FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF TESTING COMMUNICATIONS ON TOBACCO PRODUCTS (0910-0796)

TITLE OF INFORMATION COLLECTION: The Real Cost Smokeless: Wave 2 Focus Group Study of Reactions to Creative Advertising Concepts Designed to Prevent Rural Youth Tobacco Use; OMB Control Number 0910-0796.

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is seeking Office of Management and Budget (OMB) approval under generic clearance 0910-0796 to conduct focus groups with rural male youth aged 12–17 (n<=144) who are either experimental smokeless tobacco users or at-risk non-triers. For this study, we are seeking participants from rural locations, defined as those living in RUC (Rural Urban Codes) 5-9[1], with an emphasis on RUCs 7–9 (see Table 1). These locations (particularly those in codes 7-9) are often geographically isolated. The research will be used to assess advertising concepts designed to reduce youth tobacco use. Specifically, this research assesses participants' qualitative responses (such as initial reactions to the concepts, what they liked and didn't like, if the ads were relatable or grabbed their attention) to creative concepts. These responses are then used to decide whether or not to move forward and develop creative concepts into ads and are also used to further refine these concepts into ads.

For FDA's *The Real Cost Smokeless* Campaign, rural male youth aged 12-17 are the target audience. According to the National Survey on Drug Use and Health, the use of smokeless tobacco is two to three times higher in rural areas of the United States compared to metropolitan areas. In rural counties, 4.6% of youth 12–17 years old use smokeless tobacco products compared to 1.6% of urban youth 12–17 years old. Furthermore, smokeless tobacco regular use among rural non-Hispanic White males in 12th grade (16.5%) is more than double the average for all rural youth (6.8%), indicating the high level of risk for this particular demographic segment (Johnston, 2012). Per the most recent data from the FDA's Population Assessment of Tobacco and Health (PATH) study, 31.8% of rural, white males 12–17 years of age are either experimenting with, or at-risk for, using smokeless tobacco – this amounts to approximately 629,000 male youth nationwide (NIH 2016; US Census Bureau 2015).

The urgent need for a youth smokeless tobacco use prevention campaign is underscored primarily by two trends. First, the profile of smokeless tobacco users has changed dramatically. Smokeless tobacco has gone from a product used primarily by older men to one used predominantly by young men and boys. In 1970, men 65 and older were almost six times as likely as those 18-24 to use smokeless tobacco regularly, but by 1991, young men

[1] These include rural counties that are classified as non-metro based on the USDA Rural-Urban Continuum Codes (i.e., codes 5-9) (https://www.ers.usda.gov/data-products/rural-urban-continuum-codes/documentation/).

were 50% more likely than men over 65 to be regular users (CDC, 1994). According to the Centers for Disease Control and Prevention (CDC), there were about one million new users of smokeless tobacco in 2012; of those, approximately 46% were under age 18 (SAMHSA, 2014). Comparatively, youth cigarette smoking has declined nearly 55% since 1999; however, youth smokeless tobacco use has remained flat (CDC, 2016). These trends indicate a need for youth public education campaigns targeted at rural male youth. 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.

Although the main target population of this study is rural non-Hispanic White male youth, the study will also look into understanding the reactions toward creative messages and attitudes regarding smokeless tobacco among rural youth of other racial and ethnic backgrounds to ensure that these messages will be well-received among individuals of all racial/ethnic backgrounds within the targeted market areas.

Table 1: RURAL-URBAN CONTINUUM CODES DESCRIPTION	
Metro counties:	
1	Counties in metro areas of 1 million population or more
2	Counties in metro areas of 250,000 to 1 million population
3	Counties in metro areas of fewer than 250,000 population
Non-metro counties:	
4	Urban population of 20,000 or more, adjacent to a metro area
5	Urban population of 20,000 or more, not adjacent to a metro area
6	Urban population of 2,500 to 19,999, adjacent to a metro area
7	Urban population of 2,500 to 19,999, not adjacent to a metro area
8	Completely rural or less than 2,500 urban population, adjacent to a metro area
9	Completely rural or less than 2,500 urban population, not adjacent to a metro area

2. Intended use of information:

The information obtained through this study will inform the implementation of FDA's *The Real Cost (TRC) Smokeless* campaign. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Refine and optimize creative concepts to be developed into video ads for FDA's *The Real Cost (TRC) Smokeless* campaign. Specifically, the goals of this study are to take creative concepts in the form of animatics (drawn images with voice overs) and get qualitative feedback from youth. The feedback includes initial reactions to the concepts, what they liked and didn't like, and if the ads were relatable or grabbed their attention. This feedback is then used to decide if a creative concept should be further developed into an ad and is also used to refine the creative concepts into ads.

- Inform future programs, such as other health messaging campaigns, that may be designed for similar purposes.

3. Description of respondents:

Participants will be enrolled via in-person recruitment at rural middle and high schools (identified as areas with a Rural Urban Continuum code of 5 or higher, with an emphasis on RUCs 7–9, as defined by the U.S. Department of Agriculture) across the US. The screening criteria are based on sex, age, tobacco use status, intention to use tobacco in the future. Regarding tobacco use status, we are specifically interested in those who are susceptible to or have experimented with smokeless tobacco.

All potential participants will complete a screener to determine their qualification for inclusion into the focus groups. The screener survey will be distributed as a paper survey in middle and high school cafeterias during lunch periods. Researchers will sample as many individuals as well as entire groups as possible from every area of the lunchroom so that they represent different ages, genders, grades, and races/ethnicities. Researchers will never turn away individuals who ask to fill out a screener. Potential participants will be informed that any information they provide will be private and not shared with the school or their parents.

All enrolled participants will be asked to answer questions about their tobacco-related knowledge, attitudes, and beliefs, in addition to demographic information which will be collected during the screening process.

4. Date(s) to be conducted:

The study is projected to occur from February 15th to July 15th, 2018.

5. How the information is being collected:

The information is being collected by Fors Marsh Group who will conduct the focus groups. The focus groups will be segmented by school level (middle school or high school), smokeless tobacco status (at-risk or experimenter) and race/ethnicity (non-Hispanic White or all other races and ethnicities—i.e., besides non-Hispanic White). Research will take place in up to four distinct locations and will include approximately 18 focus groups with four to eight participants each (n<=144). While we anticipate traveling only to three locations, we will reserve a fourth location in the event of needing back-up focus groups to ensure desired final sample size. Approximately six focus groups will take place in each of three target locations and each focus group will take approximately 90 minutes. In each focus group, participants will see 3 to 4 rotated concepts from up to 6 total creative concepts. Participants will provide quantitative and qualitative feedback about creative concepts viewed in the focus groups.

Due to the geographic nature of the targeted rural counties, holding focus groups in a traditional focus group center in a metropolitan area is unrealistic. As a result, the focus groups will be held in local, rural schools. Previous experiences with past research in support of this campaign (e.g., Wave 1 creative concept and copy testing) and other research groups

that have conducted school-based research in rural areas (e.g., RTI) indicate that we will likely be limited to conducting the sessions during regular school hours.

The purpose of the focus groups is to gather insights on rural, adolescent males' exposure to and attitudes toward tobacco products including smokeless tobacco as well as perceptions and attitudes towards the creative concepts tested that are helpful in improving creative concepts for *TRC Smokeless* campaign. Potential participants will fill out a brief screener (Attachment A) assessing their smokeless tobacco use status. Participants that are eligible and selected for participation will be provided the appropriate parental permission/opt-out and youth assent materials (Attachment B1, B2, and C) that must be signed before participation (note: parental opt-out does not require a signature; individuals 12 years of age will be provided with a parental permission form even if that school has agreed to parental opt-out forms for individuals 13-17 years of age).

During the focus groups, the moderator will follow the discussion guide (Attachment D) to gather feedback on three to four creative concepts. First, the moderator will welcome the group and set some ground rules. The participants will then be asked to introduce themselves and participate in an icebreaker (5 minutes). The moderator will then expose the participants to three to four creative concepts (Attachment E) in turn, which may include additional executions within each concept. After participants are exposed to a creative concept, they will individually complete a concept rating worksheet (Attachment F) before the group discussion commences. The rating worksheet asks participants to reiterate the main idea of the concept, grade it, rate it on several dimensions, and specify what they found to be most compelling and what they would change. After all participants have completed the worksheet for a given concept, the moderator will lead a discussion about their reactions, thoughts, and opinions of the concept and specific executions. This process will be repeated until the participants have been exposed to all three or four concepts (75 minutes). Concepts will be randomly assigned to groups so that each concept will be shown at least once in each school. Across groups, each concept will be presented in first, second, and third place to help control for order effects. Following the concepts, participants will be asked to complete a concept ranking worksheet (Attachment G), which asks which concept was their favorite and why; which concept would make them stop and think twice, which concept they would share with a friend. Following the worksheet, the moderator will facilitate a conversation to sum up their feedback asking participants which ad would stick with them and if they feel any differently about dip after viewing all the ads (5 minutes). After the summing-up conversation, the moderator will close the group by addressing observers and asking if there are any clarifying questions, time permitting. The moderator would then ask if there are any remaining comments or questions from the participants and then inform participants that tobacco use prevention materials are available in the back of the room for anyone who is interested (5 minutes).

The study will consist of showing three to four (3-4) rotated concepts from up to five (5) creative concept storyboards to a sample of the target audience during in-person focus groups. Participants will provide quantitative and qualitative feedback about creative concepts viewed in the focus groups.

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.

Prior to the focus group facilitation, youth participants will be asked by research staff to complete an assent form and parents will be given a permission or opt-out form as appropriate (in instances where schools agree to an opt-out form parents will be given this form, in instances where schools want a consent form, parents will be given a permission form, in all instances the parents of children 12 years of age will be given a permission form (Attachment B1, B2, B3). These forms will contain a statement that no one will be able to link the respondent's identity to his responses. Additionally, at the beginning of the focus group, the facilitator will review the content of the assent form and reiterate that no one will be able to link the respondent's identity to his responses. Additionally, none of the focus group questions will ask participants to provide identifying information as part of their responses.

Before each group begins, the moderator will obtain verbal permission from the participants to audio record the session. In the event permission is not given, the contractor will refrain from audio recording the session, although live notes/transcriptions may still be taken. The permission/opt-out form will also contain a statement notifying participants that audio recording will occur.

Neither independent contractors nor focus group agencies will 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, a court order, or other legal process. Identifying information will not be included in the reports delivered to the agency. All data received by FDA will remain in a secured area or on a password-protected computer. No data will contain identifying information.

7. Amount and justification for any proposed incentive:

There is no incentive or gift provided to respondents for participation.

8. Questions of a sensitive nature:

The majority of questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess tobacco use. These questions are essential to the objectives of this information collection. Questions about messages concerning tobacco use behavior 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 assent protocol will apprise youth that these topics will be covered during the study. 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:

- 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, and that they may leave the focus group at any time without penalty.

- The screener, ranking and rating worksheets are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

- Participants will be informed that the focus group will be audio recorded and they will have an opportunity to provide or reject consent for the group to be recorded at the start of the focus group.

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

9. Description of statistical methods:

This research relies on qualitative methods to collect data. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters. The sample drawn here is designed primarily to provide information on youth perceptions of up to 5 creative concepts developed for the FDA's *The Real Cost (TRC) Smokeless* campaign.

The campaign contractor Fors Marsh Group has conducted rigorous internal review of the survey instruments. Trained researchers reviewed the screener, rating and ranking worksheets to verify that all questions are worded correctly. Researchers who will be involved in recruitment and data collection will be trained on administration of the instruments to ensure efficiencies in data collection. Moderators will be provided training on the content of the creative concepts and moderator guide to ensure they are equipped to facilitate constructive discussions that address the goals of the research.

BURDEN HOUR COMPUTATION *Number of respondents (X) estimated response or participation time in minutes (/60) = annual burden hours:*

An estimated one-time reporting burden for this collection will be approximately 276 hours (referenced in below table). This includes the time burden associated with the screener, assent/permission forms and the focus group. Based on previous experience, it is estimated that the screener and assent/permission form completion will take approximately 5 minutes. Focus group completion will take up to 90 minutes.

To obtain a final sample of 144 participants, it is estimated that approximately 432 potential respondents (three times the number of participants enrolled) will need to be screened. This number is based on previous rounds of data collection and Survey Sampling International (SSI) estimates based on prior studies and experience.

Estimated Annual Reporting Burden[1]

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	432	1	432	0.083	36
Parents of Invited Youth	Parental permission or opt-out process	144	1	144	0.083	12
Participants	Youth Assent	144	1	144	0.083	12
	Focus Group	144	1	144	1.5	216
Total Annualized Hours						**276**

[1] The total number of respondents is 432; for this study 144 represents the total number of participants

REQUESTED APPROVAL DATE: January 12th, 2018

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