U.S. Food and Drug Administration

FDA Tobacco Prevention Broad Quantitative Research Package

Supporting Statement: Part A

OMB Control No. 0910-0810

Supporting Statement: Summary

- The goal of this project is to measure target audience reactions to various tobacco-related education messages among youth ages 13-17 (N=5,500) and adults aged 18-54 (N=5,500)
- The study will be conducted using web-based surveys that are self-administered on personal computers or mobile devices. The study will consist of an online survey with youth who have experimented with tobacco products or who are at risk of experimenting with tobacco products as well as adult current and former tobacco users. The study will take approximately 20 minutes to complete per participant.
- The outcome of the survey will be an understanding of receptivity to various tobacco-related education messages, tobacco facts, and tobacco related knowledge, attitudes and beliefs. Understanding youth and adult perceptions regarding tobacco products can help refine tobacco-related messaging for future tobacco prevention campaigns.
- The resulting data will be analyzed using conventional tabulation techniques. The study questions collect information about respondents' reactions to messaging, tobacco-related facts, and also include basic demographic and tobacco use information in order to understand whether and how messaging may influence individuals' behavioral intention.

REQUEST FOR APPROVAL DATE: March 1st 2020

Participant Assent/Consent & Parental Notification and Opt-Out Forms

- Attachment A: Parental Notification and Opt-Out Form
- Attachment A1: Email Invitation
- Attachment B: Youth Assent Form
- Attachment C: Adult Participant Consent Form

Data Collection Instruments:

- Attachment D: Youth Screener
- Attachment E: Adult Screener
- Attachment F: Youth Questionnaire
- Attachment G: Adult Questionnaire

Additional Materials:

- Attachment H: Stimuli
- Attachment I: IRB Approval Letter

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SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Food and Drug Administration (FDA) was granted new authority to regulate the manufacture, marketing, and distribution of tobacco products and educate the public about the dangers of tobacco use. Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (P.L. 111-31), FDA is responsible for protecting the public health and reducing tobacco use among minors. Section 1003(d)(2)(D) of the Food, Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) and Sections 2, 3, 105, 201, 204, 904, and 908 of the Tobacco Control Act support the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA will implement multi-strategy youth-targeted public education campaigns to reduce the public health burden of tobacco that will consist of general market paid media campaigns, geo-targeted campaigns to reach specific target audiences, community outreach activities, and a comprehensive social media effort.

Tobacco use is the leading preventable cause of disease, disability, and death in the United States. More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS, 2014). Each day, more than 2,600 youth in the United States try their first cigarette, and nearly 600 youth become daily smokers (NSDUH, 2014). The FDA Center for Tobacco Products (CTP) was created to carry out the authorities granted under the 2009 Tobacco Control Act, to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information.

Through CTP, FDA researches, develops, and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels. FDA will implement youth tobacco prevention campaigns as well as adult tobacco cessation and health information campaigns, which are currently under development and will include evidence-based paid media advertising that highlights the negative health consequences of tobacco use. The objective of the proposed data collection is to measure the effectiveness of tobacco-related facts among youth aged 13 to 17 who have either experimented with smoking or are at risk of experimenting with smoking and adults aged 18-54 who are current or former tobacco users.

This study is designed to measure youth and adult perceptions of various tobacco-related facts and messages. The study will be conducted using web-based surveys that are self-administered on personal computers or mobile devices. The study will use an online survey to target approximately 5,500 youth who are 13-17 years old, and who have experimented with tobacco products or who are at risk of experimenting with tobacco products. Additional facts and messaging will also be tested with 5,500 adult current and former tobacco users ages 18-54. This study will aim to learn about opinions of tobacco product education messaging, tobacco-related facts and tobacco related knowledge, attitudes and beliefs (KABs).

Adult participants will be recruited via existing panels. An introductory email will be sent inviting them to participate in the study and requesting their consent (Attachment C/A1). If they consent, they will be redirected to the online screener (Attachment E). If they qualify to participate in the study, they will begin the survey (Attachment G).

Adult and youth participants will be recruited through an existing panel of adults, including adults with children ages 13-17 who have been prescreened for their willingness for their child to participate in online surveys. For adult recruitment, adult panelists will receive an initial email invitation. For youth recruitment, adults will also receive an email and parental notification and opt-out form that indicates their child has been invited to participate in a new survey (Attachment A/A1). Youth whose parents do not opt-out will then be sent a study assent form (Attachment B). If the youth gives their assent, they will be redirected to the online screener (Attachment D). If they qualify to participate in the study, they will begin the survey (Attachment F).

We anticipate data collection to take place over 2 years. The outcome of the survey will be an understanding of youth and adult reactions to various tobacco-related messages, facts and KABs. Understanding perceptions of tobacco facts can help refine tobacco-related messaging for future tobacco prevention campaigns.

2. Purpose and Use of the Information

The information obtained from the proposed data collection activities is collected from youth ages 13-17 and adults ages 18-54 in American households, and will be used to inform FDA, prevention practitioners, and researchers about youth's receptivity to tobacco-related facts. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Understand what type of tobacco-related facts youth and adults perceive as most effective for tobacco prevention and cessation campaigns.
- Inform FDA and other stakeholders on the impact of potential campaign messages.
- Inform future programs that may be designed for similar purposes.

To achieve these goals, data collection will consist of a survey dissemination to 5,500 youth ages 13-17 and 5,500 adults ages 18-54. The survey dissemination will occur over a 2-year period. Participants will not be re-contacted in this study.

Participants will be recruited via a participant panel composed of adults in the United States and includes adults with children ages 13-17 who have been prescreened for their willingness for their child to participate in online surveys. For youth recruitment, adults will receive an email and parental notification and opt-out form that indicates their child has been invited to participate in a new survey (Attachment A/A1). If the youth gives their assent, they will be redirected to the online screener (Attachment D). If they qualify to participate in the study, they will begin the survey (Attachment F) where they will be asked basic demographic information as well as administered the questionnaire.

All qualified adult participants will receive and email invitation and review and provide consent via an electronic Participant Consent Form (see Attachment C/A1). They will then be redirected to the online screener (Attachment E). If they qualify to participate the study, they will begin the survey (Attachment G).

Data collection will be completed by participants independently on their own electronic devices, such as a mobile phone, tablet, or home computer All potential participants will complete a screener (Attachments D and E) to determine their qualification for inclusion into the study. Upon screener completion, participants will be immediately notified if they qualify. Both the screener and copy testing questionnaire will be compatible for use on smartphones, tablets, and computers.

Questionnaire items that youth participants see will vary depending on their screener responses (i.e., their use of or susceptibility to experimentation with cigarettes, ENDS, or SLT) (see Attachment F). Adult participants will also see questions specifically tailored for that portion of the data collection (see Attachment G).

3. Use of Improved Information Technology and Burden Reduction

This study will rely on web-based survey data collection on receptivity to tobacco use education messaging, tobacco-related facts, or tobacco related KABs among youth ages 13-17 who have either experimented with tobacco use or are at risk of initiating tobacco use and adult current or former smokers ages 18-54. Using an anonymous survey allows the respondent to be more candid with their responses. This allows for more accurate data because respondents provide more honest responses than other types of research methodology, especially since it is clear that the answers will remain confidential. In addition, using a survey will allow for more participates to respond in a cost-effective and timely manner. The self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically at the end of the day, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. Finally, as noted above, this technology permits respondents to complete the interview in privacy. Providing the respondent with a methodology that improves privacy makes reporting of potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) less threatening and enhances response validity and response rates.

Participants will be recruited via a participant panel composed of adults in the United States and includes adults with children ages 13-17 who have been prescreened for their willingness for their child to participate in online surveys (e.g. Market Cube). Market Cube had a proven and demonstrated ability to orchestrate and support the sampling plan specifications of these studies. The panel includes over 600,000 adults and hundreds of thousands of households that include teens. During recruitment for this study, participants will complete the screener electronically on their own device such as a mobile phone, tablet, or computer. This allows for more accurate data collection because respondents provide more honest responses when they use their own devices.

4. Efforts to Identify Duplication and Use of Similar Information

FDA's tobacco prevention and cessation campaign efforts are relatively new, and therefore it is important to develop messages which will have the largest impact on reducing and preventing tobacco use.

There is a need for in-depth testing of youth and adult reactions to different types of tobacco facts. There are limited data sources that can help identify the most effective tobacco use prevention campaign messages. In order to ensure no duplication of efforts, we have reviewed existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's need for information on the tobacco use prevention campaign messages with respect to reducing youth tobacco initiation.

FDA collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the Centers for Disease Control and Prevention, Office on Smoking and Health (CDC/OSH), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health – National Cancer Institute (NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of proposed messages for advertisements;
- Review of questionnaires for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

FDA will share the findings from this collection of information with these agencies. CDC and FDA are developing complementary but distinct communication campaigns to educate the public about the harmful effects of tobacco products. Staff members in FDA's Health Communication and Education unit work closely with staff in OSH's Health Communications Branch. Regularly scheduled conference calls are held to review plans, discuss campaign coordination and share research findings of mutual interest. Staff members in FDA's Health Communication and Education unit are thus working closely with staff in OSH's Health Communications Branch, ASPA, ASPE, and other HHS OPDIVS as appropriate. It was determined that message testing proposed for this data collection do not duplicate CDC/OSH efforts.

Points of contact for this coordination are:

CDC: Diane Beistle, Chief, Health Communication Branch, Phone: (770) 488-5066, Email: zgv1@cdc.gov

CDC: Deesha Patel, Health Communication Specialist, Health Communication Branch, Phone: (770) 488-8503, Email: wnm2@cdc.gov

NCI: Yvonne Hunt, Program Director, Tobacco Control Research Branch, Phone: (240) 276–6975, Email: huntym@mail.nih.gov

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, specific subpopulations or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequence of Collecting the Information Less Frequently

Respondents to this collection of information will answer only once to ensure the participant burden is as low as possible. Without the information collection requested for this evaluation study, it would be difficult to determine the most effective messages to use in upcoming tobacco prevention campaigns. Failure to collect these data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for youth in the United States.

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

There are no special circumstances for this collection of information that require the data collection to be conducted in a manner inconsistent with 5 CFR 1320.5(d)(2). The message testing activities fully comply with the guidelines in 5 CFR 1320.5.

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

Not applicable.

9. Explanation of Any Payment or Gift to Respondents

As is customary with online surveys conducted via panel sampling, panelists are invited by the panel management company to respond to the survey opportunity incentivized with award points that are accrued and redeemable with the panel company for cash or other rewards. For example: 100 points is equivalent to $1 which can be redeemed through Amazon E-Gift voucher or E-Visa. The award points offered for participation in these studies will be valued at not more than $10. A participant must be eligible to participate (per the screener) and submit the questionnaire to receive the token of appreciation.

Numerous empirical studies have shown that a token of appreciation can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g.,

Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002). The use of a modest incentive is expected to enhance survey response rates without biasing responses. An incentive must be high enough to address competing demands for participants' time and to equalize the burden placed on participants with respect to their time and cost of participation. An inadequate incentive may also result in a significantly more difficult and lengthy recruitment process and/or increases in the number of participants who agree to participate and then drop out early. An inadequate incentive may thus result in a more costly and lengthy period of data collection by increasing recruitment and other associated data collection costs.

In this research, we are asking participants to respond to close-ended questions and provide thought-intensive, open-ended feedback on video ads, which requires a high level of engagement. The use of an incentive is provided as a thank you for the participants' time and the effort they expend to participate. We believe that utilizing a point award that is valued at not more than $10 as a token of appreciation in the current study will reduce overall burden by increasing participation rates, thereby reducing the number of participants needed to complete the screener in order to achieve the required sample size.

10. Assurance of Confidentiality Provided to Respondents

This study has been reviewed and approved by an Institutional Review Board (IRB). 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.

Overview of Data Collection System

All information will be collected electronically through a self-administered survey instrument hosted in a secure, online, web-based data collection system. Respondents will be recruited through an existing web-based panel system and screened for eligibility and interest prior to administration of the main information collection instrument. Youth respondents will be ages 13 to 17 who have either experimented with tobacco or are at risk of initiating tobacco, to engage in the study, parents will have had to not opted-out to prior to responding to any study questions. Adult participants will be aged 18-54 and identify as current or former tobacco users. Each respondent will give basic demographic information and then give their opinions of tobacco education messaging, tobacco-related facts or tobacco related KABs. The respondent will participate at the time of his or her choosing. There will be no recruitment of children younger than 13 years of age. FDA will not have direct contact with participants nor will FDA have access to any personal identifying information about the panelists.

Overview of How Information will be Shared and for What Purposes

Information will be collected through a web-based panel system; however, the panel will not participate in the analysis of the data. The panel will provide an aggregated dataset to FDA using a password-protected, encrypted file. The password will not be sent in the same email as the encrypted file. FDA will use this data to analyze respondents understanding and preferences of specific tobacco-related facts. Confounders such as demographic

characteristics, state of residence, and smoking status will be controlled for during the data analysis.

Overview of the Impact the Proposed Collection will have on the Respondent's Privacy
No individually identifiable information or personal identifying information (PII) is being collected. Although demographic information (e.g., gender, age, and race) will be gathered, no direct personal identifiers (e.g., full name, phone number, social security number, etc.) will be collected or maintained as part of the screener (Attachment D and E) or survey (Attachment F and G). As such, because it does not exist, no directly identifying information will be transmitted to FDA, and thus, the Privacy Act does not apply. In addition, the data at the observation level is identified through use only of sample unit identifiers. Neither the panel provider nor FDA employees working on the project will have access to any identifying information.

Overview of Voluntary Participation

During email invitation, potential respondents will be advised of the nature of the survey, the length of time it will require, and that participation is voluntary. The parental notification and opt-out form as well as the youth assent form will inform the participant that their participation is voluntary. Respondents will be assured that they will incur no penalties if they wish not to respond to the information collection as a whole or to any specific questions. Respondents on the web-based survey will have the option to decline to respond to any item in the survey for any reason and may drop out of the survey at any time. These procedures conform to ethical practices for collecting data from human participants.

Overview of Data Security

All web-based respondents will use a link to enter the survey and the survey software will assign them a unique ID and the responses will be anonymous. No Personally Identifiable Information will be linked to the survey data. All data will be reported in the aggregate only. During data collection, all data will be stored on password-protected databases to which only panel employees working on this project have access. The panel will keep the data in non-aggregate form for six months after data collection has been completed, and then the data will be deleted from the password-protected databases. All data will be sent to FDA using a password protected, encrypted file. The password will not be sent in the same email as the encrypted file. FDA will limit access to this portion of the share drive by limiting the personnel with access to this share drive to appropriate project staff.

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. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., current smoking behavior) and some demographic information, such as race, ethnicity, and income,

could be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise respondents that these topics will be covered during the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

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

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

- Participants will be provided with a toll-free phone number for the project director and a toll-free phone number for the IRB hotline should they have any questions or concerns about the study or their rights as a study participant.

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

An estimated one-time reporting burden for this collection will be approximately 5,596 hours (Table 1). This includes the time burden associated with the Screener.

To obtain a final sample of 5,500 youth ages 13-17 who are susceptible to smoking in the future, we will need to screen approximately 8,250 potential respondents. Additionally, to obtain the final sample of 5,500 adults enrolled, we estimate we will need to screen up to 8,250 adults. Because we are using a panel provider with a proven track record of being able to recruit participants that fit specifications for inclusion, we anticipate we will need to recruit 1.5 times our desired sample for this study.

Based on previous experience, we estimate that the screener completion will take no more than five minutes per participant. The parental notification and opt-out process will take an estimated two minutes to complete. The youth assent and adult consent are estimated to take two minutes to complete. Questionnaire completion will take an estimated 20 minutes.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours

Screened Youth	Screener completion	8,250	1	8,250	0.083 (5 min)	688
Screened Adults	Screener completions	8,250	1	8,250	0.083 (5 min)	688
Parents of Invited Youth	Email invite and Parental notification and opt-out process	5,500	1	5,500	0.033 (2 min)	184
Youth Participants	Youth assent	5,500	1	5,500	0.033 (2 min)	184
	Questionnaire completion	5,500	1	5,500	0.333 (20 min)	1,834
Adult Participants	Email invite and Adult consent	5,500	1	5,500	0.033 (2 min)	184
	Questionnaire completion	5,500	1	5,500	0.333 (20 min)	1,834
Total Annualized Hours						**5,596**

12b. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. FDA has conducted many smoking-related surveys of similar length among youth. We have examined diagnostic data from prior surveys and estimate that data collection for this study will take approximately 20 minutes per respondent. We have also allocated a few minutes time for parents to give their permission for their child to participate and for youth to give their assent to participate.

To calculate this cost, the mean hourly wage of $7.25 was used for youth and $23.86 was used for parents. The youth price represents the minimum wage, and the parental costs represent the Department of Labor estimated mean for state, local, and private industry earnings. There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of $7.25 and $23.86 (youth and parent), the estimated one-year annualized cost to participants will be $88,574. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage	Total Cost

			Rate	
Screened Youth	Screener completion	688	$7.25	$4,988
Screened Adults	Screener completions	688	$23.86	$16,416
Parents of Invited Youth	Email invite and Parental notification and opt-out process	184	$23.86	$4,390
Youth Participants	Youth assent	184	$7.25	$1,334
	Questionnaire completion	1,834	$7.25	$13,297
Adult Participants	Email invite and Adult consent	184	$23.86	$4,390
	Questionnaire completion (ad-viewing)	1,834	$23.86	$43,759
Total				**$88,574**

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

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with FCB New York. The total estimated costs attributable to this data collection are $1,213,089 (Table 3). There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA, data collection plan development, instrument development, reporting, IRB, and progress reporting and project management. This information collection will take place over two years and begin in 2020.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-12	5%	$77,490	$3,874
GS-13	10%	$92,145	$9,215
		Total Salary Costs	$13,089
		Contract Cost	$1,200,000.00
		Total	**$1,213,089.00**

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

The analysis will examine overall levels of perceived effectiveness and rating of tobacco-related facts that were tested. Summary statistics will be analyzed for each tobacco-related message for groups such as all youth, at-risk youth, youth who have experimented with smoking as well as for various demographic categories (e.g. age, gender, race/ethnicity). All analyses will be estimated with sampling weights that adjust for non-response and sample design. Findings from these analyses will be used to inform FDA CTP health communication strategies.

Reporting

The reporting and dissemination mechanism will consist of three primary components: (1) summary statistics (in the form of PowerPoint presentations and other briefings) on youth perceptions and preference of tobacco related facts, and (2) a comprehensive evaluation report summarizing findings from this information collection. Summary statistics will include the number of respondents in each racial category as well as respondents who identify as each subcategory of Hispanic/Latino. This Hispanic/Latino data will also be collapsed so that the minimum standard for reporting Hispanic/Latino ethnicity (Y/N) is also reported out.

The key events and reports to be prepared are listed in Table 4.

Table 4. Project Schedule

Project Activity	Date
Survey	March 2020 to March 2021 (Approximate)
Data Analysis	April 2021 to August 2021 (Approximate)
Report Writing and Dissemination	September 2021 to February 2022 (Approximate)

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

We are not requesting an exemption to this requirement. The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.

References

Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section* (pp. 533-538).

Castiglioni, L., Pforr, K., & Krieger, U. (2008, December). The effect of incentives on response rates and panel attrition: Results of a controlled experiment. *Survey Research Methods (*Vol. 2, No. 3, pp. 151-158).

Jäckle, A., & Lynn, P. (2008). Offre de primes d'encouragement aux répondants dans une enquête par panel multimodes: effets cumulatifs sur la non-réponse et le biais. *Techniques d'enquête*, 34(1), 115-130.

Singer, E. (2002). The use of incentives to reduce nonresponse in household surveys. *Survey Nonresponse*, 51, 163-177.

Shettle, C., & Mooney, G. (1999). Monetary incentives in US government surveys. *Journal of Official Statistics*, 15(2), 231.