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

TITLE OF INFORMATION COLLECTION: Rural Smokeless Creative Concept Testing – Focus Groups with Rural Youth

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 focus groups with rural males aged 12–17 who are current smokeless tobacco experimenters or susceptible to smokeless tobacco use. The purpose of the focus groups is to understand their reactions to different youth smokeless tobacco prevention campaign creative concepts.

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 (non-Hispanic) males.

The project is designed to explore reactions to various creative concepts and brand stimuli intended to prevent youth smokeless tobacco use. The focus group research will consist of exposing rural youth to up to four creative concepts and three brand stimuli and gathering their feedback and reactions. A moderator will prompt youth to answer questions regarding understanding, relevance, appeal, and motivation of the concepts presented. Focus group results will be used to identify the most promising creative and branding concepts, which will serve as the foundation for final creative development and production.

3. Description of Respondents

In order to develop the appropriate messaging to inform the public, it is important for the FDA to conduct qualitative creative concept testing research with youth at-risk for initiating smokeless tobacco use and those who have experimented with using it.

According to an analysis of 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 (SAMHSA, 2007). Furthermore, smokeless tobacco use among White (non-Hispanic) males is roughly double the average for all rural youth, indicating the high level of risk for this particular demographic segment (Johnson, 2012).

Consistent with these findings, the participants for this study will consist of White (non-Hispanic) males aged 12–17 (n = 192) who currently reside in non-metro counties and are current smokeless tobacco experimenters or susceptible to smokeless tobacco use. We estimate three children are needed to be screened for every focus group participant. A total of 576 respondents will be screened, and one third of those (192) respondents will participate in the actual focus group. The study will consist of twenty four (24) focus groups across four different markets, with eight (8) participants per group. Groups will be held in rural school districts primarily segmented by age—12 to 14 and 15 to 17. Groups will also be separated by smokeless tobacco category (i.e., current smokeless tobacco experimenters or susceptible to smokeless tobacco use). The mix of smokeless tobacco status groups (i.e., experimenter group vs. at-risk group) will be determined as recruiting permits within each school district.

Rural School District	Region	Possible DMAs	Age Range	# of focus groups	# of participants
#1	Southeast	Tri-Cities, TN-VA Clarksburg-Weston, WV Bluefield-Beckley-Oak Hill, WV Paducah et al., KY-MO-IL	12–14	2	16
			15–17	4	32
#2	"Tex-ish"	Sherman-Ada, TX-OK Oklahoma, OK Little Rock et al., AR	12–14	2	16
			15–17	4	32
#3	Great Lakes	Traverse City et al., MI Marquette, MI Ottumwa-Kirksville, IA-MO Quincy et al., IL-MO-IA	12–14	2	16
			15–17	4	32
#4	Rocky Sky	Sioux Falls et al., SD Butte-Bozeman, MT Minot-Bismark-Dickinson, ND Twin Falls, ID	12–14	2	16
			15–17	4	32
			TOTALS	**24**	**192**

4. **Date(s) to be conducted:**
   The focus groups will take place October 2014 – March 2015. A total of twenty-four focus groups (8 participants each) will be conducted in four rural school districts, from each of the target regions: Southeast, "Tex-ish", Great Lakes, and Rocky Sky. The selection of these rural markets was based on the prevalence of youth smokeless tobacco use in these areas and their collective regional diversity.

5. How the Information is being collected:

Sensis is an advertising company partnering with FDA's Center for Tobacco Products to create a smokeless tobacco prevention campaign. For the focus groups, the information is being collected by contractors, Fors Marsh Group and Michael Cohen Group, who will conduct all twenty four focus group sessions. Each focus group will last 90 minutes. The sessions will be live and face-to-face. Recruitment and screening will take place onsite at the schools. Youth Assent will be obtained from participants during screening and prior to the focus group session (written, via online form). We will implement procedures for obtaining "passive" (opt-out) parent/guardian consent for students ages 13-17 unless a school district or principal requires "active" (signed) consent from all parents and guardians. Following screening, assenting participants will be asked to obtain "active" (signed) or "passive" (opt-out) consent from their parent/guardian within 24 hours. In all cases where the Parent/Guardian opt-out procedures are followed, there will be a 24 hour minimum grace period between when the Notification form is provided to the student and when the student is scheduled to participate in a focus group. This grace period is required to allow adequate time for parents/guardians who wish to opt-out to do so. Eligible students who are 12 years old must obtain "active" (signed) consent from their parent/guardian before they can participate. We will also use the "active" (signed) parent/guardian consent for 13-17 year olds in schools where the local principal requires it (i.e., will not approve parental opt-out).

The groups will be led by a professional moderator following loosely structured guides that allow respondents to talk openly and change direction as the discussion unfolds and new topics emerge. The discussion guide is grouped into six sections (see Appendix B for full protocol):

- Introduction to Focus Group/Icebreaker (5 min): moderator will introduce him/herself to the participants and review the purpose of the focus groups. Participants will engage in an ice-breaker to introduce themselves to group.
- Warm-up Activities 5 min): moderator will ask participants about commercials they like, popular brands, and their activities/hobbies. This discussion will serve as a warm-up activity to get participants comfortable talking in the group.
- Creative Concepts (50 min): moderator will present the creative concepts one by one in random order (see Appendix D: Creative Concept & Branding Stimuli). After viewing each concept, participants will complete an individual rating exercise (see Appendix C: Participant Rating Sheet) and then the moderator will facilitate a group discussion reviewing their reactions to the concept.
- Branding Stimuli (15 min): moderator will present the branding concepts one by one in random order (see Appendix D: Creative Concept & Branding Stimuli). After viewing each brand stimuli, the moderator will facilitate a group discussion reviewing their reactions to the concept.
- Comparison (10 min): moderator will ask participants to write responses to three comparison questions including their favorite concept, least favorite concept, and favorite branding logo on colored cards and facilitate a discussion about their responses.
- Closing (5 min): the moderator will wrap up with any remaining comments, thank, and debrief participants.

6. Confidentiality of Respondents

All data will be collected with assurance that the respondents' answers will remain private to the extent allowable by the law. The assent and consent forms contain a statement that no one will be able to link the respondent's identity to his responses. The following measures will be used to answers remain private to the extent allowable by law: (1) Full names of the participants are never used on any focus group materials (typed lists of participants, IP addresses, transcripts, reports, or during the audio recorded discussion) – instead each participant will be assigned a unique ID and will be referred to only by their first name and last initial (James M.); (2) Transcripts and reports do not contain any personally identifying information and are stored securely on a password-protected computer; (3) Quotes that might be used in the final report to illustrate a discussion-derived theme are not attributed to the individual; (4) Any sessions that are live streamed for real-time observation will be accessed via a secure connection by invitation only. The live stream feed will not be recorded and cannot be replayed; thus, no personally identifying information will be captured or stored.

Researchers will never tie respondents' personal information to their answers. Additionally, discussion interviewers 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 agency. All analyses will be done in the aggregate and respondent information will not be appended to the data file used.

Because tobacco use by adolescents is illegal in most states, any information collected about their tobacco use behavior is sensitive. In this study, such sensitive information is necessary to obtain during the screening process to ensure that focus group participants are truly representative of the campaign's target audience. To determine group categorization ("at risk" and "experimenter"), the screener asks a series of questions including (see Appendix A: Screener):

- Have ever tried smokeless tobacco
    - If yes:
        - Have used chewing tobacco, snuff, or dip at least 20 times in entire life
    - If no:
        - Likelihood to use smokeless tobacco soon
        - Likelihood to use smokeless tobacco in the next year
        - Likelihood to use smokeless tobacco if one of their best friends offered it to them

Additionally, smokeless tobacco usage may come up in the focus group discussions. For this reason, the following process is in place to protect this sensitive data. Recruiters will inform school staff, parent(s)/guardian(s) and youth that they will not divulge the youth's responses to the smokeless tobacco-related questions and/or their smokeless tobacco usage status to school staff or parent(s)/guardian(s). Raw data that include sensitive information are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval. Tobacco-specific questions will only be discussed under conditions that protect the youth's privacy as detailed in the previous section. The informed consent form and notification of research will include language telling parents/guardians that the researchers will not share

any information their son provides about his tobacco-related attitudes, beliefs and behaviors. Additionally, recruiters will share the nondisclosure policy of the youth's tobacco-related responses to youth during the screening process. The research team will also inform school staff that they will not divulge the youth's responses to the smokeless tobacco-related questions and/or their smokeless tobacco usage status to the school or parent(s)/guardian(s).

Sessions will not be video recorded, but, when possible, will be live streamed. As mentioned, because the groups will not be held in traditional focus group facilities, there will be no two-way mirror observation. Live streaming will allow additional study personnel from FDA, Sensis, Fors Marsh Group, and Michael Cohen Group to observe without the burden of travel. If used, live streaming will not be recorded and will be utilized only for real-time observation. Sessions will be audiotaped; however, only the people analyzing the data will have access to these recordings to serve as a memory aid for report development. Participants and their parents/guardians will be informed of the audio recording and possibility of live streaming in the consent/assent forms and notification of research. Transcripts of the audio recordings will be used to assist in campaign development and to provide FDA with a written record of the sessions. Identifying information will not be included in the transcripts or reports delivered to the agency. All data received by FDA will remain stored on a password protected computer. 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

Eligible participants who show up for the focus group will receive $25 as a token of appreciation. The proposed incentive amount will be provided to participants for their entire burden time, which includes screening time, obtaining active/passive parental consent, and participating in the 90-minute focus group session.

As participants often have competing demands for their time, incentives are used to encourage participation in research. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation (Halpern, 2004).

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, 2000). If the incentive is not adequate, 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, facility rental, and moderator and observer time (Morgan, 1998). Incentives are also necessary to ensure adequate representation among harder-to-recruit populations such as youth, low socio-economic groups, and high risk populations (current or former tobacco users and those susceptible to tobacco use) (Groth, 2010).

In the context 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). Thus, it is critical to provide adequate incentives to encourage participation among the limited number of potential youth participants.

In the market research community, 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). In other focus groups conducted in schools with youth by Michael Cohen Group, similar incentive values were offered. An incentive less than $25 per interview will greatly inhibit the ability to successfully recruit participants who will show up for their focus group session. As a minimal intervention study with low burden, the incentive amount is considered appropriate.

The participation incentive will be paid directly to the participant via a VISA gift card that functions as a prepaid 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

It is important to evaluate the creative concepts for the rural smokeless campaign with youth who are at-risk for using or are experimenting with smokeless tobacco. This means excluding outliers within the target (i.e., youth who are "closed" to using smokeless tobacco and youth who have used smokeless tobacco more than 20 times). 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 some 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 Statistical Methods

Focus groups are based on qualitative methods and are not intended to yield results that are statistically projectable. Data will be analyzed with standard qualitative data analysis procedures to identify emergent themes and patterns; this may include using content coding software, such as NVivo. Participants will not be re-contacted for any reason for this study.

BURDEN HOUR COMPUTATION

Screener | estimated participation time: 5 minutes
Youth/Parent Assent/Opt-out | estimated participation time: 5 minutes
Focus Group Discussion: 90 minutes

Burden calculation = Number of responses (*) (Estimated participation time in minutes/90)

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
12-14 years old: (Screener, Youth Assent/Parental Consent or Opt Out)	192	10	32
15-17 years old: (Screener, Youth Assent/Parental Consent or Opt Out)	384	10	64
Screened	576		
Actual Participants			
12–14 years old: (Focus Group Discussion)	64	90	96
15–17 years old: (Focus Group Discussion)	128	90	192
Participants	192		
Total [1]	**576**		**384**

[1] **The total number of respondents is 576; one-third of those (192) represent the total number of participants in this study.**

REQUESTED APPROVAL DATE: August 29, 2014

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

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