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

TITLE OF INFORMATION COLLECTION: Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Reduce Tobacco Use; 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 focus groups with youth aged 12–17 who have experimented with cigarettes (i.e., have smoked less than 100 cigarettes) to assess their perceptions about advertising concepts designed to reduce youth tobacco use.

2. Intended use of information:

The information will be used to inform CTP's efforts to implement public education campaign messaging related to reducing tobacco use among youth aged 12–17, with a focus on those who have experimented with non-menthol and/or menthol cigarettes.

This project is designed to evaluate emotional and cognitive reactions to creative advertising concepts meant to reduce tobacco use in youth experimenting with cigarettes. The in-person focus groups will consist of exposing youth to up to five (5) TV advertisement concepts and four (4) concepts for a youth tobacco use prevention brand and having them discuss their responses. A moderator will prompt youth participants to answer questions regarding understanding, relevance, and impact of the shared concepts. The results will inform the refinement of the creative concepts and messages to guide the creation of advertisements.

The study will also assess potential differences between those youth who are menthol users and those who are non-menthol users.

3. Description of respondents:

The study will consist of twelve (12) focus groups, each with approximately six (6) youth aged 12–17 who are self-reported experimenters (i.e., have reported smoking between 1 and 100 cigarettes total). Groups will be segmented by grade, gender and self-reported menthol preference (i.e., menthol users vs. non-menthol users). This information will be gathered during the screening process. Two (2) groups will include only youth aged 15-17 who prefer menthol (1 male group and 1 female group). The other ten (10) groups will be split by gender and age and include both non-menthol and menthol users (see table for breakdown). Groups will be diverse by race/ethnicity. For each group, eight (8) youth will be recruited in order to obtain the desired number of participants.

Summary of Group Distribution		
	Male	Female
15-17 year old Experimenters: Menthol-only	1 group	1 group
15-17 year old Experimenters: Non-menthol & Menthol	2 groups	2 groups
12-14 year old Experimenters: Non-menthol & Menthol	3 groups	3 groups
TOTAL	**6 groups**	**6 groups**

4. **Date(s) to be conducted and location(s):**
The focus groups will begin on July 29, 2013 and will be completed by August 6, 2013.[1] The focus groups will be conducted in research facilities located in Morristown, NJ, Knoxville, TN, and Milwaukee, WI. These markets were selected for their reported higher prevalence of youth cigarette smoking, our research partner's past success with local recruitment and research facilities, and the absence of recent FDA youth tobacco use research in these areas.

5. **How the information is being collected:**
A professional moderator with experience leading focus groups with youth will collect the information through twelve (12) in-person, moderated focus groups. The moderator will ask a series of questions using a semi-structured discussion guide, encourage participants to respond openly and spontaneously, and record the respondents' answers and reactions to those questions. The focus groups may be audiotaped if all participants provide consent before discussions begin.

6. **Confidentiality of respondents:**
There will be twelve (12) focus groups with up to six (6) youth each for a total of 72 respondents representing a diverse population.

   Before each group begins, the moderator will obtain verbal consent from the participants to audiotape the session. In the event consent is not given, the contractor will refrain from audiotaping the session.

   The contractor will produce transcriptions of the tapes to assist in report writing and to provide the FDA with a written record of the sessions. One paper and one electronic copy of the transcripts will be supplied. The audiotape and transcript for a given group will be available to the FDA within two weeks of the completion of that data collection. To ensure participant privacy, the contractor will redact the recordings and transcripts.

   All data will be collected with an assurance that the respondents' discussions will remain private to the extent provided by law. The study moderator's guide and consent form will contain a statement that no one outside of the discussion group will be able to link the respondent's identity to his/her responses. Identifying information will not be included in the data files delivered by contractors to the agency.

[1] Pending approval dates and recruitment time.

Neither independent contractors nor focus group agencies will share personal information regarding panel members 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 data collected through the study, including transcripts and digital recordings, will be kept on a password-protected computer and/or in locked cabinets for a period of three years, and then will be destroyed either by the secure shredding of documents or the permanent deletion of electronic information.

All participants will be asked to respect the privacy of the other focus group members. Everyone will be asked to not discuss/reveal anything said during the discussion.

7. Amount and justification for any proposed incentive:

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. In this particular research we are asking respondents to provide thought-intensive open-ended feedback on concepts that require a high level of participation. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.[2]

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[3] as well as provide enough motivation for them to participate in the study rather than another activity. 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 facility rental and moderator and observer time.[4] Additionally, this can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research both of which lead to increased costs. 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).[5]

In the context of this study, the target population is considered a harder-to-recruit population (youth aged 12–17 who are also experimenting with cigarettes). The study also requires respondents to comment on an activity that is a sensitive subject matter and could cause them to be reluctant to participate. Additionally, the nature of the study requires participants to incur costs to travel to the research facility and participate. Thus, it is critical to provide adequate incentives to encourage and retain participation among the limited number of potential youth respondents.

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[2] Halpern, SD., Karlawish, JH., Casarett, D., Berlin, JA., Asch, DA. Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine.* 2004; 164(7), 80l-803.

[3] Russell, ML., Moralejo, DG., Burgess, ED. Paying research subjects: Participants' perspectives. *Journal of Medical Ethics.* 2000;26(2), 126-130.

[4] Morgan, DL, Scannell, AU..Planning Focus Groups. Thousand Oaks, CA: Sage, 1998.

[5] Groth, SW. Honorarium or coercion: use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*. 2010.

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 similar focus groups conducted by our research partner in the past year, the average incentive value was $100 (the recommended incentive for this study), and the lowest incentive was $75. Due to the difficult nature of this recruit, the research vendor has cautioned FDA that the research will be delayed if an insufficient incentive is offered, with costs of up to $10,000 for each day of delay. Additionally, the research partner will refuse to conduct the study if no incentive is provided. For these reasons the minimum incentive fee requested for this research is $50 per respondent.

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, income, 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/her 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. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

FDA tobacco communications may also be concerned with discouraging tobacco use by youth before they start. The FDA acknowledges the sensitivity of questions about the purchase and use of tobacco, which is illegal for minors in most states. Because questions are being asked of youth aged 12–17, interviews will be conducted by moderators specifically trained for interactions with youth.

Raw data from data collections that include sensitive information (e.g., screening questionnaires and audiotapes) 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.

9. Assurance of privacy provided to respondents:

Before each group begins, the moderator will obtain verbal consent from the participants to audiotape the session. In the event consent is not given, the contractor will refrain from audiotaping the session.

The contractor will produce transcriptions of the tapes to assist in report writing and to provide the FDA with a written record of the sessions. One paper and one electronic copy of the transcripts will be supplied. The audiotape and transcript for a given group will be available to the FDA within two weeks of the completion of that data collection. To ensure participant privacy, the contractor will redact the recordings and transcripts.

All data will be collected with an assurance that the respondents' discussions will remain private to the extent provided by law. The study moderator's guide and consent form will contain a statement that no one will be able to link the respondent's identity to his/her responses. Identifying information will not be included in the data files delivered by contractors to the agency.

Neither independent contractors nor focus group agencies will share personal information regarding panel members 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. Upon final delivery to the FDA, transcripts and digital recordings will be destroyed. All data received by the FDA will remain in a secured area. No data will contain identifying information.

10. Description of statistical methods (e.g., sample size and method of selection):

This research relies on qualitative methods and is not intended to yield results that are statistically projectable. Participants will be identified using standard telephone recruitment procedures that employ screening questions about age; current, past and intended cigarette smoking; race and ethnicity; and gender. Recruitment will continue until a representative sample of the required number of participants for each group is obtained.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
15-17 year old Experimenter Screener: Menthol Only	36	5	3
15-17 year old Experimenters: Menthol-Only	2 groups of 6 = 12	90	18
15-17 year old Experimenter Screener: Non-menthol & Menthol	72	5	6
15-17 year old Experimenters: Non-menthol & Menthol	4 groups of 6 = 24	90	36

12-14 year old Experimenter Screener: Non-menthol & Menthol	108	5	9
12-14 year old Experimenters: Non-menthol & Menthol	6 groups of 6 = 36	90	54
Total	288	90	126

REQUESTED APPROVAL DATE: July 25, 2013

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