimed to determine how incentives affect response rates for paper and web-based surveys. Findings from the first study indicate that inclusion of a \$5 cash incentive in the initial survey mailing produced significantly higher response rates for both mail and web-based survey respondents compared to non-incentive groups. In the “push to mail” group, the response rate was 52.5% among the incentive group and 39.2% in the non-incentive group. Similarly, in the “push to web” group, the response rate was 31.1% for the incentive group and 13.4% for the non-incentive group ($p \leq 0.05$). To further determine how incentives affect response rates, the second study aimed to determine how using a second incentive in a follow-up mailing impacts response rates. Response rates for the web-based survey were not significantly different using the second \$5 incentive compared to those that did not receive the second incentive. However, for the paper survey, respondents who received the second incentive had a significantly higher response rate than those who did not receive the second incentive (68.4% versus 59.3%).

A similar study was conducted in Wisconsin to determine how incentives affected response rates on a paper survey and whether a second incentive increases the response rate (Dykema et al., 2012). The Survey of Health of Wisconsin was conducted among 2,608 households in Wisconsin. Households were randomly assigned to receive a cash

incentive of \$2 or \$5 in the initial survey mailing. The group that received the \$5 incentive had a significantly higher response rate than the group that received the \$2 incentive (60.9% and 53.4%, respectively). Respondents who received the \$5 second incentive had a response rate of 69.5%, which was higher than the response rate for respondents who received the second \$2 incentive (64.2%). However, this observed difference is not significantly different.

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 (Stevenson et al., 2011). Respondents were randomly assigned to be in the “push to mail” 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.

Particularly interesting is a study that sought to determine how different incentives affect online survey response rates among technologically savvy respondents (Birnholtz et al., 2004). It is important to note that this survey used a convenience sample. The incentives tested included \$5 cash or \$5 Amazon.com gift code. The distribution method of the Amazon.com gift code was either mailed or emailed with survey instructions. The respondents who received the \$5 cash incentive had a significantly higher response rate (57%) than the \$5 Amazon.com gift code sent via mail (40%) or email (32%) ($p < 0.01$). Authors of this study concluded that cash is a superior incentive for an online survey, even when conducted among technologically savvy respondents.

In a two phase sampling study for the 2011 NHES field test, both \$2 and \$5 cash incentives were used at the screening stage. 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 cost associated with nonresponse follow-up mailings (Han et al., 2012). 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. 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%) (Montaquila et al., 2013).

The National Immunization Survey (NIS) previously described also conducted an experiment to determine how incentives affect response rates (Ward et al., 2014). 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 10 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 who 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 Privacy 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, data analysis and reporting, and will receive the utmost emphasis. The Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection, has reviewed and approved the protocols for the surveys. The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

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 of the Web-based media tracking surveys will be assured in a number of ways: (1) GMI, the subcontracting organization that manages the internet-based research panel, will invite adolescent panel participants to complete the survey through an invitation to their parents asking for their consent to have their child's opinions, which is fully compliant with COPPA's revised standards; each respondent will remain completely anonymous and will be known only by a unique alphanumeric variable; (2) participants will log onto RTI's secure server using a link provided by GMI and this unique identifier, with the result that no information about the respondent's identity will be downloaded to or housed on RTI's server; (3) respondents will be informed before they encounter the first survey item that their data will be kept private consistent with laws governing privacy; (4) respondents will be required to provide their assent to freely participate before they encounter the first survey item; (5) respondents will have the option to decline to respond to any item in the survey for any reason; and (6) redirect links embedded in the survey will direct adolescents back to GMI 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 is 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 and coding). All data

files on multi-user systems will be under the control of a database manager, with access limited to project staff on a “need-to-know” basis only. 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 privacy agreement that emphasizes the importance of respondent privacy and describes their obligations.
- All data entered via the Web-based survey system 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 share.
- Respondents will be given a unique alphanumeric variable and will log onto RTI’s secure server using a link provided by GMI and this unique identifier, with the result that no information about the respondent’s identity will be downloaded to or housed on RTI’s server.

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 answers will not be shared with family members and 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 (SSN). 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. For example, Section 911 of the FD&C Act requires that we understand the potential impact of marketing an MRTP on the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products (including never users and former users) of all ages. Thus, it is important to understand adolescents’ responses to MRTP claims. In order to identify those adolescents at risk of smoking or already smoking we need to ask the adolescents potentially sensitive questions about tobacco use. These questions are potentially sensitive because tobacco use among adolescents under 18 years of age is illegal in a few states and sales to adolescents under 18 years of age is illegal in

all states. 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:

1. 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.
2. Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.
3. 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

12 a. Annualized Hour Burden Estimate

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. The estimated total hour burden of the collection of information is 1,899 hours. Approximately 30,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take approximately 2 minutes (0.030 hours), for a total of 900 hours for screening activities. Three thousand respondents will complete the full study, estimated to last 20 minutes (0.333 hours), for a total of 999 hours for completion of both adult and one adolescent study. The total estimated burden is 1,899 hours.

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Adult Screener	24,000	1	24,000	0.030	720
Study 1 (Adults)	1,800	1	1,800	0.333	599

Study 2 (Adults)	600	1	600	0.333	200
Total Adult Hours					1,519
Adolescent Screener	6,000	1	6,000	0.030	180
Study 3 (Adolescent)	600	1	600	0.333	200
Total Adolescent Hours					380
Total Burden Hours					1,899

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is 36,674.27 (Table 2). This is calculated by multiplying the burden hours for adolescents (n=380) by the federal hourly minimum wage (\$7.25) for a total of \$2,755.00; multiplying the burden hours for adults (n=1,519) by the 2013 mean hourly wage as reported by the United States Department of Labor, Bureau of Labor Statistics (\$22.33) for a total of \$33,919.27. These numbers were added together to arrive at the total annualized cost burden.(United States Department of Labor, 2013)

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Total Hours	Cost per Hour	Total Cost
Total Adults	24,000	1	24,000	1,519	\$22.33	\$33,919.27
Total Adolescents	6000	1	6,000	380	\$7.25	\$2,755.00
Total	30,000		30,000	1,899		\$36,674.27

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 cost of data collection including programming and hosting the survey, managing the data collection and delivering the data to RTI is estimated at \$28,851, which is included in the estimated total cost to the Federal Government for this information collection of \$358,565. 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 various study stimuli depicting MRTP.

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to inform the Agency about the impact of marketing of modified-risk tobacco products on how consumers perceive and understand these products, how claims about modified risk or exposure influence intentions to try or purchase the product and how individual characteristics such as current tobacco use and/or brand loyalty might influence these outcomes.

Table 2. Project Schedule

Activity	Date
Conduct pretests and finalize questionnaire	Within 3 months following OMB approval
Conduct Internet Experimental Survey (Complete data collection)	Within 3 months of approval of final questionnaire
Receive data files and syntax files	Within 2 month of end of data collection
Receive final methodology report	Within 4 months of receipt of data files
FDA completes internal analysis and dissemination	Within 12 months of final methodology report

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." The dissemination may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site. In describing the information collection in any forthcoming publications, reports, or presentations, FDA

will clearly acknowledge the convenience sampling methodology employed and the inherent limitations of online web panels, and that the data do not provide nationally representative estimates and are thus not generalizable to broader populations.

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

No exceptions are requested.