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

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TITLE OF INFORMATION COLLECTION: Consumer Risk Perceptions of Tobacco Products: Initial 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 Initial Focus Group Study," to assess consumer perceptions of the relative risks of various tobacco products, which 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 Tobacco Control 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, 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 risk of tobacco products and of modified-risk tobacco products.

   The findings from these focus groups will inform the development of the protocol and stimuli to be used in a second round of 16 focus groups to be conducted in early 2012. The second set of focus groups will explore the potential impact of modified-risk products and claims on consumer perceptions and inform the development of the protocol and stimuli to be used in an experimental study to be conducted in fall 2012. The purpose of the experimental study is to assess consumer attitudes and beliefs about the risks of using various tobacco products and to identify and assess the effects that various types of modified-risk products and claims may have on those attitudes and beliefs.

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: Raleigh, NC; Bethesda, MD; Atlanta, GA; and Indianapolis, IN. So that the groups are homogeneous, the groups will be segmented by gender, age (18 to 24, 25 to 34, 35+), and smoking status (recent former users/quitters, light users/chippers, current users). Additionally, two groups will be conducted with individuals currently enrolled in college and the remaining groups will include a mix of education levels. Two groups will be conducted with African Americans only, and one group will be conducted with English-speaking Hispanics only; the remaining groups will comprise a mix of races and ethnicities. One group will be conducted with male users of noncombustible products only (i.e., smokeless tobacco products), and the remaining groups will include a mix of

users of combustible and noncombustible products. The table below provides the segmentation for the 16 groups.

Focus Group Segmentation

Raleigh	Atlanta	Bethesda	Indianapolis
Female, 25-34 Current users	Male, 18-24 Light users and chippers	Female, 18-24 Light users and chippers	Male, 25-34 Current users *Smokeless products only*
Male, 18-24 Current and light users/ chippers *College Educated*	Female, 35+ Current users	Male, 18-24 Current users	Male, 35+ Current users
Male, 25-34 Current users *English-speaking Hispanics*	Male, 25-34 Current users *African Americans*	Female, 35+ Current users	Female, 18-24 Current users
Female, 18-24 Current and light users/ chippers *College Educated*	Female, 25-34 Current users *African Americans*	Male, 18+ Recent former users and quitters	Female, 18+ Recent former users and quitters

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 January and February 2012. The focus groups will be conducted in Raleigh, NC; Bethesda, MD; Atlanta, GA; and Indianapolis, IN.

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. With respondent consent, each group will be audio- and video-recorded and monitored by FDA 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 currently available tobacco products to gain an understanding of consumer perceptions of the health risks for various 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**

   The amount of the proposed incentive is $50. Given the lower prevalence of smokers in the general population and the potential difficulties associated with recruiting English-speaking Hispanics, we intend to provide respondents with $50 as an incentive and as a token of appreciation.

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 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**

~~Methodologies and sample sizes are based on a review of the relevant literature, consultation with experts in the field, and a baseline of data gathered over many years of pretesting materials and conducting research on cancer and other negative tobacco-related health outcomes among professional, patient, and public audiences.~~

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 and a subsequent focus group 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. We will select a purposeful sample of individuals who meet certain qualifications that reflect characteristics typical of the target audience. Response rate is not applicable because this methodology 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 over recruiting may be done to compensate for nonrespondents (i.e., no shows).

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)
Current Users (9 groups)	108	96	172.8
Current and Light Users and Chippers (2 groups)	24	96	38.4
Light Users and Chippers (2 groups)	24	96	38.4
Recent Former Users and Quitters (2 groups)	24	96	38.4
Current Smokeless Tobacco Users (1 group)	12	96	19.2
Total	192		307.2

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