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

TITLE OF INFORMATION COLLECTION: Focus Groups with Rural Youth to Test Strategic Concepts Designed to Prevent Youth Smokeless Tobacco Use

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 users or susceptible to smokeless tobacco use. The purpose of the focus groups is to understand their reactions to different youth smokeless tobacco prevention campaign messaging strategies.

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.

   The project is designed to explore reactions to various strategic concepts intended to prevent youth smokeless tobacco use. The focus group research will consist of exposing rural youth to up to five strategic messaging approaches 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 strategic concepts, which will serve as the foundation for creative concept development.

3. **Description of Respondents**

   In order to develop the appropriate messaging to inform the public, it is important for the FDA to conduct qualitative strategic 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 = 128) who currently reside in non-metro counties and are current smokeless tobacco users or susceptible to smokeless tobacco use. The study will consist of sixteen (16) focus groups, with an average of eight (8) your participants per group. Groups will be primarily segmented by smokeless use/susceptibility and age.

White (non-Hispanic) males	**Paducah, KY-MO-IL**	**Charleston, WV**	**Wichita, KS**	**Oklahoma City, OK**
Ages 12-14 At-risk for smokeless use	1	1	1	1
Ages 12-14 Smokeless experimenter	1	1	1	1
Ages 15-17 At-risk for smokeless use	1	1	1	1
Ages 15-17 Smokeless experimenter	1	1	1	1
Total Number Focus Groups per Market:	**4**	**4**	**4**	**4**

4. **Date(s) to be conducted:**
   The focus groups will take place in March 2014. A total of sixteen focus groups (8 participants each) will be conducted in four rural markets: Paducah, KY; Charleston, WV; Wichita, KS; and Oklahoma City, OK. 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:**
   For the focus groups, the information is being collected by a contractor, Fors Marsh Group, who will conduct all sixteen focus group sessions. Each focus group will last 90 minutes. The sessions will be live and face-to-face. Assent/consent will be obtained from participants and their parents both during the telephone screener (verbally) and prior to the focus group session (written, via online form).

   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 seven sections (see Appendix B for full protocol):
   - Introduction to Focus Group/Opening Exercise (10 min): moderator will introduce him/herself to the participants and review the purpose of the focus groups. Participants will engage in an ice-breaker and the moderator will take a "quick poll" where participants will respond by raising red, yellow or green cards.
   - Smokeless Tobacco – General Discussion (5 min): moderator will show participants the top 5 answers from their homework assignment task, which asked their top of mind impressions of smokeless tobacco. This discussion will be guided into a discussion about the risks of smokeless tobacco and the perceived harmfulness of smokeless versus cigarettes.
   - Strategic Concepts (50 min): moderator will present the strategic concepts one by one in random order. After viewing each concept, participants will complete an

individual rating exercise ("Participant Rating Sheet") and then the moderator will facilitate a group discussion reviewing their reactions to the concept.

- Image Matching (10 min): moderator will display images and ask participants to match the image to the different concepts ("Image Matching Sheet") and then the moderator will facilitate a group discussion evaluating the images.
- Comparison (10 min): moderator will ask participants to rank the five concepts on key criteria ("Concept Ranking Sheet") and facilitate a general discussion on concept comparison.
- Closing (5 min): the moderator will wrap up with any remaining comments and debrief participants. Study staff will debrief and thank participants' parents/guardians.

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/her responses. The following measures will be used to answers remain private to the extent allowable by law: (1) 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); (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.

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, it is essential to collect tobacco-related sensitive information during the screening process to group youth by smokeless tobacco status ("at risk" and "experimenter"). To determine group categorization, the screener asks a series of questions including (see Screener):

- Personal risk-taking behavior
- Awareness that teens their age use smokeless tobacco
- Belief that smokeless tobacco use among peers is not "a big deal" and not "disgusting"
- Have friends, family, or teammates that use smokeless tobacco (at least one of these groups)
- Have ever tried smokeless tobacco
- 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

Further, smokeless tobacco usage may come up in the interview discussion. For this reason, the following process is in place to protect this sensitive data. Raw data from data collections 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 during the focus group under conditions that protect the youth's privacy. The informed consent form 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 both the parent/guardian and youth during the screening process.

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. Sessions will not be video recorded, but will be livestreamed. Due to the unique nature of the rural location for the focus groups, we will be utilizing meeting rooms in community centers and/or conference centers in hotel venues rather because traditional focus group facilities are not located in rural areas. Because the groups will not be held in traditional focus group facilities, there will be no two-way mirror observation. Livestreaming will be necessary to allow research staff including note takers to observe from a separate room rather than potentially causing disruption by observing from the room utilized for the group discussion. Livestreaming will also allow additional study personnel from FDA, Sensis, and Fors Marsh Group to observe without the burden of travel. Livestreaming will not involve recording of any kind and will be utilized only for real-time observation. Either the service FocusVision or a similar set-up by Fors Marsh Group using their own equipment will be used for the livestreaming. Access to livestreaming by observers who are not at the research site will be controlled by email invitation. Invitations to view the livestream will be sent only to personnel directly involved in the campaign research. Participants and their parents/guardians will be informed of the audio recording and livestreaming during the screening process and will provide verbal consent/assent. The written consent/assent forms for participants and their parent/guardian will also include language regarding the audio recording and livestreaming. Discussion transcripts 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.

7. Amount and Justification for any Proposed Incentive

The proposed incentive amount is $75, to be distributed as follows:

- Participants will receive $50, which includes $40 for the focus group session and an additional $10 contingent on completion of a homework assignment, and
- Participants' parent/guardian will receive $25.

The proposed incentive amount will be provided to participants and their parent/guardian as a token of appreciation, which includes telephone screening time, travel to and from the focus group facility, and participating in (or waiting during 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 tobacco use and located in rural counties). Additionally, there is the burden on participants and their families due to travel time to and from focus group facilities that are located in metropolitan areas. 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). Due to travel time to and from focus group facilities in rural areas of the country and given the hard-to-recruit nature of the target population, our research partner cannot recruit successfully against less than $75 per interview in addition to mileage reimbursement. 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 check. The parent/guardian incentive will be paid directly to the parent/guardian via check. The mileage reimbursement will also be paid directly to the parent/guardian via check. Checks will be issued to participants and parents/guardians at the end of the focus group. This method of payment requires no additional personal information to be gathered. If during the screening process, a parent/guardian indicates that they are unable to cash a check, a gift card that functions as a prepaid debit card will be substituted. If a gift card is chosen, participants will **not** be required to pay any potential fees associated with activating the card.

8. Questions of a Sensitive Nature

It is important to evaluate the strategic concepts for the rural smokeless campaign with youth who are truly at-risk for using and/or have experimented with using smokeless tobacco. This

means excluding outliers within the target (i.e., youth who strongly have no intention to use smokeless tobacco in the future or if offered by a best friend, regardless if they have ever previously used or not). In order to identify these youth, we need to ask potentially sensitive questions regarding their general risk behavior, awareness and attitudes toward peer usage of smokeless tobacco, history of smokeless usage, and likelihood to use smokeless tobacco in the future. 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.

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. Participants will not be re-contacted for any reason for this study.

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

Type/Category of Respondent	**No. of Respondents**	**Participation Time for Screening, Homework and Focus Group (minutes)**	**Burden (hours)**
Four focus groups (8 participants each); white (non-Hispanic) males, ages 12-14, living in rural counties, at risk for smokeless use	32	120	64
Four focus groups (8 participants each); white (non-Hispanic) males, ages 12-14, living in rural counties, smokeless experimenter	32	120	64
Four focus groups (8 participants each); white (non-Hispanic) males, ages 15-17, living in rural counties, at risk for smokeless use	32	120	64
Four focus groups (8 participants each); white (non-Hispanic) males, ages 15-17, living in rural counties, smokeless experimenter	32	120	64
Total	**128**		**256**

REQUESTED APPROVAL DATE: February 28, 2014

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

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