FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Consumer Risk Perceptions of Tobacco Products: Second Focus Group Study; OMB Control Number 0910-0497

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 0910-0497 to conduct exploratory focus groups, "Consumer Risk Perceptions of Tobacco Products: Second Focus Group Study," to assess consumer perceptions of tobacco products and their reactions to claims about tobacco products that purport to pose a reduced risk to the user. This research will inform the Agency's efforts to implement the provisions of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) related to modified-risk tobacco products.

2. **Intended use of information:**
   Section 911 of the Food, Drug, & Cosmetic Act authorizes FDA to grant orders to manufacturers to allow the marketing of products that may reduce the harm or risk of tobacco-related disease associated with commercially marketed tobacco products. FDA may allow the marketing of these products, so called modified-risk tobacco products, if it is deemed appropriate for the promotion of public health. To assess the potential impact that the marketing of modified-risk tobacco products may have on the likelihood of initiation and cessation of tobacco use, FDA requires information regarding consumer perceptions of modified-risk tobacco products.

   The research literature demonstrates that, historically, consumers have *inferred* that a tobacco product poses modified risk based on its label or labeling, for instance from the manufacturers' use of descriptors such as "light".[1,2] Section 911 prohibits tobacco product manufacturers from making expressed or implied claims that their product poses reduced risk to health, or reduces exposure to harmful or potentially harmful constituents, to the consumer unless the manufacturer submits and application to FDA and FDA issues an order allowing the marketing of the modified risk product. To our knowledge, no research to date has explored how consumers might perceive, interpret, and respond to modified risk information about tobacco products. FDA needs to better understand

[1]Kozlowski LT, Goldberg ME, Yost BA, White EL, Sweeney CT, Pillitteri JL. Smokers' misperceptions of light and ultra-light cigarettes may keep them smoking. *American Journal of Preventive Medicine* 1998; 15(1): 9-16.

[2]Shiffman S, Pillitteri JL, Burton SL, Rohay JM, Gitchell JG. Smokers' beliefs about "Light" and "Ultra Light" cigarettes. *Tobacco Control* 2001; S1:i17-23.

consumer responses to modified risk information in order to assess the impact a modified risk tobacco product may have on public health.

The purpose of these focus groups is to explore consumers' perceptions of and reactions to claims describing (hypothetical) modified risk tobacco products. The study findings will inform the development of the protocol and stimuli to be used in an experimental study to be conducted in winter 2013, which will assess the impact of modified risk claims on consumer attitudes and beliefs about the relative risks of using various tobacco products.

3. Description of respondents:

Respondents will participate in one of 16 focus groups. Four focus groups will be conducted in each of the following locations, which have relatively high rates of tobacco use: Shreveport, LA or Jackson, MS; Oklahoma City, OK; Burlington, VT; and Bethesda, MD. So that the groups are homogeneous in terms of tobacco use, the groups will be segmented by gender and smoking status: light users/chippers (smoke fewer than 10 cigarettes per day), current users (smoke 10 cigarettes or more per day), heavy users (smoke more than 30 cigarettes per day), poly-users (currently use more than one tobacco product), and smokers with an interest in quitting (planning to stop smoking within the next 60 days). Unless otherwise specified, each group will include a mix of ages, races/ethnicities, and education levels. The table below provides the segmentation for the 16 groups.

Focus Group Segmentation

	Shreveport, LA or Jackson, MS	**Oklahoma, City, OK**	**Burlington, VT**	**Bethesda, MD**
Current Smokers		Male, 30-65 yrs	Female, 30-65 yrs	
Chippers	Male, Rural, Mix*	Female, Mix*	Male, Mix*	Female, Mix*
Heavy Smokers		Female, 30-65 yrs	Male, 30-65 yrs	
Poly-users (male)	Male, Rural, 25-45 yrs			Male, Urban, 18-24 yrs
Quit Interest	Female, Mix*	Male, Mix*	Female, Mix*	Female, Mix*
	Male, Mix*			Male, Mix*

Mix* = mix of races, ages, and education levels.

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 read, understand, and speak English. Respondents cannot have participated in a focus group or a similar study in the past 6 months. Additionally, no individual 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 individual 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); and/or
- Centers for Medicare & Medicaid Services (CMS).

4. **Date(s) to be conducted and location(s):**
   The focus groups will be conducted in spring 2013. The focus groups will be conducted in Shreveport, LA or Jackson, MS; Oklahoma City, OK; Burlington, VT; and Bethesda, MD.

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 outline, which allows him/her to change direction as the discussion unfolds and new topics emerge. Focus groups are valuable in exploring consumer reactions to message concepts before additional resources are put into development.

   For this study, each focus group will be conducted at a local marketing research firm. For the two groups conducted in a rural location, we will conduct the groups in a hotel or other type of facility. With respondent consent, each group will be audio-recorded and monitored by FDA representatives from behind a two-way mirror. Using a structured moderator guide, a professional moderator will lead each group through a discussion, which will revolve around a discussion of claims communicating modified risk of (hypothetical) tobacco products.

6. **Number of focus groups:**
   There will be 16 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 (Fieldwork Denver, personal communication, March 22, 2012), establishing a market rate that makes recruitment more difficult. Additionally, incentives typically are higher for harder-to-recruit populations (Stewart, Shamdasani, and Rook, 2007).

   The amount of the proposed incentive is $50. The justification for this incentive is to compensate each respondent for their time and participation and to ensure that there will

be between 8 and 10 participants within each group to make this a meaningful study. Adults who use tobacco products are a difficult-to-reach population given the prevalence of tobacco use in the general population. Further difficulties in recruitment of participants will result from the study's need for participants who vary by tobacco use (e.g., types of product, intensity of use).

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 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 (Morgan and Scanell, 1998). Given FDA's need to understand consumer perceptions of tobacco 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 potential adult tobacco users. Thus, in order to obtain the sample of participants required by our study, while also minimizing biases in self-selection, and balancing recruitment expenses, it is critical that we offer a sufficient level of incentive.

Stewart, D.W., Shamdasani, P.N., Rook, D.W. (2007). *Focus Groups: Theory and Practice*. Thousand Oaks, CA: Sage Publications.
Morgan, D.L. & Scanell, A.U. (1998) *Planning Focus Groups.* Thousand Oaks, CA: Sage Publications.

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 and anonymous. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

Because FDA tobacco communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, 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, which are not necessarily as personal as those about sexual behavior, household income, or religious beliefs, still require some sensitivity in how they are worded and approached. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with their environment. 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 tapes) 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. However, the findings from this study will be used to inform the development of an experimental study on consumer risk perceptions of tobacco products and the effects that various types of modified-risk products and claims may have on consumer perceptions. 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)
Current Users (2groups)	24	66	26.4
Chippers (4 groups)	48	66	52.8
Heavy Users (2 groups)	24	66	26.4
Poly-Users (2 groups)	24	66	26.4
Smokers with Quit Interest (6 group)	72	66	79.2
Total	192		211.2

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