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

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TITLE OF INFORMATION COLLECTION: Tobacco Retailer Education Program: In-depth Interviews to Inform the Development of Educational Materials**;**
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 qualitative research with tobacco retailer managers and clerks aged 18 years old and older (n = 60) working in convenience or convenience/gas stores; grocery, discount or drug stores; and tobacco outlets. The research involves showing near final versions of educational materials to assess their initial reactions and gather feedback on clarity, comprehension and usability.

This research will be fielded for the purposes of (1) determining the most attractive and memorable creative strategy to encourage managers and clerks to engage with the materials, (2) assessing the clarity, comprehension and usability of specific types of materials, and (3) identifying the most compelling tobacco fact statements to help motivate voluntarily compliance with federal tobacco regulations that help protect youth from tobacco.

2. Intended use of information:

The information obtained as part of this data collection will be used to evaluate emotional and cognitive reactions to creative advertising concepts. Participants will be shown creative concepts and asked for their feedback on level of attractiveness and memorability, as well as the likelihood of future engagement. Participants will then be asked to provide feedback on five educational materials within a creative concept to assess the clarity, comprehension, and usability of each one. The information obtained will be used to optimize the materials for final production, generate new ideas on how to distribute and display the materials in stores, and gather suggestions for additional materials that may be considered in the future.

Participants will also be asked to review eight related tobacco facts and provide feedback on level of believability and memorability. This information will be used to help identify the most compelling tobacco fact statements that will be used to help promote voluntary compliance with federal tobacco regulations that help protect youth from tobacco.

3. Description of respondents:

The study will consist of sixty (60) in-depth interviews in three markets (urban, suburban, and rural) with tobacco retailer managers and clerks aged 18 years old and older working in convenience or convenience/gas stores; grocery, discount or drug stores; and tobacco outlets. Employees will be defined as those who sell tobacco products as part of their job duties (clerk) or those who supervise someone who sells tobacco products at the store (manager). Approximately 240 adults will be screened in order to obtain a sample size of 60.

Table 1 – Data Collection Requirements

<table>
<tr><td></td><td></td><td></td><td>Total</td></tr>
<tr><td rowspan="3">Convenience or Convenience/Gas Stores</td><td>Market 1: Urban</td><td>6 Managers
6 Clerks</td><td rowspan="3">32</td></tr>
<tr><td>Market 2: Suburban</td><td>6 Managers
6 Clerks</td></tr>
<tr><td>Market 3: Rural</td><td>4 Managers
4 Clerks</td></tr>
<tr><td>Grocery, Discount & Drug Stores</td><td colspan="2">7 Managers
7 Clerks</td><td>14</td></tr>
<tr><td>Tobacco Outlets</td><td colspan="2">7 Managers
7 Clerks</td><td>14</td></tr>
<tr><td colspan="3">Total Respondents</td><td>60</td></tr>
</table>

Note: These quotas were selected based on recent research showing that nearly two-thirds of cigarette sales come from convenience or convenience/gas station retailers, 12.0% come from grocery, discount and drug stores, and 17.1% come from tobacco outlets.[1]

Additional criteria for inclusion in the research include the following:

- Has not participated in a research study involving tobacco in the past 6 months
- Does not work for a tobacco company (including self and anyone in household)
- Speaks and reads English

Further, the following considerations will be made for participant selection:

- Mix of gender and race/ethnicity
- Mix of types of store ownership (not part of a chain, part of a small chain, part of a large chain)

4. Date(s) to be conducted:

The study is projected to occur between January 1, 2015 and May 31, 2015.

5. How the information is being collected:

[1] See page 3-4 of RTI International (2014, September). *Year 3, Quarterly Report #2: Point-of-Sale (POS) Literature Review*. Prepared for the U.S. Food and Drug Administration, Center for Tobacco Products.

The information is being collected using a professionally trained interviewer. The interviewer will engage sixty (60) participants in a series of questions using semi-structured discussion guides, and educational materials; encourage participants to respond openly and spontaneously; and, with participants' permission, audio-record participants' answers and reactions to those answers. Each interview will last up to 90 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.

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, interview 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.

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. Further, if a participant makes a direct threat of harm to his/herself or others, we reserve the right to take action out of concern for him/her and concern for others.

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.

Given FDA's need to understand the ability of these materials to educate retailers about federal tobacco regulations, and the limited number of eligible participants, it is critical to this data collection that we provide adequate incentives to encourage participation. Thus, in order to obtain the sample of participants required by our study, while also minimizing self-selection biases and balancing recruitment expenses, it is critical we offer a sufficient level of incentive. 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. Furthermore, an insufficient incentive level increases recruitment difficulty (thereby reducing cost efficiency) and increases the likelihood that recruits who do agree to participate in groups, will end up not showing

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

up for the discussion. Low participation may result in inadequate data collection, or, in the worst cases, cancellation of groups and loss of costs associated with facility rentals, recruitment, travel costs, and moderator and observer time.[3]

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.[4]

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, inclusive of those who work at retail locations (as known from previous research conducted among this audience).[5]

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 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).

Raw data from data collections that include sensitive information (e.g., screening questionnaires, audiotapes, and videotapes) 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.

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[3] Morgan, D.L. & Scanell, A.U. (1998) *Planning Focus Groups.* Thousand Oaks, CA: Sage Publications.

[4] 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.

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

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 recruiting procedures that employ screening questions about age; English proficiency; participation in past research; affiliation with a market research firm, ad agency or tobacco company; and current job tasks. 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:*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Questionnaire	240	.08	20
Consent		.08	20
Total Screened	240		40
In-Depth Interview Participants			
In-Depth Interviews	60	1.5	90
Total Participants	60		90
Total[1]	**240**		**130**

[1] **The total number of respondents is 240; the total number of participants in this study is 60.**

REQUESTED APPROVAL DATE: December 22, 2014

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