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

.

TITLE OF INFORMATION COLLECTION: Online Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Youth 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 online quantitative research (i.e., copy testing[1]) with youth aged 12–17 in the United States who 1) have experimented with non-menthol cigarettes (i.e., have reported smoking up to 99 cigarettes); 2) have experimented with menthol cigarettes (i.e., have reported smoking up to 99 cigarettes and prefer menthol cigarettes); or 3) are at high risk for initiation (i.e., would smoke if their friend offered them a cigarette).

   The research will be fielded for the purpose of assessing FDA's draft (or "rough-cut") Youth Experimenter Tobacco Prevention Campaign television advertisements 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:**
   The study will consist of showing six (6) rough-cut versions of campaign advertisements to a sample of the campaign 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 in order to address 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?

   This study is the second and last phase of primary formative research that will inform the development of FDA's Youth Experimenter Tobacco Prevention Campaign. This study follows a series of focus groups that assessed youth experimenters' perceptions about advertising concepts designed to reduce youth tobacco use.

3. **Description of respondents:**

[1] "Copy testing" is a marketing term synonymous with "communications check" that involves showing draft versions of TV ads (i.e., "rough-cuts") to a small sample of the target audience to assure understanding of messages and assess any potential unintended consequences as part of the message development and testing phase.

The study participants will consist of 525 youth aged 12–17 who have experimented with non-menthol cigarettes (i.e., have reported smoking up to 99 cigarettes), 525 youth aged 12-17 who have experimented with menthol cigarettes (i.e., have reported smoking up to 99 cigarettes and prefer menthol cigarettes), and 525 youth aged 12-17 who are at high risk for initiation (i.e., would smoke if their friend offered them a cigarette). Each of the three audiences will represent a diverse population in terms of age, race, and gender. Each rough-cut advertisement will be viewed by 150 participants of each target group for a total of 450 participant views per advertisement. Within each target group an additional 75 participants will not view a rough-cut advertisement. The total sample size will be 1,575.

Population*	Ad 1	Ad 2	Ad 3	Ad 4	Ad 5	Ad 6	No Ad
Youth non-menthol cigarette experimenters (N = 525)	N = 150		N = 150		N = 150		N = 75
Youth menthol cigarette experimenters (N = 525)	N = 150		N = 150		N = 150		N = 75
Youth at high risk for initiation (N = 525)	N = 150		N = 150		N = 150		N = 75
	Total: Ad Group = 1,350						Total: No Ad Group = 225
Total Participants = 1,575							

**Each participant will view 2 ads*

4. Date(s) to be conducted:

The testing will begin on October 16, 2013 and will be completed by October 24, 2013.[2] The study will be conducted online.

5. How the information is being collected:

The information is being collected by a contractor using an online self-administered survey with youth aged 12–17. Parents of youth participants will complete a consent letter allowing their children to participate in the study. The youth participant will then complete an assent letter to take part in the study. Qualified participants will be randomly assigned to either view two (2) rough-cut advertisements or no advertisement. Participants selected to view the advertisements will view two (2) of six (6) possible rough-cut advertisements. Participants will view the first randomly selected advertisement 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. Following completion of the questionnaire, participants will view the second randomly selected advertisement and will then be prompted to complete the same questionnaire provided after viewing the first advertisement.

[2] Depending on approval dates and recruitment time.

All rough-cut advertisements will average thirty (30) seconds in length. Following completion of both advertisement questionnaires, 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 and will not be used to assess an advertisement's ability to change tobacco attitudes, beliefs or behaviors through one-time exposure.

Participants selected not to view any advertisements 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 being included to measure for unintended consequences.

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 assent and consent forms 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 tag generated by the online survey operator. 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 the online survey provider 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 for participation is a $20 eGift card. Participants who are age 16 and older will receive the entire $20 incentive. Participants who are under age 16 will receive a split incentive (i.e., the youth participant will receive a $10 eGift card and their parent or guardian will receive another $10 eGift 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 feedback on rough-cut advertisements that require a high level of engagement and participation. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.[3]

[3] 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), 80l-803.

Incentives must be high enough to equalize the burden placed on respondents in respect to their time and cost of participation,[4] 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 the set-up of the study. 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 cost. Incentives are also necessary to ensure adequate representation among harder-to-recruit populations such as youth, low socioeconomic 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 on multiple accounts (youth aged 12-17 who are experimenting with or susceptible to tobacco use). 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. 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. The FDA acknowledges the sensitivity of questions about the purchase and use of tobacco, which is illegal for minors in most states.

9. Description of statistical methods:

[4] Russell, M.L., Moralejo, D.G., & Burgess, E.D. (2000). Paying research subjects: Participants' perspectives. Journal of Medical Ethics, 26(2), 126-130.

[5]

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. The results of the study will not be published.

Participants will be identified using standard mall 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 (525 youth non-menthol cigarette experimenters, 525 youth menthol cigarette experimenters, and 525 youth at high risk for initiation) is obtained.

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)
Parental consent letter	1,575	5	132
Youth assent letter/screener	1,575	5	132
Youth at high risk for initiation	525	10	88
Youth non-menthol cigarette experimenters	525	10	88
Youth menthol cigarette experimenters	525	10	88
Total	**1,575**		**528**

REQUESTED APPROVAL DATE: September 30th, 2013

NAME OF PRA ANALYST & PROGRAM CONTACT:

PRA Analyst **Jonna Capezzuto**
301-796-3794
JonnaLynnn.Capezzuto@fda.hhs.gov

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

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