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

TITLE OF INFORMATION COLLECTION: The Real Cost Smokeless: Wave 2 In-depth Interviews 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 in-depth interviews in schools with rural male youth aged 12–17 (n=22) who are either experimental smokeless tobacco users, established smokeless tobacco users, or at-risk for using but have not tried smokeless tobacco. 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 gain a richer understanding of the target audience, including their lifestyle, values, and exposure to smokeless tobacco. Specifically, the insights collected from these interviews will inform development of strategic and creative concepts by ensuring that these concepts speak to experiences that our target can relate to, use imagery and settings that resonate with the target, and talk about the risks of smokeless use that are the most salient to this target.

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 (Kasza, 2017).

Table 1: RURAL-URBAN CONTINUUM CODES DESCRIPTION

[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/).

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

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 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 who are eligible according to other screening criteria to ensure that messages developed for this campaign will be well-received among individuals of all racial/ethnic backgrounds within the targeted market areas.

2. Intended use of information:

The information obtained through this study will inform the implementation of FDA's *The Real Cost Smokeless* campaign in the following ways. One-on-one interviews with students will be held in schools to gain insight into the lifestyle, values, and trends of the target audience (i.e. male rural youth), which will help inform the development of strategic and creative messaging strategies that feel authentic to this audience. Additionally, these in-school interviews will be used to better understand the tobacco environment that surrounds

the participants and their own experiences with tobacco usage in order to better understand how to interrupt this behavior through creative messaging strategies (see Table 2).

Table 2: IN-SCHOOL INTERVIEW DISCUSSION GUIDE SECTIONS AND HOW INSIGHTS WILL INFORM CAMPAIGN DEVELOPMENT

In-School Interview (90 minutes)
SECTION I: Introduction The moderator will explain the purpose of the research, present the ground rules and privacy steps, allow the participant to ask any questions, and get to know the participant.
SECTION II: Day in the Life The purpose of this section is to understand the background life of the participant–including their values, typical behavior, likes and dislikes, and overall home life. This section also includes an activity in which the participant is asked to list some of their favorite things and write out why they are important. • Insights gathered from this portion of the discussion will help create messages that use settings and scenarios that feel authentic to this audience
SECTION III: Tobacco Environment The purpose of this section is to understand situations where participants see and hear about tobacco products. • Insights gathered from this portion of the discussion will help in creating prevention messages that target what negative aspects of smokeless use might most resonate with this audience
SECTION IV: Formative Smokeless Tobacco Experience and Other Tobacco Products The purpose of this section is to gain a deep understanding of each participant's personal experience with smokeless tobacco and, if applicable, their first-hand experience with using it. • Insights gathered from this portion of the discussion will help in creating prevention messages that target what negative aspects of smokeless use might most resonate with this audience
SECTION V: Summary/Messaging Territories The purpose of this section is to get creative insight from youth on messaging areas that they believe would resonate with peers in order to prevent smokeless tobacco usage. • Insights gathered from this portion of the discussion will help in creating prevention messages that target what negative aspects of smokeless use might most resonate with this audience. This section will also allow us to gather insights regarding language and phrasing that would feel most authentic to this audience.
SECTION VI: Community Assignment The purpose of this section is to better understand the participant's larger community. The moderator will show a map of the participant's town and will ask the participant to outline key places they visit. • Insights gathered from this portion of the discussion will help create messages that use settings and scenarios that feel authentic to this audience.
SECTION VII: Closing The moderator wraps up discussion and ensures that all questions have been answered and all comments have been heard.

3. Description of respondents:

Participants will be enrolled via in-person recruitment at rural middle and high schools (identified as areas with a RUC code of 5 or higher) across the US. For this study, locations will be based on high rurality (RUC code greater than 5, with an emphasis on RUCs 7–9 (see Table 1) and high smokeless tobacco prevalence (prevalence rate higher than 6%). The screening criteria are based on sex (males only), age (12-17), tobacco use status, and intention to use tobacco in the future. Specifically, for this study we are interested in recruiting participants who

are either susceptible to smokeless tobacco use, have experimented with smokeless tobacco, or are established users of smokeless tobacco.

All potential participants will complete a screener to determine their qualification for inclusion into the in-depth interviews. The screener survey will be distributed as an electronic survey in middle and high school cafeterias during lunch periods and study halls. Researchers will sample as many male individuals as possible from every area of the lunchroom so that they represent different ages, grades, and races/ethnicities, reflective of the school's male population. 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/guardians.

During the interview, participants will be asked to answer questions about their life such as hobbies, home life, friends, and media usage as well as tobacco-related knowledge, attitudes, and beliefs.

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 in-depth interviews. In-depth interviews will be segmented by school level (middle or high school) and smokeless tobacco status (at risk, experimenter, or established user). The sample will include a mix of races and ethnicities that comprise the target audience – rural, male youth. Research will take place in three distinct locations, with between 6 and 8 interviews taking place in each location for a total of 22 in-depth interviews.

Due to the geographic nature of the targeted rural counties, holding in-depth interviews in a traditional focus group center in a metropolitan area is unrealistic. As a result, the in-depth interviews will be recruited for in local, rural schools as well as held in the 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.

Potential participants will complete a brief screener (Attachment A) assessing their smokeless tobacco use status. The following day, participants that are eligible and selected for participation will be provided the appropriate parent/guardian permission/opt-out form and youth assent materials (Attachments B-D), to be completed by the participant and scheduling information (i.e., where and when their session is).

For all in-depth interviews, the moderator will follow a discussion guide and engage participants with activities (Attachments E-I) to gather insight on the target audience's lifestyle as well as their attitudes, behaviors, and perceptions toward the use of smokeless tobacco.

The interview will last up to 90 minutes. The moderator will lead the participant through discussion (see Table 2), focusing on certain sections based on the participant's smokeless tobacco usage status (i.e., At-risk, Experimenter, Established User).

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 in-depth interview facilitation, participants will be asked by research staff to complete the parent/guardian permission form/opt-out form and youth assent form that will contain a statement that the respondent's identity will not be linked to the interview responses at any time; instead, each participant will be assigned a unique identifier (UID) at the time of recruitment. This UID will be tied to a participant's parental/guardian permission/opt-out and youth assent forms for tracking purposes. Interview questions will not ask participants to provide identifying information as part of their responses. Participant names and contact information will be temporarily linked to their screener responses to determine eligibility; however, only the recruiting team will have access to this linked information—which will be password-protected at all times and destroyed immediately upon completion of the sessions. All participants will be notified that the interviews will be audio-recorded during screening and when signing the assent form. Parents/guardians will also be notified of the audio recording through a parent/guardian consent/opt-out form.

Fors Marsh Group will produce transcriptions of the digital recordings to assist in report writing and to provide the FDA with a written record of the sessions. Electronic copies of the transcripts will be supplied. The contractor will redact the transcripts for any personally identifiable information (PII). Respondents' discussions will remain private to the extent provided by law. The discussion guide for in-depth interviews as well as parent/guardian permission/opt-out forms and youth assent form will contain statements that no one will be able to link a respondent's identity to his responses.

Fors Marsh Group 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, a court order, or other legal process. Identifying information will not be included in the transcripts and digital recordings delivered to the agency. All project information will remain in a secured area or on a password-protected computer. FDA will receive transcripts and a summary report for the in-depth interviews. To ensure participant

privacy, Fors Marsh Group will redact the recordings and transcripts of any personally identifiable information (PII); no identifying information will be provided to FDA at any time. All project information received by the FDA will remain in a secured area and 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:
We will ask potential participants a series of screening questions as part of the recruitment process. In order to reach a wide range of participants, this may require asking questions about race/ethnicity. Respondents will be assured that providing this information is completely voluntary and will be treated as private to the extent allowed by law.

In addition, given the nature of this research effort, participants will be asked about their smokeless tobacco use status, other tobacco product use status, and their perceptions and attitudes toward smokeless tobacco use and other tobacco products. This information is necessary in order to gain insight into which types of messages, strategies, and materials will be most effective among the target audience. Though not as personal as questions about sexual behavior or religious beliefs, for instance, questions of this nature still require some sensitivity in how they are worded and approached. Participants will be informed prior to actual participation about the nature of the project, and the parent/guardian permission form, parent/guardian opt-out form, and youth assent form will emphasize that their participation is completely voluntary, they can skip any questions they do not feel comfortable answering, and they may leave the study at any time for any reason and will still receive their incentive.

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.

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 smokeless tobacco perceptions to inform the FDA's *The Real Cost Smokeless* campaign.

The campaign contractor Fors Marsh Group has conducted rigorous internal review of the instruments. Trained researchers reviewed the screener and discussion guides 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 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 54 hours (referenced in below table). This includes the time burden associated with the screener, assent/permission forms, and interviews. Based on previous experience, it is estimated that the assent/permission form completion will take approximately 5 minutes. Time to complete the screener is approximated at 15 minutes. The in-school interview will take approximately 90 minutes.

To obtain a final sample of 22 participants, it is estimated that approximately 66 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	66	1	66	0.25	17
Parents of Invited Youth	Parental permission or opt-out process;	22	1	22	0.083	2
Participants	Youth Assent	22	1	22	0.083	2
	In-school Interview	22	1	22	1.5	33
Total Annualized Hours						**54**

[1] The total number of respondents is 66; for this study 22 represents the total number of participants.

REQUESTED APPROVAL DATE: January 12th, 2018

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

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