

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF PRETESTING OF TOBACCO COMMUNICATIONS (0910-0674)

TITLE OF INFORMATION COLLECTION: Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Smokeless Tobacco Use Among Rural Youth; OMB Control Number 0910-0674

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of Need

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance 0910-0674 to conduct surveys with rural white males aged 12–17 who are current smokeless tobacco experimenters or susceptible to smokeless tobacco use (N=798). The purpose of the surveys is to understand their reactions to different youth smokeless tobacco prevention campaign rough cut advertisements. Research results will be used to assess whether rough-cut advertisements provide an understandable and engaging message about the harms of smokeless tobacco use without potential unintended adverse or counterproductive effects.

2. Intended Use of Information

The information will inform CTP's efforts to develop and implement public education campaign messaging related to preventing smokeless tobacco use among rural youth aged 12–17, with a focus on those most susceptible to use—white males. Surveys will be conducted to explore the target audience's reactions to five rough-cut advertisements. The sample of participants will be divided into exposure and control groups. Participants in exposure groups will view two advertisements each. Participants in the control group will not take the portion of the survey focusing on reactions to the rough cut ads. The study will answer the following questions:

- Do the rough-cut advertisements provide understandable messages about the harms of smokeless tobacco use?
- Do the rough-cut advertisements provide engaging messages about the harms of smokeless tobacco use?
- Do the rough-cut advertisements have any potential unintended adverse or counterproductive effects related to beliefs around the harms of smokeless tobacco use?

3. Description of Respondents

Participants for this study will consist of white males aged 12–17 (n = 798) who currently reside in non-metro counties and are experimenting with smokeless tobacco (i.e., have tried smokeless tobacco, but have used it less than 100 times in their lifetime) or are at-risk for smokeless tobacco use (i.e., indicate that they are curious about smokeless tobacco, would use smokeless it in the future, and/or would use it if a friend offered it to them). Based on prior research that has been conducted for this campaign, it is estimated that three youth will need to be screened for every one youth that is enrolled as a survey participant. An estimated 2,394 youth will be screened, and one-third of those (N=798) respondents will participate in

the actual survey. A total of 570 participants will be in the ad view group, and another 228 participants will not view a rough-cut advertisement.

	Ad View Group*	No Ad View Group*	Total
Experimenters	285	114	399
At-Risk	285	114	399
Total Respondents	570	228	798

*The overall sample will be 798, but cell sizes may vary slightly, depending on participant enrollment and randomization.

4. Date(s) to be conducted:

The study is projected to take place between September 1, 2015 – August 31, 2016, pending study approval.

5. How the Information is being collected:

The information is being collected by research staff from Fors Marsh Group and Michael Cohen Group who will administer the surveys in a series of school-based survey sessions with eligible students. Depending on school preferences, surveys will be administered during elective periods, lunch periods, or when other extra-curricular activities are taking place at the school.

The administration of surveys will be conducted as follows. Once participants are identified as eligible and given proper time for parental notification and/or consent, they will be notified of the time and location of their survey appointment. Upon arrival, students will be given a brief overview of the study and instruction on how to complete the survey [3 minutes]. Participants will then complete the survey [15 minutes]. Upon completion of the survey, participants will be given incentives for taking part in the study and instructed to return to their ongoing classes [2 minutes].

In the event that participants are unable to take the survey while in school, they will be provided with an in-home option. The survey will be identical to the tablet-based version except properly rendered for standard internet browsers. This option will only be employed if students are entirely unavailable to take the survey during the school-based process described above. The students will be given a card with a URL directing them to the survey. This option will only be employed if additional participants are needed and there are difficulties in scheduling times to take the survey in schools. IP addresses will not be collected by the online survey system, and survey links and access codes that are uniquely coded for each participant will not be used to identify participants or link them to the results. No first- or third-party cookies will be stored during questionnaire completion and/or during the gift card distribution process. Although 12 year-olds are part of the campaign target audience, at home administration will only be used as an option among those 13-17 in order to adhere to regulations set forth in the Children’s Online Privacy Protection Act (COPPA).

Participants selected to view advertisements (Ad View Group) will first be provided with questions about their exposure to smokeless tobacco use and lifetime smokeless tobacco use. Following these questions, participants will view a rough-cut advertisement and will then be prompted to complete a questionnaire designed to assess whether the advertisement provides an understandable and engaging message about the harms of smokeless tobacco use. They will then view a second advertisement and will then be prompted to complete the same questionnaire provided after viewing the first advertisement.

Following completion of the advertisement questions, participants will be provided with general questions about their attitudes and beliefs about the harms of smokeless tobacco use as well as additional demographic questions. The questions targeting general attitudes and beliefs about the harms of smokeless tobacco use are being collected to assess potential unintended consequences.

Participants selected not to view any advertisements (No Ad View Group) will only be provided with the questions about exposure to smokeless tobacco use and lifetime use, the questions about attitudes and beliefs around the harms of smokeless tobacco use, and the additional demographic questions. Participants who do not view any advertisements are being included to measure for unintended consequences.

6. Confidentiality of Respondents

All data will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law. Each participant will be assigned a unique ID and will be referred to only by their first name and last initial (James M.) during the recruitment process. The following measures will be used to ensure privacy once the survey process begins: (1) Full names of the participants are never used on any survey materials – instead we will only use the participant unique ID during the survey process; (2) The surveys do not ask for the recording of any personally identifying information and any lists or logs with first names are stored securely on a password-protected computer; and (3) given responses to the survey are not attributed to the individual. No identifying information will be included in any data, reports or slides delivered to the FDA.

Personally Identifying Information. The youth assent and parental consent/opt-out forms contain a statement that no one will be able to link the respondent's identity to his responses. The survey will not ask participants to provide identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the FDA. The contractor will not share personal information regarding participants with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. All identifying information, including information collected during screening will be kept on a password-protected computer by the PI in locked cabinets for a period of at least three years, and then will be destroyed either by the shredding of documents or the permanent deletion of electronic information.

All data will be reported in aggregate form such that data collected cannot be traced back to particular participants or schools. Researchers will never tie respondents' personal information to their answers. All analyses will also be done in the aggregate and respondent information will not be appended to the data file used.

Data Security. In-school data will be collected via electronic tablet (e.g., iPad) and paper in the event a backup is required. FMG ensures encryption of electronic data, and all data will be encrypted in transit using HTTPS. In-home data will be collected via an online survey. As noted above, IP addresses will not be collected by the online survey system, and survey links and access codes that are uniquely coded for each participant will not be used to identify participants or link them to the results. No first- or third-party cookies will be stored during questionnaire completion and/or during the gift card distribution process. All data received by FDA will remain stored in a locked filing cabinet or on a password protected computer or server. After three years, all of the collected data will be destroyed by securely shredding documents or permanently deleting electronic information.

7. Amount and Justification for any Proposed Incentive

The amount of the incentive is \$20, which will be provided in the form of a prepaid gift card. The amount proposed for the incentive will be provided to participants for their entire burden time, which includes screening time, obtaining active/passive parental consent, and participating in the survey.

Incentives must be high enough to equalize the burden placed on respondents in respect to their time and cost of participation, as well as provide enough incentive to participate in the study rather than another activity (Russell, Moralejo, & Burgess, 2000). Incentives are now common practice in most all forms of survey research as a method of ensuring adequate response rates (Singer & Ye, 2013). If the incentive is not sufficient, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with recruitment and staff time (Morgan & Scannell, 1998). Incentives are also necessary to ensure adequate representation among harder-to-recruit populations such as youth, low socioeconomic groups, and high risk populations (current or former tobacco users and those susceptible to tobacco use) (Groth, 2010).

Given the specific parameters of this study, the target population is considered a harder-to-recruit population on multiple accounts (youth aged 12-17 who are also susceptible to or currently experimenting with smokeless tobacco use and located in rural counties). In the previous round of research for this study, which involved focus groups with a sample of the same population, an average of only 37 students per school were eligible based on their smokeless tobacco status. With a hard to reach population, ensuring high participation rates among the qualified sample is instrumental to reducing recruiting and travel costs to reach these individuals. Incentives are effective in motivating participation among a qualified sample (Singer & Kulka, 2002). Thus, it is critical to provide adequate incentives to encourage participation among the limited number of potential youth participants.

Incentives are standard practice for all work conducted and are suggested by organizations that set the standards for conducting ethical market research among human subjects (CASRO Code of Standards and Ethics for Survey Research). The same incentive proposed for this study was used in the last round of research in this campaign and response rates were near 100%. An incentive less than \$20 per survey could potentially inhibit the ability to successfully recruit participants who will show up for the survey. In terms of response quality there is little evidence so far suggesting that an incentive of this amount will have any negative effect (Singer & Couper, 2008; Singer & Ye, 2013). As a minimal intervention study with low burden, the incentive amount is considered appropriate and based in precedent.

The participation incentive will be paid directly to the participant via a pre-paid gift card that functions as a debit card (participants will **not** be required to pay any potential fees associated with activating the card). There are several benefits to paying participants with a gift card versus cash or check, including: (1) Providing gift cards will prevent research staff from having to carry around large sums of cash while on campus, (2) Any sensitivity toward paying youth with cash is avoided (i.e., ability to use cash for illicit substances like drugs, alcohol or tobacco), and (3) Any issues preventing participants and/or their parent/guardian from cashing a check (e.g., no bank account) are avoided.

8. Questions of a Sensitive Nature

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, 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>).

FDA tobacco use communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, and some projects may involve asking questions about (or discussing) how one perceives his own personal risk for serious illness. This information is needed to gain a better understanding of the target audience so that the messages, strategies and materials designed will be appropriate and sensitive. Questions of this nature, while not as personal as those about sexual behavior or religious beliefs, for instance, still require some sensitivity in how they are worded and approached. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation.

FDA tobacco communications may also be concerned with discouraging tobacco use by youth before they start. This study will copy test the rough-cut advertisements for the rural smokeless campaign with youth who are at-risk for using or are experimenting with smokeless tobacco. This means excluding youth who are “closed” to using smokeless tobacco and youth who have used smokeless tobacco more than 100 times or currently use

smokeless tobacco “about every day” or “more than once a day.” In order to identify these youth, we need to ask potentially sensitive questions regarding their own tobacco use behavior and intentions. These questions are potentially sensitive since tobacco use among adolescents under 18 years of age is illegal in most states and sales to youth under 18 years of age is illegal in all states. Guardians of youth participants will be made aware that FDA/CTP does not encourage the use or sale of tobacco products.

9. Description of Data Analysis

The surveys will yield quantitative data that can be used for certain types of statistical analyses. Statistical software (such as R, SPSS or Stata) will be used to clean and organize the data before analyses. The analyses may include but are not limited to comparisons of means, *t*-tests, calculation of summary statistics and cross-tabulations and any appropriate estimates of uncertainty. Although some statistics will be calculated, the convenience sampling procedures for the survey do not allow for results that are nationally representative and any point estimates may not represent the population at-large.

BURDEN HOUR COMPUTATION

Burden calculation = Number of respondents Estimated participation time in minutes/60*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
12-17 years old: (Screener, Youth Assent)	2,394	10	399
Parental Consent or Opt Out		5	200
Actual Participants			
12–17years old: (Surveys)	798	20	266
Total ¹	2,394		865

¹The total number of respondents is 2,280; one-third of those (798) represent the total number of participants in this study.

REQUESTED APPROVAL DATE: August 24, 2016

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FDA CENTER: Center for Tobacco Products (FDA/CTP)

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