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

TITLE OF INFORMATION COLLECTION: Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Youth 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 quantitative research (i.e., copy testing) with multicultural youth aged 12 to 17 (n = 1,410) who affiliate with Hip Hop culture and who have experimented with cigarettes (i.e., have reported smoking fewer than 100 cigarettes in lifetime) and youth aged 12–17 who are at risk of initiating (e.g., would smoke if a friend offered them a cigarette).

The research will be fielded for the purpose of assessing FDA's first wave of draft (or "rough-cut") advertisements for its Multicultural At-Risk Youth Tobacco Prevention Campaign ("Fresh Empire") prior to launch. Research results will be used to assess whether rough-cut advertisements provide an understandable and engaging message about the harms of tobacco use without potential unintended adverse or counterproductive effects.

2. Intended use of information:

Information obtained through this study will inform the implementation of FDA's "Fresh Empire" campaign. This study follows a series of focus groups that assessed at-risk youth and youth experimenters' perceptions of advertising concepts designed to reduce youth tobacco use.

The study will consist of showing six (6) rough-cut campaign advertisements to a sample of the target audience. Copy testing results for each rough-cut advertisement will be assessed individually, as well as compared across all six (6) tested rough-cut advertisements to answer the following questions:

- Does the rough-cut advertisement provide an understandable message about the harms of tobacco use?
- Does the rough-cut advertisement provide an engaging message about the harms of tobacco use?
- Does the rough-cut advertisement have any potential unintended adverse or counterproductive effects related to beliefs around the harms of tobacco use?

Results will be used to refine and finalize rough cut ads.

3. Description of respondents:

Study participants will consist of 705 youth aged 12–17 who report having at least one puff of a cigarette, but no more than 99 cigarettes in a lifetime ("experimenters") and 705 youth aged 12-17 who indicate that they are current non-tobacco users, but are susceptible to future smoking ("at-risk non-triers"). Each rough cut ad will be viewed by 470 respondents per target group. Additionally, another 235 respondents per target group will not view a rough cut ad. The total sample size will be 1,410. Approximately 4,230 youth will be

screened in order to obtain a sample size of 1,410.

	Ad View Group	No Ad Control Group	Total
Hip Hop Youth Experimenters	470	235	705
Hip Hop Youth At-Risk Non-Triers	470	235	705
Total Respondents	940	470	1,410

4. Date(s) to be conducted:
The study is projected to occur between November 1, 2014 and September 30, 2015.

5. How the information is being collected:
The information is being collected by a contractor using a self-administered survey via handheld tablets with youth aged 12-17. Youth participants will be randomly assigned to view one (1) to two (2) rough cut ads or no ad.

Participants selected to view advertisements (Ad View Group) will first be provided with three (3) questions about their exposure to tobacco use and past 30 day tobacco use. Following these questions, participants will view a rough cut ad and will then be prompted to complete a questionnaire designed to assess whether the advertisement provides an understandable and engaging message about the harms of tobacco use. If applicable, following completion of the questionnaire, participants will view a second randomly selected advertisement and will then be prompted to complete the same questionnaire provided after viewing the first advertisement.

The rough-cut ads will average thirty (30) seconds in length. Following completion of the advertisement questionnaire(s), participants will be provided with general questions about their attitudes and beliefs about the harms of tobacco use as well as additional demographic questions. The questions targeting general attitudes and beliefs about the harms of tobacco use are being collected to assess potential unintended consequences.

Participants selected not to view any advertisements (No Ad Control group) will only be provided with questions about attitudes and beliefs around the harms of tobacco use, followed by additional demographic questions. Participants who do not view any advertisements are primarily being included to measure for unintended consequences.

Data will be collected in school settings.

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.

Researchers will inform youth in the assent form that the information they provide in the screener for recruitment will only be viewed by the researchers. Additionally, survey 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.

Identifying information will not be included in the reports delivered to the agency. All data received by FDA will remain in a secured area or on a password-protected computer. No data will contain identifying information.

Neither the contractor nor subcontractors associated with this study will share personal information regarding research participants with any third party without the participants' permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or another legal process.

7. Amount and justification for any proposed incentive:

The amount of the incentive as a token of appreciation is a $20 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, ratings, and open-ended feedback on rough cut ads that require a high level of engagement. This incentive amount is considered an adequate compensation for time spent participating in the study, and not an inducement for 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 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 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 facilitator 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 (experimenters and at-risk non-triers).[4]

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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.

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 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 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.

Raw data that include sensitive information (e.g., screening questionnaires, youth or parent contact 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.

9. Description of statistical methods:

This research relies on quantitative methods and will use convenience samples rather than probability samples. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

Youth participants will be directly identified using school-based intercept recruitment procedures that employ screening questions about age; current, past, and intended tobacco use; race and ethnicity; and gender. Recruitment will continue until a representative sample of the required number of participants for each category (705 youth experimenters and 705 youth at-risk non-triers) is obtained.

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

Youth Screener and Assent | estimated participation time: 7 minutes
Parental Opt-Out/Consent | estimated participation time: 5 minutes
Youth Participants | estimated participation time: 10 minutes

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Youth Screening Questionnaire and Assent	4,230	7	493
Parental Opt-Out / Consent		5	352
Screened	4,230		845
Youth Participants			
Youth Experimenters: Survey Participation	705	10	117
Youth At-Risk Non-Triers: Survey Participation	705	10	117
Participants	1,410		234
Total[1]	**4,230**		**1079**

[1] **The total number of respondents are 4,230; one-third of those (1,410) represent the total number of participants in this study.**

REQUESTED APPROVAL DATE: 10/3/2014

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