FDA DOCUMENTATION FOR THE GENERAL CLEARANCE OF PRETESTING COMMUNICATIONS ON TOBACCO PRODUCTS (OMB Control No. 0910-0796)

TITLE OF INFORMATION COLLECTION: Creative Concept Testing Designed to Prevent Youth ENDS, Cigarette and Other Tobacco Product Use

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (TCA) (Public Law 111-31) was signed into law. The TCA granted to the Food and Drug Administration (FDA) important new authority to regulate the manufacture, marketing, and distribution of tobacco products; to inform the public on health-related issues; and to protect public health by reducing tobacco use and by preventing death and disease caused by tobacco use.

Tobacco use is the leading preventable cause of disease, disability, and death in the United States. More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS, 2014). Each day, more than 2,600 youth in the United States try their first cigarette, and nearly 600 youth become daily smokers (NSDUH, 2014). The FDA Center for Tobacco Products (CTP) was created to carry out the authorities granted under the 2009 Tobacco Control Act, to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information.

To develop appropriate messaging to inform youth about the risks of using tobacco products (e.g. cigarettes, ENDS, cigars/little cigars/cigarillos, smokeless tobacco, or hookah), it is important for the FDA to conduct research to gain insight into youth perceptions of tobacco products and reactions to draft advertising concepts. Information obtained through this study will be used to develop and refine messaging related to preventing tobacco products use among youth aged 12 to 17 who are at risk of initiating or who have experimented with tobacco products.

The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance OMB No. 0910-0796 to conduct focus groups with youth aged 12–17 (n=1620) who: (1) are at risk of initiating tobacco use; (2) have experimented with tobacco; or (3) have experimented with multiple tobacco products. Youth will be diverse in terms of race/ethnicity, gender, and geographical location; we will ensure geographic diversity by conducting focus groups in several locations in the United States.

The purpose of these focus groups is to assess participants' emotional and cognitive reactions to draft strategic and creative advertising concepts designed to reduce youth tobacco use. In addition, we will ask participants about their perceptions regarding use of these products.

These responses are then used to decide whether or not to move forward and develop creative concepts into ads and are also used to further refine these concepts into ads.

2. Intended use of information:

Information obtained through this study will inform the development and implementation of FDA's public health campaigns designed to reduce youth tobacco use. Specifically, focus group participants will answer questions regarding comprehension, relevance, and potential impact of draft campaign strategic and creative advertising concepts. Study results will help identify the most promising creative and strategic concepts as well as indicate areas for further refinement to guide creation of effective advertisements.

3. Description of respondents:

The study will consist of up to 180 focus groups, each with up to 9 youth aged 12–17 who: (1) are at risk of initiating tobacco use; (2) have experimented with tobacco (do not use or experiment with combustibles); or (3) have experimented with multiple tobacco products. The total sample size will be no more than 1620 participants. Groups will be segmented by age and self-reported tobacco product use. Groups will be otherwise diverse by other demographic variables (e.g., race/ethnicity).

4. Date(s) to be conducted:

The study is projected to occur between January 2020 and July 2022.

5. How the information is being collected:

The information will be collected through up to 180 in-person focus groups led by a professional moderator with experience leading focus groups with youth. Each group will be shown strategic (written statements) and/or creative concepts (animatic storyboards or finalized ad) and asked a series of questions using a semi-structured discussion guide to encourage participants' feedback around understanding, relevance, impact and motivation of the shared concepts and strategic concepts (see Moderator Guide). In each focus group, participants will be exposed to up to 10 creative concepts. Additionally, up to 10 strategic concepts will be tested in each group. The moderator will encourage participants to respond openly and spontaneously. Data will be collected in professional meeting rooms or focus group facilities and will be audio recorded. Each focus group will last 95 minutes. The focus groups will also be observed by FDA and campaign contractor staff.

Strategic and Creative Concepts Focus Groups (95 minutes): After a study introduction (5 minutes), the first activity will consist of an ice breaker, such as a discussion about advertising, "TV Ads," which will include questions regarding favorite television advertisements and other advertisements (ads) related to the dangers of smoking cigarettes and/or using e-cigarettes (5 minutes). Next, participants will discuss "Tobacco Use Perceptions," which will involve a group discussion regarding perceptions around tobacco products (10 minutes). Then, participants will engage in a discussion of "Reactions to Strategic and/or Creative Concepts and Ads," when they will be shown up to 10 strategic concepts and up to 10 creative concepts per focus group (65 min). See the Stimuli attachment for examples. After each strategic and/or creative concept is shown, the moderator will ask a series of questions specific to the strategic and/or creative concept (such as feelings about the concept and perceived main message of the concept) to obtain qualitative feedback from the group. Once all of the concepts have been viewed, the moderator will lead youth through a discussion to garner their "Reactions to Concepts as a Whole" as a means to query their reactions to all of the creative concepts and to gain comparative information across the concepts. Finally, the moderator will end the focus group and assist participants with collecting their incentives and checking out of the focus group (10 minutes).

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.

Parents/guardians of all participants will complete a parent permission form prior to their child's participation. The parent/guardian will provide verbal consent on the phone, and then be e-mailed the consent information that they will review to either sign electronically or during the check-in process on the day of the focus group. The consent form clearly states that youth participants must be accompanied to the research facility by a parent/guardian who can give consent.

Qualifying focus group youth participants will be asked to provide verbal assent on the phone during screening. They will also be e-mailed an assent form to review and either sign electronically or during the check-in process on the day of the focus group.

Before each group begins, the moderator will obtain verbal assent from the youth participants to audiotape the session. In the event assent is not given, the contractor will refrain from audiotaping the session, although live notes/transcriptions may still be taken. The parent permission and youth assent forms will also contain a statement notifying participants that audio recording will occur.

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:

CTP will be offering a $25 gift card to participants and a $25 gift card for the parent/guardian of participants as a token of appreciation. The $25 card for the participants is provided as thanks for their entire burden time, which includes obtaining youth assent, time needed to get to and from the interview facility and participating in the 95-minute focus group session.

The $25 gift card for the parent is provided as a token of appreciation for the burden related to getting their child to and from the focus groups, providing parental permission, and any disruption to the normal routine that their child attending this focus group may result in.

As participants often have competing demands for their time, incentives are used to encourage participation in research. 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 also help 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). 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).

Additionally, 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). The contractors conducting this research consistently use this type of incentive structure for studies conducted in schools with youth. An incentive less than the suggested amount per focus group will greatly inhibit the ability to successfully recruit participants who will show up for the focus group session. As a minimal intervention study with low burden, the incentive amount is considered appropriate.

The participation token of appreciation will be issued directly to the participant via 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 debit card versus cash or check, including (1) Providing debit cards will prevent research staff from having to carry around large sums of cash; (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.

In previous studies, CTP has conducted with similar groups of youth (e.g. participants either susceptible to or having experimented with tobacco products) using similar protocols (e.g. 90 minute focus groups in focus group facilities), CTP has used tokens of appreciation of this amount and, with this token of appreciation, was successfully able to recruit and complete the focus groups within the relatively tight schedule for focus group research (4 geographic locations in 4 weeks).

The previous studies that CTP has successfully used tokens of appreciation for focus groups in focus group facilities are as follows: Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Reduce Tobacco Use (OMB 0910-0674); Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Reduce Tobacco Use among General Market Youth (OMB 0910-0674); Wave 3 Phase 1 Qualitative Research: General Market ("The Real Cost") At-Risk Youth Tobacco Prevention Focus Groups (OMB 0910-0674); The Real Cost General Market: Wave 4 Creative Concept Testing Designed to Prevent Youth ENDS Use (0910-0796).

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, and/or health behaviors 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, focus groups 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. Description of statistical methods:

This research relies on qualitative methods and is not intended to yield results that are statistically projectable. Participants will be identified using standard recruitment procedures that employ screening questions about age; current, past and intended tobacco use; race and ethnicity; and gender. We estimate we will need to screen 2.5 times the number of participants to attain our sample number. 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:*

Estimated Burden Hours:

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Youth	Screener completion	4050	1	4050	0.08 (5 minutes)	338
Parent/Guardian	Screener completion	4050	1	4050	0.08 (5 minutes)	338
Parent/Guardian of Invited Youth	Permission	1620	1	1620	0.08 (5 minutes)	135
Participants	Youth Assent	1620	1	1620	0.08 (5 minutes)	135
	Focus Group	1620	1	1620	1.6 (95 minutes)	2,565
Total Annualized Hours						**3, 511**

REQUESTED APPROVAL DATE: December 20, 2019

NAME OF PRA ANALYST & PROGRAM CONTACT:

PRA Analyst: **Ila S. Mizrachi**
301-796-7726
Ila.Mizrachi@fda.hhs.gov

Program Contact: **Tesfa Alexander**
301-796-7745
Tesfa.Alexander@fda.hhs.gov

FDA CENTER: **Center for Tobacco Products**

REFERENCES:

CASRO. (2013) *CASRO Code of Standards and Ethics,* Available at: http://www.casro.org/?page=TheCASROCode. Accessed on: 06/07/2013.

Groth, S.W. (2010). Honorarium or coercion: use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*, *41*(1), 11.

Halpern, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(7), 801-803.

Morgan, D.L. & A.N. Scannell. (1998) *Planning Focus Groups*. Thousand Oaks, CA: Sage.
National Institute on Drug Abuse (NIDA). (2009). Smokeless tobacco. (Topics in Brief).