Multicultural Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Multicultural Youth Tobacco Use

Supporting Statement: Summary

- The goal of this project is to conduct quantitative copy testing of Wave 3 video ads for FDA's Multicultural Youth Tobacco Education Campaign (Multicultural Campaign) among youth ages 13 to 17 (N = 593 enrolled) who are influenced by the Hip Hop peer crowd and are either tobacco users or non-users open to using tobacco (open non-users).

- Participants will be enrolled via a screener survey using targeted advertisements on social media, such as Facebook or Instagram. Participants who qualify for study inclusion will complete the questionnaire online using their own device. Five hundred ninety-three youth who are 13-17 years old, tobacco users or open non-users, and influenced by the Hip Hop peer crowd will be enrolled. Youth must be ages 13-17 to participate in order to comply with Children's Online Privacy Protection Act (COPPA) regulations. The screener will take no more than seven minutes to complete, and the questionnaire will take no more than 25 minutes for participants to complete.

- The study will consist of showing one (1) randomly assigned rough-cut campaign video advertisement from three (3) potential advertisements to a sample of the target audience. Among enrolled respondents, 444 will be randomly assigned to the ad-viewing study group and 149 will be randomly assigned to the non-ad-viewing (control) study group. Up to 8,895 youth will be screened in order to enroll 593.

- The outcome of the study will be an understanding of overall ad performance and potential unintended consequences for Wave 3 video ads for FDA's Multicultural Campaign. Understanding the target audience's receptivity of these video ads can help optimize messaging for FDA's Multicultural Campaign.

- The resulting data will be analyzed using conventional tabulation techniques for quantitative data. Qualitative analysis of open-ended items will also be conducted. The study questions collect information about respondents' reactions to Wave 3 video ads for FDA's Multicultural Campaign and also include basic demographic and tobacco use information in order to understand whether and how these factors may influence individuals' responses to the video ads.

- **REQUESTED APPROVAL DATE:** April 24, 2018

Data Collection Instruments

- Attachment A: Screener
- Attachment B: Questionnaire

Participant Assent/Consent & Parental Opt-Out Forms

- Attachment C: Parental Opt-Out Form
- Attachment D: Participant Assent/Consent Form
- Attachment E: Parent & Participant Electronic Communications

Study Stimuli

- Attachment F: Video Ad Stimuli
- Attachment G: IRB Approval Letter

Multicultural Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Multicultural Youth Tobacco Use

0910-0810

SUPPORTING STATEMENT: PART A

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 to 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 and young adult-targeted public education campaigns to reduce the public health burden of tobacco. FDA has contracted with Rescue Agency (Rescue) for the development of FDA's Multicultural Youth Tobacco Education Campaign (Multicultural Campaign). This campaign will utilize video advertising, community engagement activations, and a comprehensive social media effort targeted to multicultural youth ages 12-17 who are influenced by the Hip Hop peer crowd in order to reach individuals who are at-risk for tobacco use with a tobacco prevention message.

Tobacco use is the leading preventable cause of disease, disability, and death in the United States (USDHHS, 2014). More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS, 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.

For FDA's Multicultural Campaign, youth ages 12-17 who are influenced by the Hip Hop peer crowd were selected as the target audience. It is estimated that more than 80% of adult smokers begin smoking before age 18. The Centers for Disease Control and Prevention (CDC) report that youth cigarette use declined sharply from 1997-2003, but declines have slowed in recent years (CDC, 2010). Today, cigarette use continues to be a significant health risk to youth as 8.0% of high school students and 2.2% of middle school students reported current cigarette use in 2016 (Jamal et al., 2017). Additionally, other tobacco products such as e-cigarettes, cigar products, and hookah have become increasingly common among US teens, even as cigarette smoking continues to decline. From 2011 to 2016, the National Youth Tobacco Survey found that while use of cigarettes decreased significantly among teens, increased use of other products, including e-cigarettes and hookah, offset these decreases, resulting in no significant change in the overall rate of any tobacco product use among teens (Jamal et al., 2017). This trend indicates a need for youth public education campaigns to include a variety of tobacco

products in their messaging efforts.

Additionally, for FDA's Multicultural Campaign, the Hip Hop peer crowd was selected as the target audience as they are a prominent youth peer crowd and demonstrate above average rates of tobacco use (Jordan et al., 2018; Lee, Jordan, Djakaria, & Ling, 2014; van der Rijt, D'Haenens, & van Straten, 2002). Research has consistently noted higher rates of tobacco use among youth influenced by the Hip Hop peer crowd as compared to other youth peer crowds (Jordan et al., 2018; Lee et al., 2014; van der Rijt et al., 2002). In one study, the odds of smoking were roughly twice as high for Hip Hop youth as compared to youth primarily influenced by the Mainstream peer crowd (OR=1.97, 95% CI: 1.03, 3.76) (Lee et al., 2014). Therefore, the target audience of this campaign represents a population that is at high risk of using tobacco products, and thus is in need of health education messaging.

As part of FDA's Multicultural Campaign, FDA will implement video advertising that highlights the negative health and addiction consequences of tobacco use. Before these video ads may be used in this campaign, they must undergo copy testing to assess overall ad performance and the potential for unintended consequences related to viewing the ads. The objective of the proposed data collection is to measure ad perceived effectiveness and unintended consequences of viewing the ads among the campaign target audience of youth who are at-risk for tobacco use and influenced by the Hip Hop peer crowd.

This study is designed to measure participant reactions to three video ads (Attachment F). The study will be conducted using an online screener and questionnaire. Five-hundred ninety-three youth who are 13-17 years old, influenced by the Hip Hop peer crowd, have a valid email address, and who are either tobacco users or non-users open to using tobacco (open non-users) will be enrolled. Participants must be ages 13-17 to participate in order to comply with Children's Online Privacy Protection Act (COPPA) regulations. Although part of FDA's Multicultural Campaign's target audience, youth age 12 will not be permitted to participate in this online study due to COPPA regulations. Participants will be randomly assigned to the control group, where they will not view any ads, or to the ad-viewing group, where they will be asked to view one randomly assigned ad and provide responses to quantitative items and give qualitative feedback about the ad. All participants will be asked to answer questions about their knowledge, attitudes, and beliefs about tobacco use as a check for potential unintended consequences of viewing the video ads.

2. Purpose and Use of the Information Collection

The information obtained through this study will inform the implementation of FDA's Multicultural Campaign. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Optimize video ads for FDA's Multicultural Campaign.
- Inform future programs that may be designed for similar purposes.

Participants will be targeted for recruitment based on factors such as age, geographic location, and interest in Hip Hop cultural pages, keywords, or hashtags. Data collection will be completed by youth independently on their own electronic devices, such as a mobile phone, tablet, or home computer. All potential participants will complete a

screener (Attachment A) to determine their qualification for inclusion into the study. Upon screener completion, participants will be immediately notified if they qualify. All qualified participants will then be prompted to provide their parent/guardian's email address, to facilitate emailing the parental opt-out form (Attachment C) to a potential participant's parent or guardian, and if desired to provide their cell phone number to receive the study link and up to two reminders by text message. Qualified youth whose parents' email does not bounce back and whose parents do not opt them out will be emailed and texted (if selected) a link to complete the participant assent/consent form (Attachment D) and the questionnaire (Attachment B) no less than 24 hours after the parental opt-out form is emailed to their parent/guardian, to allow sufficient time for parental-opt out to occur. Both the screener and copy testing questionnaire will be compatible for use on smartphones, tablets, and computers.

All participants will complete a participant assent/consent form before beginning the questionnaire. The participant assent/consent form will be presented electronically at the start of the questionnaire to collect assent from youth ages 13-17, or consent in the event that a participant was 17 at the time of screening but turned 18 before beginning the questionnaire. Youth will be prompted to read the form and provide their assent/consent by selecting a radio button option. If they do not provide assent/consent, they will not be able to complete the questionnaire. Additionally, if youth who were 17 at the time of screening indicate they are 18 at the time of starting the questionnaire, they will not be able to complete the questionnaire. After providing assent/consent, participants will automatically receive an electronic copy of the form via email. Qualified participants who complete the screener but do not complete the questionnaire will be contacted up to two times via email and text message (if selected) with a reminder to complete the questionnaire (Attachment E).

Participants will be randomly assigned to the control group, which will not view any ads, or the ad-viewing group, which will view one randomly assigned ad from the three video ads being tested. Control and ad-viewing participants will complete a series of questions in the questionnaire to assess sensation-seeking, lifetime and past 30-day use of tobacco products, household tobacco use, and peer cigarette use. These questions will be used to assess effectiveness of the randomization process, ensure there are no confounding differences between groups, and act as control variables (i.e., covariates) in analyses. Following exposure to an ad, ad-viewing participants will be presented with a series of questions designed to assess their initial reactions to the ad, including what they liked or disliked, how the ad made them feel (e.g. sad, afraid, inspired), and, among other things, whether they felt the ad was powerful, informative, meaningful, convincing, terrible, or silly. Additionally, questions will be asked on whether the ad influenced the participant's thoughts about smoking, the degree to which the claims in the ad were believable, and if anything about the ad was confusing or unclear. Finally, all participants will complete a series of questions assessing tobacco-related knowledge, attitudes, and beliefs, which are used to examine for the presence of unintended consequences.

3. Use of Improved Information Technology and Burden Reduction

The use of electronic screener and questionnaire surveys offers a number of benefits. First, computerized administration permits the instrument designer to incorporate into the instruments routings that might be overly complex or not possible using a paper-based

survey. For example, screener surveys can be programmed to implement skip patterns based on a respondent's previous answers. Interviewer and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. Second, electronic administration increases the consistency of the data. The electronic screener and questionnaire can be programmed to identify inconsistent responses and attempt to resolve them through respondent prompts. This approach reduces the need for most manual and machine editing, thus saving time and money. In addition, it is likely that respondent-resolved inconsistencies will result in data that are more accurate than when inconsistencies are resolved using editing rules. Third, electronic data collection permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry, will be minimized). These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. Finally, this technology permits respondents to complete the instruments 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.

During recruitment for this study, participants who click on a social media ad 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, since it is clear that the answers will remain private. In addition, use of social media as a recruitment tool will cast a wider net to identify eligible study respondents who are members of this very specific population. Recruitment via social media, such as Facebook or Instagram, will also help to contain costs, allowing for a sample that is geographically diverse without driving up research costs for travel during data collection.

This study, which relies on electronic data collection to provide accurate records of questionnaire completion, will reduce burden by increasing participation rates, thereby reducing the number of participants needed to complete the Screener in order to achieve the desired sample size.

4. Efforts to Identify Duplication and Use of Similar Information

The video ads being tested in this study are original to FDA's Multicultural Campaign and have not previously been copy tested or publically aired. As such, there are no existing datasets that can be used or modified to address FDA's need for information on reactions to the video ads for FDA's Multicultural Campaign. Additionally, FDA's Multicultural Campaign targets a specific subpopulation, i.e. youth ages 12-17 who are at-risk for tobacco use and influenced by the Hip Hop peer crowd. As such, there are no national level surveys or datasets that focus on this specific target audience. This type of focused recruitment of youth in the target audience is necessary to test the effectiveness of ads developed for FDA's Multicultural Campaign. Therefore, we have determined that the proposed information collection does not duplicate previous efforts.

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. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the participant burden. 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, it would be difficult to measure target audience reactions to video ads for FDA's Multicultural Campaign. Failure to collect this data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for multicultural 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 CRF 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

The following individuals inside the agency have been consulted on the design of the copy testing plan, survey development, or intra-agency coordination of information collection efforts:

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The following individuals outside of the agency have been consulted on questionnaire development:

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9. Explanation of Any Incentive or Gift to Respondents

In the current study, the token of appreciation for participation is $10 in redeemable gift credits, sent electronically via email as a thank you for the participant's time. The $10 per participant in redeemable gift credits will be distributed through Giftbit, a third party online gift credit distributor. To redeem gift credits, participants will have the option to choose one or more online vendors. A youth 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.

The target audience for the current data collection, multicultural youth ages 13-17 who are influenced by the Hip Hop peer crowd and at-risk for tobacco use, represents a highly specific population which is more difficult to recruit than a general population, increasing the need for an incentive to recruit and retain participants. At-risk youth often experience a number of factors that can lead to decreased engagement and retention in research and prevention programs, such as financial and neighborhood stress, low social support, instability at home, and mistrust of research programs (Hooven, Walsh, Willgerodt, & Salazar, 2011; Zand et al., 2006; Post, Gilljam, Bremberg, & Galanti, 2012). Research participation and retention has also been shown to be lower among multicultural populations (Patel, Doku, & Tennakoon, 2003; Siddiqui, Flay, & Hu, 1996; Giuliano et al., 2000; Murthy, Krumholz, & Gross, 2004). However, a monetary token of appreciation has been demonstrated to be an effective means of recruiting and retaining at-risk and multicultural participants (Martinson et al., 2000; Booker, Harding, & Benzeval, 2011; Caldwell, Hamilton, Tan, & Craig, 2010; Walter, Burke, & Davis, 2013).

For all of the message testing studies regarding the FDA's Multicultural Campaign, an incentive, or token of appreciation, was used. For the first wave of message testing (OMB #0910-0674, Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use among Multicultural Youth) a token of appreciation of $20 was used. The entire in-school study took participants 17 minutes, which included the screener, assent form, and ad-viewing questionnaire. Out of those who were qualified via the screener, 72.4% of participants who were invited to complete the survey completed the final questionnaire.

For the second wave of message testing (OMB #0910-0810, Fresh Empire Campaign: Wave 2 Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use) a token of appreciation of $25 was used for an online survey that took 29 minutes to complete from screener through questionnaire. Out of those invited to complete the questionnaire, 39.0% completed the questionnaire.

While we will take non-monetary steps to increase participation of the target audience such as the use of mobile device-responsive electronic surveys and the delivery of reminders to screener-qualified youth who have not completed their questionnaire, evidence indicates that an incentive for participation is also necessary. As such, we believe that the current study requires the use of $10 in redeemable gift credits as a token of appreciation in order to overcome potential recruitment difficulties for this special at-risk population of multicultural youth, and to promote participation and efficient data collection from the target audience for FDA's Multicultural Campaign.

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, and is similar to the incentive that has been offered for similar surveys. For example, FDA and Rescue previously conducted copy testing research in support of FDA's Multicultural Campaign, "Wave 2 Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use"

(OMB No. 0910-0810). The Wave 2 study utilized online recruitment via social media advertisements following the same procedures outlined for the current study, featured an identical 24-hour parental opt-out waiting period between screener and questionnaire completion, and had a similar time burden estimate. In the Wave 2 study, an incentive of $25 total was found to be critical to minimizing nonresponse after the 24-hour waiting period, with 40% of screener-qualified youth returning to complete the Questionnaire after the waiting period. As these studies share many similarities in target population, recruitment method, parental opt-out waiting period, and time burden estimate, we believe that the requested incentive of $10 in redeemable gift credits is acceptable but participation could increase with a higher incentive. Additionally, we believe that utilizing $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. Privacy Impact Assessment Information

This study has been reviewed and approved by Chesapeake/Advarra IRB, an independent institutional review board. FDA IRB will also review and approve the protocols and forms for this study. The IRBs' primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

The screener will be completed independently online using the participant's personal electronic device. All potential participants will be required to provide electronic informed assent/consent before they begin the questionnaire. The participant assent/consent form will inform participants that the information they provided on the screener and questionnaire will only be viewed by the researchers and that their responses will not be connected with any identifiable information they provided. All analyses will be conducted in the aggregate and participant contact information will not be appended to the data file used.

IP address, participant email address, and zip code will be collected from all respondents. IP address will be automatically collected, and will be used to manage potential duplicate entries and confirm study completion from US-based respondents. All respondents will be asked to provide their email address, which will be checked against all current respondent data to avoid duplicates and reduce fraudulent activity, and will be used to facilitate necessary invitation/reminder communications after the 24-hour parental opt-out period, and delivery of the token of appreciation. All respondents will also be asked to provide their zip code, which will be used to determine geographic eligibility.

Only participants who qualify on the screener will be prompted to provide parent/guardian's email address, and provided an option to provide cell phone number for text-message delivery of invitation/reminder communications if preferred. Therefore, this additional contact information will only be collected from qualified youth. Parent/guardian email will be collected from all qualifying youth to facilitate distribution of the parental opt-out form. Participant cell phone number will be used to send communication about the study, including the link to the questionnaire, via text message if selected by participants. Researchers will only contact participants via email and text message (if selected) to share the link to the questionnaire and up to two reminders, and via email to

deliver the token of appreciation. Researchers may also contact participants in the unlikely case that there is a breach of privacy, for example as a result of hacking or an issue with redeemable gift credit delivery.

After data collection is complete, screener and questionnaire databases will be merged together for analysis, but all personally identifiable information (i.e. email address, cell phone number, IP address, etc.) will be deleted after final data cleaning is conducted and prior to data analysis. That is, all identifying information will be removed from the database before analysis.

The research team will not share personal information regarding participants with any third party unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process. All data will remain on a password-protected computer and/or in locked cabinets for a period of three years after the end of the study, and then will be shredded and/or destroyed. As with any research study, there is a chance that privacy could be compromised. However, great effort is taken to protect participant identity and all responses will be private.

Data Management

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 contained in their regulations. Qualtrics will be the software used for data collection and storage. Qualtrics is a trusted survey tool used by both researchers and marketing companies alike. To be more specific, Qualtrics software is provided via an application service provider, accessed using a modern internet browser where data are stored in a single secure data center. All Qualtrics data are stored in a cloud and are encrypted at rest, and in transit, under password protection in both instances. Data will be stored via the Qualtrics data center under secure monitoring by Qualtrics staff. As the privacy of their customers is of utmost importance to Qualtrics, only the researchers will have access to the data.

For raw data collected during this research, all servers are hosted using industry standard firewalls. Industry standard firewalls include the ability to allow or block traffic based on multiple forms of connection (e.g., state, port, and protocol), rather than only one connection, meaning that access is limited to those who are allowed entry. In addition, Rescue will follow the Standard of Good Practice (SoGP, https://www.securityforum.org/research/thestandardofgoodpractice2016/) security practices which emphasize security management, safe business application protocol, safe computer installations, network fidelity, awareness of systems development requirements, and safety of the end-user environment. Following these guidelines, the monitoring of data and sensitive information will take place following the SoGP security practices such as limiting access to information and data encryption. Members of the research team will access the information through a secure log-in using a password on an HTTPS site, which ensures that data will be in an encrypted format when it is transmitted. This data transfer will occur via an encrypted and secure broadband connection.

11. Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of the target audience that the FDA is trying to reach. This may require asking questions about age, sex, race/ethnicity, and/or health behaviors on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that the FDA speaks with the kinds of people for whom its messages are intended. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

In order to identify multicultural youth at-risk for tobacco use, researchers need to ask sensitive survey-based questions about race/ethnicity and tobacco use behavior. Raw data that includes both personally identifiable and sensitive information (e.g., contact information and tobacco use in the screener survey) will be managed so personally identifiable information is not retained once the data have been extracted and aggregated. Personally identifiable information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

In addition, this study includes the following procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- The screener and questionnaire are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

- Participants will be provided with an email address and phone number for the Rescue project manager should they have any questions or concerns about the study or their rights as a study participant.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection is 1,376 hours (Exhibit 1). This includes the time burden associated with the Screener.

To obtain a final sample of 593 enrolled participants, we estimate that we will need to screen up to 8,895 potential respondents. This is because, based on previous experience, we anticipate one in every 15 participants who complete the screener will qualify for inclusion and return after the 24-hour parental opt-out waiting period to complete the questionnaire.

Based on previous experience, we estimate that screener completion will take no more than seven minutes per participant. The parental opt-out process and electronic communications will take an estimated six minutes to complete. The youth assent/consent and electronic communications are estimated to take six minutes to complete. Questionnaire completion will take an estimated 25 minutes for ad-viewing participants and 10 minutes for control participants.

Exhibit 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	8,895	1	8,895	0.117	1,041
Parents of Invited Youth	Parental opt-out process including Participant Electronic Communications	800	1	800	0.083	66
Participants	Youth assent/consent including Participant Electronic Communications	593	1	593	0.10	59
	Questionnaire completion (ad-viewing group)	444	1	444	0.417	185
	Questionnaire completion (control group)	149	1	149	0.167	25
Total Annualized Hours						**1,376**

12b. Annualized Cost Burden Estimate

Respondents participate on a voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. Rescue has conducted many studies of similar length and content among youth.

To calculate this cost, an hourly wage of $7.25 was used for youth and $23.86 for parents. These prices represent the federal minimum wage and average hourly wages for US youth and adults, respectively, according to the U.S. Department of Labor (DOL) Bureau of Labor Statistics. There are no direct costs to respondents associated with participation in this study. Thus, assuming an average hourly wage of $7.25 for youth and $23.86 for parents, the estimated cost to participants will be $11,072.26. The estimated value of respondents' time for participating is summarized in Exhibit 2.

Exhibit 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Screened Youth	Screener completion	1,041	$7.25	$7,547.25
Parents of Invited Youth	Parental opt-out process	66	$23.86	$1,574.76
Participants	Youth assent/consent	59	$7.25	$427.75
	Questionnaire completion (ad-viewing group)	185	$7.25	$1,341.25

	Questionnaire completion (control group)	25	$7.25	$181.25
Total		**1,376**		**$11,072.26**

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 Rescue. The total estimated costs attributable to this data collection are $899,219.40 (Exhibit 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 occur in 2018.

Exhibit 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	5%	$ 94,796	4,739.80
GS-13	10%	$ 94,796	9,479.60
		Total Salary Costs	$14,219.40
		Contract Cost	$885,000.00
		Total	**$899,219.40**

15. Explanation for Program Changes or Adjustments

This is a new individual generic data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The analysis will examine perceived effectiveness scores by ad, and knowledge, attitudes, and beliefs about tobacco use. Perceived effectiveness scores will be analyzed for all viewers of each ad, and may also be analyzed by demographic characteristics (i.e. gender, race/ethnicity). Responses to the knowledge, attitude, and belief questions will be compared between ad-viewing and control participants to identify any statistically significant differences. Findings from these analyses will be used to optimize video ads for FDA's Multicultural Campaign.

Reporting

The reporting and dissemination mechanism will consist of one primary component: summary statistics (in the form of PowerPoint presentations and other briefings) on participant reactions to video ads and potential unintended consequences. The key events and reports to be prepared are listed in Exhibit 4.

Exhibit 4. Project Schedule

Project Activity	Date
Survey	May 2018 to July 2018 (Approximate)
Data analysis	July 2018 to August 2018 (Approximate)
Presentation of findings	August 2018 to September 2018 (Approximate)

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

Not applicable. All data collection instruments will display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable. There are no exceptions to the certification statement.

References

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