FDA DOCUMENTATION FOR THE GENERAL 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 among Multicultural Youth; 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 at-risk multicultural youth aged 12 to 17 (*n* = 80) who identify with Hip Hop culture and are current tobacco users or susceptible to tobacco use. The purpose of these focus groups is to assess participants' perceptions about advertising brands and concepts designed to reduce youth tobacco use. These brands and creative concepts are part of a pilot campaign focused on multicultural youth in the southeast region of the United States.

2. **Intended use of information:**
   Information obtained during focus group discussions will be used to inform the development of a pilot public education campaign to reduce tobacco use among at-risk multicultural youth aged 12-17 who live in the southeast and identify with Hip Hop culture. Specifically, focus group participants will answer questions regarding comprehension, relevance, and impact of several campaign brand and creative concepts. Results will be used to refine the brand and creative concepts.

3. **Description of respondents:**
   Focus groups will be conducted with youth aged 12-17 (*n* = 80) who live in the southeast, identify with Hip Hop culture and are current tobacco users or susceptible to tobacco use. Participants will be recruited from middle (*n* = 16) and high schools (*n* = 64) in the Atlanta and Charlotte metropolitan areas.

   The study will consist of ten (10) focus groups, each with an average of eight (8) youth participants aged 12–17 who are current tobacco users (e.g., report any type of tobacco product use within the past 30 days) or are susceptible to tobacco use (e.g., report risk factors for tobacco use initiation). Focus groups will not be conducted with less than three (3) participants.

   In each city (Atlanta and Charlotte) there will be four (4) high school focus groups and one (1) middle school focus group, for a total of eight (8) high school focus groups and two (2) middle school focus groups. High school and middle school focus groups will be conducted separately. Focus groups will also be separated by user/non-user status, and researchers will not mix groups. The types of groups held at each school will depend on the number of current tobacco users recruited. Depending on the number of users at a school, researchers may conduct the research with two (2) groups of users or two (2) groups of susceptible non-users. In each middle school, the goal will be to recruit all users. However, if there are not enough users, researchers will recruit susceptible non-users only. Regardless, tobacco use status will only be known by the researchers; participants will not be asked to reveal their tobacco use history in a group context.

The table below provides a breakdown of the number of groups in each location and the number of participants in each group.

Summary of Group Distribution				
City	School Type and #	# of Focus Groups	Participants Per Group	Total Number of Participants
Atlanta, GA	2 High School	4	8	32
	1 Middle School	1		8
Charlotte, NC	2 High School	4		32
	1 Middle School	1		8
TOTAL	**6 schools**	**10 groups**		**80 participants**

4. Date(s) to be conducted and location(s):

The focus groups will begin on February 5, 2014 and will be completed by February 22, 2014.[1] The focus groups will be conducted at two (2) middle and four (4) high schools located in Atlanta, GA and Charlotte, NC. These locations were selected because the pilot campaign targets at-risk multicultural youth in the southeast region of the United States where there are above average tobacco use rates and a large concentration of multicultural youth.

5. How the information is being collected:

This study will recruit potential participants from middle and high schools in Atlanta, GA and Charlotte, NC. Each researcher will conduct screener surveys at schools where students are present during lunch. Potential participants will be assessed by the screener, and selected based on meeting inclusion criteria requirements, including their Hip Hop identification. Students will be informed that the discussion and any information they provide during screening will be private and not shared with the school or their parents.

The age of the participants will determine how parental consent will be handled. Participants who are under the age of 13 will be required to have a signed Parental Consent Form prior to participating in a focus group. For participants who are 13 years of age or older, passive parental consent (Parental Opt-Out Form) will be used.

Written assent will be obtained from all participants prior to the start of the focus group.

A professional moderator and two research assistants with experience leading youth focus groups will moderate each group and collect information. The moderator and assistants will engage participants in a series of activities and questions using a semi-structured discussion guide and surveys; encourage participants to respond openly and spontaneously; and, with participants' permission, audio-record participants' answers and reactions to those questions.

After a study introduction, the first activity will consist of a *Check-In Survey* that includes questions regarding demographics, tobacco use, social media use, and peer crowd affiliation. This survey will be completed individually by each participant. Next, participants will complete *Campaign Brand Testing*. This involves a *Hip Hop Brand Test Survey* (Version A and Version B both have same content but presented in different order for counterbalancing purposes) and group discussion. After participants complete each brand-

[1] Pending approval dates and recruitment time.

related question on the *Brand Test Survey* individually, the moderator will ask a series of questions to obtain qualitative feedback from the group. Finally, participants will engage in *Preliminary Creative Concept Testing* where they will be shown six (6) campaign advertising storyboards. Similar to the *Brand Test Survey*, the order in which the creative concepts are shown are also reversed between focus groups for counterbalancing purposes. After each creative concept is shown, participants will individually complete the relevant portion on the *Hip Hop Creative Concept Survey*, and the moderator will ask a series of questions specific to the creative concept to obtain qualitative feedback from the group.

6. Confidentiality of respondents:

All data will be collected with an assurance that the respondent's responses will remain private to the extent allowable by law. The moderator will obtain and audio record verbal assent from individual participants at the beginning of the focus groups. Only school identification number will be associated with the audio recording. If any participant does not agree to be audio recorded, the discussions will not be audio recorded. All participants will be asked to respect the privacy of the other focus group members. Everyone will be asked to not discuss or reveal anything said during the discussions.

There are no discussion questions that ask participants to provide identifying information as part of their responses, and participants will be advised not to share any personal details, including their tobacco use status. If any personal information is included in a participant's comment, it will be redacted from the recordings and transcripts. All analyses will be conducted in the aggregate and participant information will not be appended to the data file used.

Contractors will produce transcriptions of audio recordings to assist in report writing and provide the FDA with a written record of the sessions. One paper and one electronic copy of the transcript will be supplied for each group. The audio recordings and transcripts for a given group will be available to the FDA within four (4) weeks of the completion of that data collection, and will be stored on a password-protected computer. Identifying information will not be included in the transcripts and digital recordings delivered to the FDA. Quotes that might be used in the final report to illustrate a discussion-derived theme will not be attributed to the participant.

Neither contractors nor subcontractors associated with this project will share personal information regarding participants with any third party without the participant's written permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process. Upon final delivery of the research report to the FDA, any copies of transcripts and digital recordings held by contractor will be destroyed by deletion and secure shredding.

7. Amount and justification for any proposed incentive:

The amount of the incentive for participation is a $25 VISA gift card. Only students who screen in and attend a focus group will receive a gift card. No incentive will be given for completing the screener.

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 brand and creative 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.

Incentives must be high enough to equalize the burden placed on participants 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. Inadequate compensation for time spent participating in a study may result in a difficult and lengthy recruitment process and/or participants who agree to participate and then do 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 youth, low socio-economic groups and high-risk populations (current or former tobacco users and those susceptible to tobacco use).[4]

Also, this study requires participants to comment on an activity that may be sensitive subject matter to the participants and could cause them to be reluctant to participate. Thus, it is critical to provide adequate incentives to encourage and retain participation among the limited number of potential youth respondents.

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. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation.

FDA tobacco communications may also be concerned with discouraging tobacco use by youth before they start. It is important to understand perceptions about smoking from youth

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[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.

who use tobacco or who are susceptible to use because their opinions are valuable in informing campaign development. In order to identify youth who have used tobacco, researchers need to ask sensitive survey-based questions about current tobacco use. The FDA acknowledges such questions are potentially sensitive since tobacco use among youth under 18 years of age is illegal in some states and selling tobacco use to minors is illegal in all states. Moderators will not ask youth to report their tobacco use history or status during group discussions.

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 both quantitative and qualitative data methods to collect data.

In general, focus group discussions and interviews rely on qualitative methods and are not intended to yield results that are statistically projectable or generalizable. Data will be analyzed with NVivo brand qualitative data analysis software to identify emergent themes and patterns. Aggregate data from this study may be used in future research and/or shared with other researchers.

Quantitative data will be collected and analyzed from two different groups of activities, as outlined numerically below. These data will not be statistically projected; aggregate data from this research phase will benefit the pilot campaign by guiding the brand and creative concepts development. Quantitative data will be analyzed and interpreted with the objective of informing knowledge about the youth sample from this research phase. Thus, as an initial step for the quantitative data analysis for each of these specific activities, descriptive analyses will be used such as means, standard deviations, and percentages. We will conduct additional analyses in order to inform our understanding of the sample:

1. *Check-In Survey* – Data from the picture selection will be utilized to measure and describe the extent to which participants identify with the Hip Hop peer crowd based on their Hip Hop score. These data will be correlated with social media use and tobacco use in order to better understand participant behaviors and preferences. The contractor is utilizing photos of paid models in the research conducted for which they have obtained full consent and authority.

2. *Hip Hop Brand Test Survey and Hip Hop Creative Concept Test Survey* – If there are relatively equal numbers of current tobacco users and susceptible non-users recruited, researchers will plan to statistically test group differences in perceptions of brands and creative concepts in order to better understand responses from the two participants groups.

No school, classroom, or participant identification data will be reported. Participants will not be contacted again for this study for any reason.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (Hours)
Screener			
Initial Screener Form (Recruitment Survey Sample) Atlanta, GA High School	200	0.115 (7 minutes)	23
Initial Screener Form (Recruitment Survey Sample) Atlanta GA Middle School	50	0.115 (7 minutes)	6
Initial Screener Form (Recruitment Survey Sample) Charlotte, NC High School	200	0.115 (7 minutes)	23
Initial Screener Form (Recruitment Survey Sample) Charlotte, NC Middle School	50	0.115 (7 minutes)	6
Total Screener Burden:			58
Parental Consent Under 13 years of Age			
Parental Consent:: Under 13 years of age, Atlanta, GA Middle School	8	0.084 (5 minutes)	.67
Parental Consent: Under 13 years of age, Charlotte, NC Middle School	8	0.084 (5 minutes)	.67
Parent Opt-Out Over 13 years of Age			
Parental Opt-Out Form (Participants 13 years of Age and older):Atlanta, GA High School	32	0.084 (5 minutes)	3
Parental Opt-Out Form (Participants 13 years of Age and older):Charlotte, NC High School	32	0.084 (5 minutes)	3
Total Parental Consent and Opt-Out Burden:			7
Participant Assent			
Participant Assent Form: Atlanta, GA High School	32	0.084 (5 minutes)	3
Participant Assent Form: Atlanta, GA Middle School	8	0.084 (5 minutes)	.67
Participant Assent Form: Charlotte, NC High School	32	0.084 (5 minutes)	3
Participant Assent Form: Charlotte, NC Middle School	8	0.084 (5 minutes)	.67
Total Assent Burden:			7
90 Minute Focus Group			
90 focus group (Includes Check-In Survey, Brand Test Stimuli, Hip Hop Brand	32	1.5 (90 minutes)	48

Test Survey[Ver A and B], Preliminary Creative Concept Testing Stimuli, Hip Hop Creative Concept Survey Spreadsheet, and the Moderator Guide) Atlanta, GA High School			
90 focus group (Includes Check-In Survey, Brand Test Stimuli, Hip Hop Brand Test Survey[Ver A and B], Preliminary Creative Concept Testing Stimuli, Hip Hop Creative Concept Survey Spreadsheet, and the Moderator Guide) Atlanta, GA Middle School	8	1.5 (90 minutes)	12
90 minute focus group (Includes Check-In Survey, Brand Test Stimuli, Hip Hop Brand Test Survey[Ver A and B], Preliminary Creative Concept Testing Stimuli, Hip Hop Creative Concept Survey Spreadsheet, and the Moderator Guide) Charlotte, NC High School	32	1.5 (90 minutes)	48
90 minute focus group (Includes Check-In Survey, Brand Test Stimuli, Hip Hop Brand Test Survey[Ver A and B], Preliminary Creative Concept Testing Stimuli, Hip Hop Creative Concept Survey Spreadsheet, and the Moderator Guide) Charlotte, NC Middle School	8	1.5 (90 minutes)	12
Total Assent Burden:			120
TOTAL BURDEN	**192 hours**		

REQUESTED APPROVAL DATE: January 8, 2014

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