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

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TITLE OF INFORMATION COLLECTION: Point-of-Sale Creative Concept Testing – Focus Groups with Current Adult Smokers; OMB Control Number 0910-0796.

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 0910-0796 to conduct focus groups with current cigarette smokers (*n*=128) aged 25-54 who have attempted to quit smoking within the past year (i.e., had quit smoking for at least 24 hours within the past year). The purpose of these focus groups is to assess participants' emotional and cognitive reactions to draft creative advertising concepts designed to encourage current adult smokers to make another quit attempt through messaging in and surrounding tobacco retail outlets.

2. **Intended use of information:**
   Information obtained through this study will inform the development and implementation of a Point of Sale Public Education Campaign designed to motivate smokers to take steps towards their next quit attempt. Specifically, focus group participants will answer questions regarding comprehension, relevance, believability, and potential impact of draft creative advertising concepts. Study results will help identify the most promising creative concepts as well as indicate areas for further refinement to guide creation of effective advertisements.

3. **Description of respondents:**
   The study will consist of thirty-two (32) focus groups; each with approximately four (4) current smokers aged 25-54 who have previously attempted to quit smoking within the past year. Additionally, participants must visit a convenience store at least once a month and must at least occasionally buy cigarettes at convenience stores. Groups will be a mix of adult smokers who currently only use cigarettes and poly-tobacco users—current cigarette smokers who also currently use one or more other types of tobacco products (i.e., cigars, smokeless tobacco, hookah/water pipe, cigarillos, and/or electronic cigarettes). Groups will be segmented by age, and this information will be gathered during the screening process. Groups will otherwise be diverse by race/ethnicity and gender. Approximately 512 adults will be screened in order to obtain a sample size of 128.

4. **Date(s) to be conducted:**
   The study is projected to occur between March 22, 2016 and February 28, 2017.

5. **How the information is being collected:**
The information is being collected through thirty-two (32) in-person focus groups led by a professional moderator with experience leading focus groups on sensitive topics including tobacco use. Participants will each complete a short quit journey worksheet prior to group discussion. Then, the moderator will expose each group to up to three (3) creative concepts and ask a series of questions using a semi-structured discussion guide to encourage participants' feedback around understanding, relevance, believability, impact, and motivation of the creative concepts. The moderator will encourage participants to respond openly and spontaneously. If all participants provide consent before discussion begins, their responses may be audio recorded and transcribed. Data will be collected in focus group facilities. Each focus group will last up to 90 minutes. The focus group will also be observed by FDA and campaign contractor staff.

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.

The consent form will contain a statement that no one will be able to link the respondent's identity to his/her responses, and each participant will only be identified by a unique, unidentifiable ID. Additionally, focus group questions 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 data received by FDA will remain in a secured area or on a password-protected computer.

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

The contractor will also produce transcriptions of the recordings 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 audio recording 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 of any PII.

All data will be collected with an assurance that the respondents' discussions will remain private to the extent provided by law. The moderator's guide and consent form will contain a statement that no one will be able to link a 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 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 data received by the FDA will remain in a secured area. No data will contain identifying information.

7. Amount and justification for any proposed incentive:

The amount of the incentive as a token of appreciation is a $75 non-retailer specific electronic gift card.

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.[1]

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[2] 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.[3]

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 low socio-economic groups and high-risk populations (current or former tobacco users and those susceptible to tobacco use).[4]

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 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 providing the information is voluntary and it will be treated as private to the extent

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[1] 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.

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

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

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

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.

Raw data from data collections that include sensitive information (e.g., screening questionnaires, audio recordings) 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. **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 recruiting procedures that employ screening questions about age; current smoking status; past attempts to quit smoking; frequency of visiting convenience stores; gender; and race and ethnicity. Recruitment will continue until a representative sample of the required number of participants for each group is obtained.

BURDEN HOUR COMPUTATION *Number of respondents (128) estimated response or participation time in minutes (/60) = annual burden hours:*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Screening Questionnaire	512	5	43
Consent		5	43
Total Screened	512		86
Focus Group Participants			
Focus Group	128	90	192
Total Participants	128		192
Total[1]	**512**		**278**

[1] **The total number of respondents is 512; the total number of participants in this study is 128.**

REQUESTED APPROVAL DATE: March 22, 2016

NAME OF PRA ANALYST & PROGRAM CONTACT:

PRA Analyst **Amber Sanford**
301-796-8867
Amber.Sanford@fda.hhs.gov

Program Contact **Tesfa Alexander**
301-796-9335
Tesfa.Alexander@fda.hhs.gov

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