FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS

TITLE OF INFORMATION COLLECTION:

Qualitative Study on Consumer perceptions of Cigarettes Health Warning Images; OMB Control Number 0910-0796

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is seeking OMB approval under the generic clearance 0910-0796 to conduct exploratory focus groups, "Qualitative Study on Consumer perceptions of Cigarettes Health Warning Images," to evaluate consumer comprehension, perceptions, and reactions to cigarette graphic health warning images. To achieve this objective, a series of focus groups will be conducted with a wide-ranging sample of the population that covers various ages, races, and levels of educational attainment. The data collected during these focus groups will help finalize images that will be tested in a future quantitative study. The focus groups will be designed to answer the following questions:

1. What information do the images alone convey to consumers? What information do people take away from the image?
2. Which images convey the clearest information to consumers about the health consequences of cigarette smoking?
3. Which image-statement parings convey the clearest information to consumers about the health consequences of cigarette smoking?
4. Does each image accurately depict the health consequence of smoking described in its paired warning statement?
5. Are the people/organs/conditions depicted in each image believable/realistic?
6. How do the images aid in comprehension/understanding of the health effect of smoking beyond the statement alone?
7. In instances where there are multiple images for the same health condition, which image statement pairing provides the clearest information to consumers?

Section 201 of the Tobacco Control Act (TCA) requires nine new health warning statements on cigarette packages and in advertising. It also directs FDA to issue regulations "that require color graphics depicting the negative health consequences of smoking" to accompany the nine new health warning statements. FDA issued a cigarette graphic health warning (GHW) rule in 2011, which was challenged in court. Ultimately, FDA announced that rather than pursuing appeal of negative ruling against the rule, it was planning to undertake research to support a new rule for cigarette graphic health warnings. This focus group project is one step in that research. The knowledge gained from these groups will be used to refine the image element of warnings that will eventually be paired with text warning statements. To fulfil this mandate, FDA's Center for Tobacco Products (CTP) requires a qualitative study that builds on prior qualitative research to gain insight on consumer comprehension, perceptions, and reactions to cigarette graphic health warning images.

2. **Intended use of information:**

The study is intended to evaluate consumer comprehension, perceptions, and reactions to cigarette graphic health warning images. Results will be used to refine images to effectively communicate the negative health consequences of smoking.

As with all qualitative research, results from this focus group study are not generalizable. As such, FDA will not use findings from this study to inform policy.

Findings from this study will inform revisions to the image element of warnings to ensure that they are understandable and believable. In addition, findings from this study will help to narrow down the number of potential images to eventually be paired with text warning statements. Those text warning statement will be tested in a separate study (ICR Reference No: 201708-0910-011) and the eventual full Graphic Health Warnings pairing the image and statement will be tested together in a future quantitative study.

3. **Description of respondents:**

Respondent Characteristics and Group Segmentation

Respondents will participate in one of 20 focus groups. Five focus groups will be conducted in each of the following cities: Riverside, CA; Albuquerque, NM; Philadelphia, PA; and St. Louis, MO. These locations were chosen for geographic and racial/ethnic diversity, access to populations for which English is not their first language, and rates of adult and adolescent cigarette smoking. Geographic diversity is achieved by selecting one site on the east coast, one in the mid-west, one site in the southwest and one site on the west coast. Each group will include a mix of ages, races/ethnicities, education levels, and first language (although all groups will be conducted in English).

Because this study is exploratory, it is important to capture a full range of responses from a variety of people. Recruitment characteristics include: age (adolescent, young adult, adult) and smoking status (e.g., current smoker, susceptible to smoking). As is standard in focus group studies[1], groups will be segmented to achieve relative homogeneity within groups. Respondents are grouped together based on common characteristics (e.g., age and smoking status) to maximize compatibility and facilitate group discussions. Groups will be segmented as follows:

Adolescents: Six groups will be conducted exclusively with adolescents (ages 16-17). The adolescent groups will be segmented by smoking status: current users (adolescents who have smoked a cigarette in the past 30 days are preferred, but those who have smoked in the past 90 days will be accepted if groups are not able to be filled with past-30-day users) and those susceptible to smoking (based on a validated 3-item scale[2]). Each group will contain an approximately equal number of males and females.

Adults: Adults: Fourteen groups will be conducted with adults (≥18 years old) who are current smokers. Each group will contain an approximately equal number of males and females. Half of the groups will be with young adults (18-29) and half will be with older adults (30+).

[1] Stewart, D.W., Shamdansani, R.N., & Rook, D.W. (2007). *Focus groups: Theory and practice.* Thousand Oaks: Sage Publications.

[2] Pierce, JP., Choi, W.S., Gilpin, E.A., Farkas, A.J., & Merritt, R.K. (1996). Validation of susceptibility as a predictor of which adolescents take up smoking in the United States, *Health Psychology*, 15(5), 355-361.

While there will be differences in the characteristics of the groups, this study is not designed to examine differences between the groups. Rather, the analysis will identify major themes across groups.

Recruitment

The contractor will recruit 12 individuals for each focus group discussion, with the expectation of having 8 to 10 participants per group. To be eligible to participate, respondents must be able to understand and speak English and must be comfortable talking in a group of people of a similar age. Respondents cannot have participated in a focus group or a similar study in the past six months. Additionally, no adult participant will be included to participate if he/she or a household member ever lobbied on behalf of the tobacco industry or personally represented or worked on behalf of a tobacco company in connection with a tobacco lawsuit. No participant will be included to participate if he/she or a household member worked in the past 5 years for any of the following entities:

- a tobacco or cigarette company;
- a public health or community organization involved in communicating the dangers of smoking or the benefits of quitting;
- a marketing, advertising, or public relations agency or department;
- U.S. Food and Drug Administration (FDA);
- National Institutes of Health (NIH);
- Centers for Disease Control and Prevention (CDC);
- Substance Abuse and Mental Health Services Administration (SAMHSA);
- Centers for Medicare & Medicaid Services (CMS).

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

The focus groups will be conducted in January and February, 2017. The focus groups will be conducted in Riverside, CA, Albuquerque, NM, Philadelphia, PA and St. Louis, MO.

5. **How the Information is being collected:**

Focus groups are used to obtain insights into target audience perceptions, beliefs, and attitudes in the early stages of the communication process (i.e., in concept, strategy, and materials development) and to inform the development of quantitative research. Focus groups are usually composed of 8 to 10 people who have characteristics similar to the target audience or subgroups of the target audience. The groups are conducted by a professional moderator who keeps the session on track while allowing respondents to talk openly and spontaneously. The moderator uses a loosely structured discussion guide, which allows him/her to change direction as the discussion unfolds and new topics emerge. Due to the number of images to be discussed, each group will focus on one of four sets of images and associated statements (see Moderator guide Sets 1-4 and Participant Booklet Sets 1-4). Focus groups are valuable in exploring consumer reactions to message concepts before additional resources are put into development.

For this study, each 90-minute focus group will be conducted at a local marketing research firm. With respondent consent, each group will be digitally audio-recorded. Focus groups will be monitored by FDA representatives from behind a one-way mirror. Focus groups will also be video-streamed such that FDA representatives can view them via a live webcast. Using a structured moderator guide, a professional moderator will lead each group through a discussion, which will revolve around a discussion of participants' reactions to graphic health warning images and potential image-statement pairings presented in a participant booklet.

6. **Number of focus groups:**

There will be 20 focus groups representing a diverse population.

7. Amount and justification for any proposed incentive:

Potential participants have competing demands for their time, so incentives are used to encourage participation in focus groups. Incentives must be high enough to cover travel costs, time, and to provide enough incentive to attend the focus group rather than another activity. Focus group studies run by industry offer incentives at much higher levels than those typically allowed by government studies, establishing a market rate that makes recruitment more difficult. Additionally, incentives typically are higher for harder-to-recruit populations.[3]

The proposed incentive is $75 for adults, $40 for adolescents (plus $35 for their parent/guardian). FDA seeks to ensure a high-show rate, and to ensure that the data collected will be of a sufficiently high quality of data to allow FDA to have confidence in the findings to properly inform its efforts to continue development of cigarette Graphic Health Warnings.

Adults who use tobacco products are a difficult-to-reach population given the low prevalence of tobacco use in the general population. Similarly, adolescents who use—or are susceptible to tobacco use—are also a minority of the overall population. Additionally, participation in focus groups requires substantial commitment and investment of time on the part of the participant, in that they must make a commitment to attend the discussion at a certain time on a specific date. Participation also requires participants to travel to a designated location, with the average commute in the United States metropolitan areas estimated at about 25.1 minutes,[4] and may also require that the participant obtain child care for a fee. Thus, incentives have long been considered a standard practice in conducting qualitative research such as focus groups.

The proposed incentive amounts are in line with other federal information collections (e.g., for OMB No. 0583-0166: Professional Services to Support Requirements Gathering Sessions for Safe Food Handling Instructions (SHI); OMB No. 0583-0141: Consumer Research, Assessing the Effectiveness and Application of Public Health Messages Affecting Consumer Behavior Regarding Food Safety; and OMB No. 0584-0561: Healthy Incentives Pilot Evaluation) using similar methods. These standards also exist to provide fair compensation for costs incurred by participants while attending groups (i.e., travel and child care expenses). In addition to covering reasonable costs of participation, payment to participants is necessary to ensure that a sufficient number of respondents from the target populations participate in the study. Incentives to participants must encourage potential participants to agree to allocate their time to the focus group discussion and maintain that commitment on the day of the research ensuring high-quality data.

Offering no incentive or a smaller incentive could potentially exclude sections of the population who cannot attend the groups, either due to the cost of child care and/or travel or the cost of missing work. Excluding sections of the population would limit the quality of the information that would be gained through the focus group discussion and potentially bias the information needed to address the research questions of interest, thus negatively impacting data quality. An insufficient incentive level also increases recruitment difficulty (thereby reducing cost

[3] Stewart, D.W., Shamdasani, P.N., Rook, D.W. (2007). *Focus Groups: Theory and Practice*. Thousand Oaks, CA: Sage Publications.

[4] McKenzie, B., & Rapino, M. (2011). *Commuting in the United States: 2009. Supplemental Table C. Mean travel time to work by means of transportation and selected characteristics*: 2009. Washington, DC: U.S. Census Bureau.

efficiency) and increases the likelihood that recruits who do agree to participate in groups, will end up not showing 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. Given FDA's need to understand consumer reactions to graphic health warnings among varied and vulnerable populations, it is critical to this data collection that we provide adequate incentives to encourage participation among the limited number of eligible adult and adolescent tobacco users and susceptible adolescents. Thus, to obtain the sample of participants required by our study, while also minimizing biases in self-selection and balancing recruitment expenses, it is critical we offer a sufficient level of incentive.

We anticipate that without the cash incentive, we would need to screen more people to achieve the desired cooperation rate and among those that agree to participate the quality of information collected would be lower. The current estimated burden for the participant screening is 259 hours. Without the incentive, we expect the burden to be approximately 362 hours, an increase of approximately 40%. The cost to respondents and the federal government would increase accordingly.

8. Questions of a Sensitive Nature:

Some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. This may require asking a question about race/ethnicity and education level on the initial screening questionnaire used for recruiting. Potential participants are informed that these questions are asked to ensure that FDA speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information they provide is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (62 FR 58782).

In this study, participants will be asked what images (alone) and images and statements (together) teach them about the relationship between smoking and specific smoking-related health conditions (e.g., cancer), however the questions could potentially provoke responses of a personal nature. Participants are informed prior to actual participation about the nature of the activity. Additionally, the moderator makes it clear at the beginning of each group that respondents do not have to respond to any question that makes them uncomfortable.

Raw data from data collections that include sensitive information (for example, screening questionnaires and audio recordings) 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 (i.e., Sample Size & Method of Selection):

In general, focus group research relies on qualitative methods and is not intended to yield results that are statistically projectable. Quota sampling will be used to select a convenience sample of individuals who meet certain qualifications that reflect characteristics typical of the target audience. Response rate is not applicable to quota sampling because this type of sampling results in a nonprobability sample that is not representative of the population. For this focus group study, all respondents will be initially contacted by telephone, and some overrecruiting may be done to compensate for nonrespondents (i.e., no shows).

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)
Adolescents (16-17 years old): 6 groups with 12 participants per group			
Initial Screener	1080	6	108
Parent Permission Form	72	10	12
Adolescent Assent Form	72	10	12
Focus group discussion	72	90	108
Adults (≥18 years old): 14 groups with 12 participants per group			
Initial Screener	1512	6	151
Adult Consent Form	168	10	28
Focus group discussion - Adults	168	90	252
Total	**2,832**		**671**

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