

SUPPORTING STATEMENT: PART A

LGBT Campaign: Wave 1B Online Quantitative Study Designed to Prevent Young Adult Tobacco Use

Supporting Statement: Summary

- The goal of this project is to conduct quantitative copy testing of Wave 1B video ads for FDA's Lesbian, Gay, Bisexual and Transgender (LGBT) Campaign among LGBT young adults aged 18 to 24 (N = 1,050 enrolled) who have smoked a cigarette on 1-29 days out of the past 30 days, but not every day.
- 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 copy testing questionnaire online using their own device. One-thousand fifty young adults who are 18-24 years old, who have smoked a cigarette on 1-29 days out of the past 30 days, but not every day will be enrolled. The screener will take approximately 4 minutes to complete, and the questionnaire will take approximately 2 minutes for control participants and 10 minutes for ad-viewing 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. Approximately 700 enrolled respondents will be randomly assigned to the ad-viewing study group and approximately 350 enrolled respondents will be randomly assigned to the non-ad-viewing (control) study group. Approximately 3,150 young adults will be screened in order to enroll 1,050.
- The outcome of the study will be an understanding of overall ad performance and potential unintended consequences for the Wave 1B video ads for FDA's LGBT young adult campaign. Understanding the target audience's receptivity of these video ads can help optimize messaging for FDA's LGBT young adult 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 1B video ads for FDA's LGBT young adult 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:** January 3, 2017

Data Collection Instruments

- Attachment A: Screener
- Attachment B: Questionnaire

Consent Form & Reminder Emails

- Attachment C: Informed Consent Form
- Attachment D: Reminder Emails

Social Media Advertisements & Study Stimuli

- Attachment E: Social Media Advertisements
- Attachment F: Video Ad Stimuli

- Attachment G: IRB Approval Letter

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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 young adult-targeted public education campaigns to reduce the public health burden of tobacco. FDA has contracted with Rescue Social Change Group (Rescue) for the development of FDA's Lesbian, Gay, Bisexual and Transgender (LGBT) young adult campaign. This campaign will utilize video advertising, community engagement activations, and a comprehensive social media effort targeted to LGBT young adults in order to reach individuals who are current but not daily tobacco users 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 LGBT young adult campaign, LGBT young adults ages 18-24 were selected as the target audience. The LGBT population is comprised of sexual and gender minorities that face disparities in access to health care, overall health status, risk for mental health illness, and are more likely to engage in risk behaviors such as smoking and alcohol and substance abuse (The Joint Commission, 2011). Therefore, the target audience of this campaign represents a population that is at high risk of smoking, and thus is in need of health education messaging.

As part of FDA's LGBT young adult campaign, FDA will implement video advertising that highlights the negative health 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 perceived ad effectiveness

and unintended consequences of viewing the ads among the campaign target audience of LGBT young adults ages 18-24 who have smoked a cigarette at on 1-29 days out of the past 30 days, but not every day.

This study is designed to measure participant reactions to 3 video ads (Attachment F). The study will be conducted using an online screener and questionnaire. One-thousand fifty LGBT young adults who are 18-24 years old, influenced by LGBT culture, have a valid email address, and who have smoked a cigarette at on 1-29 days out of the past 30 days, but not every day will be enrolled. 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 1 randomly assigned ad and provide quantitative and 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 LGBT young adult tobacco prevention 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 LGBT young adult campaign
- Inform future programs that may be designed for similar purposes.

Participants will be selected using targeted online social media recruitment. Social media advertisements will target potential participants based on factors such as age, geographic location, and interest in LGBT-related keywords. All potential participants will complete a screener (Attachment A) to determine their qualification for inclusion into the copy testing study. Upon screener completion, participants will be immediately notified if they qualify. All qualified participants will then be automatically directed to an informed consent form (Attachment C) where participants will be required to provide consent before starting the copy testing questionnaire (Attachment B). Both the screener and copy testing questionnaire will be compatible for use on smartphones, tablets, and computers.

Participants will review the study consent document and provide consent via an electronic informed consent form (Attachment C) presented prior to the start of the copy testing questionnaire. At the start of the copy testing questionnaire, participants will be prompted to read the form and provide consent electronically. Participants must complete the informed consent form to continue to the copy testing questionnaire. After providing consent, participants will automatically receive an electronic copy of the informed consent form via email. Qualified participants who complete the screener but do not complete the copy testing questionnaire will be contacted up to two times via email with a reminder to complete the copy testing questionnaire. Participants will be randomly assigned to the control group, which will not view any ads, or the ad-viewing group, which will view 1 randomly assigned ad from the 3 video ads being tested. All participants will complete a short series of questions in the questionnaire to assess participants' current use of any tobacco products, household use of any tobacco products,

and peer cigarette use. These questions will be used to assess the effectiveness of the randomization process and ensure there are no confounding differences between groups. 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, confident), 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 the actions they might take in response to the ad (e.g. sharing the ad, mentioning it to a friend). All participants will complete a series of questions assessing understanding of the health consequences of tobacco, whether smoking cigarettes is good or bad, enjoyable or not enjoyable, and other attitudes about tobacco use. These questions 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 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 LGBT young adult 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 LGBT young adult campaign. Additionally, FDA's LGBT young adult campaign is relatively new and targets a specific subpopulation, i.e. LGBT young adults ages 18-24 who are non-daily cigarette smokers. As such, there are no national level surveys or datasets that focus on this specific target audience. This type of focused recruitment of young adults in the target audience is necessary to test the effectiveness of ads developed for FDA's LGBT young adult 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 LGBT young adult campaign. Failure to collect these data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for LGBT young adults 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

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:

Tesfa Alexander
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Center for Tobacco Products
Food and Drug Administration

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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

The amount of the incentive for participation is a \$15 online gift card, sent electronically via email within 72 hours of survey completion as a thank you for the participant's time. For the online gift card incentive, participants will have the option to choose one of several online gift card vendors.

In this research, we are asking participants to provide both close-ended questions and thought-intensive, open-ended feedback on video ads that require a high level of engagement. The use of incentives is provided as a 'thank you' for the participants' time and the effort they expend to participate. The incentive is similar to incentives that are offered for other surveys of this type.

Numerous empirical studies have shown that incentives 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 modest incentives is expected to enhance survey response rates without biasing responses. Incentives must be high enough to equalize the burden placed on participants with respect to their time and cost of participation, as well as provide enough motivation for them to participate in the study rather than another activity.

10. Privacy Impact Assessment Information

FDA IRB has reviewed and approved the protocols and consent 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 informed consent form will inform participants that the information they provide in the screener will only be viewed by the researchers and will not be connected with any other identifiable information they provide. The screener will be completed independently online using the participant's personal electronic device. In addition, all potential participants will be required to provide electronic informed consent before they begin the copy testing questionnaire. All analyses will be conducted in the aggregate and participant contact information will not be appended to the data file used.

IP addresses will be collected from all participants in order to help manage potential duplicate entries and study completions from non-US based respondents. However, IP address will not be retained after data cleaning is conducted. The Participant's email address will be collected during the screener and if the participant does not complete the questionnaire immediately after screener qualification, email address will be collected again during the beginning of the questionnaire. All participants regardless of qualification will be asked to provide their email address. Participants will be asked to provide their email address to facilitate necessary invitation/reminder communication and to deliver their online gift card incentive. Email addresses will also be checked against all current respondent data to avoid duplicates and reduce fraudulent activity. Researchers

may contact participants if follow-up regarding copy testing questionnaire completion is required or in the unlikely event of a confidentiality breach.

Self-reported age as well as birth month and year from screeners will be used to confirm age eligibility, and used as a fraud detection measure. System-calculated age from participant's self-reported birth month and year must correspond to their self-reported age in years. Participant's birth month and year will be deleted from the screener database prior to analysis. Thus, all data will be completed de-identified prior to 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 confidential.

Data Management

During data collection, all data will be stored on a HTTPS secure website and data will be managed by the research team on their password-protected computers.

After data collection is complete, screener and questionnaire databases will be merged together for analysis, but all identifying information (i.e. email address, IP address, month/date of birth, etc.) will be deleted after final data cleaning is conducted prior to data analysis. That is, all identifying information from the screener database will be deleted, resulting in a de-identified dataset.

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 race/ethnicity, sexual orientation, income, education, health behaviors and/or health status 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 LGBT young adults, researchers need to ask sensitive survey-based questions about gender identity and sexual identity. The FDA acknowledges such questions are potentially sensitive. However, because recruitment efforts will utilize sexual identification targeting, it is assumed that the large majority of potential respondents already self-identify as LGBT.

Raw data that include both personally identifiable and sensitive information (e.g., contact information and gender and sexual identity in screening questionnaires) 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

12 a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection will be approximately 427 hours (Exhibit 1). This includes the time burden associated with the screener.

To obtain a final sample of 1,050 enrolled participants, we estimate that we will need to screen approximately 3,150 potential respondents. This is because, based on previous research conducted with this target audience, we anticipate approximately 1/3 of participants who complete the screener will qualify for inclusion and complete the copy testing questionnaire.

Based on previous experience, we estimate that screener completion will take approximately 4 minutes per participant. The informed consent form will take 5 minutes to complete. Questionnaire completion will take approximately 10 minutes for ad-viewing participants, and approximately 2 minutes for control participants.

Exhibit 1. Estimated Annual Reporting Burden

*Rounded figure

Type of Respondent	Activity	Number of Respondent ¹	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Screened Participants	Screener	3,150	1	3,150	0.067	210
Participants	Informed Consent/reminder email	1,050	1	1,050	0.083	87
	Questionnaire (ad-viewing group)	700	1	700	0.17	119
	Questionnaire (control group)	350	1	350	0.03	11
Total Annualized Hours						0*

¹The total number of respondents is 3,150; for this study 1,050 represents the total number of participants

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. Rescue has conducted many surveys of similar length and content among LGBT young adults.

To calculate this cost, the mean hourly wage of \$25.53 was used, this price represents the average hourly wage according to the U.S. Department of Labor (DOL) Bureau of Labor Statistics as of April 2016. There are no direct costs to respondents associated with participation in this study. Thus, assuming an average hourly wage of \$25.53, the estimated cost to participants will be \$10,873.23. The estimated value of respondents' time for participating in the information collection is summarized in Exhibit 2.

Exhibit 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Screened Participants	Screener completion	210	\$25.53	\$5,361.30
Participants	Informed Consent/reminder email	87	\$25.53	\$2,221.11
	Questionnaire completion (ad-viewing group)	119	\$25.53	\$3,038.07
	Questionnaire completion (control group)	11	\$25.53	\$280.83
Total		427		0

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 approximately \$296,077 (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 2017.

Exhibit 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	5%	\$ 73,846	\$3,692.30
GS-13	10%	\$ 73,846	\$7,384.70
		Total Salary Costs	\$11,077.00
		Contract Cost	\$285,000.00
		Total	\$296,077.00

15. Explanation for Program Changes or Adjustments

This is a new 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. sexual orientation, 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 LGBT young adult tobacco prevention 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 LGBT young adult 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	January 2017 to March 2017 (approximate)
Data analysis	March 2017 to April 2017 (approximate)
Presentation of findings	April 2017 to June 2017 (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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