FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS

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 Perceptions Related to Harmful and Potential Harmful Constituents in Tobacco Products; OMB Control Number 0910-0674

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 0910-0674 to conduct a set of focus groups, "Consumer Perceptions Related to Harmful and Potential Harmful Constituents in Tobacco Products", to assess consumer perceptions and knowledge with respect to harmful and potentially harmful (H-PH) tobacco constituents, which will inform the Agency's efforts to implement the mandatory publicly available list of H-PH constituents required by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

2. **Intended use of information:**
   Section 904(d)(1) of the Tobacco Control Act states "Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful and potentially harmful constituents] established under subsection (e)."

   In order to develop information that is understandable and not misleading, FDA must conduct research to gain insight on consumer perceptions and knowledge with respect to harmful and potentially harmful (H-PH) tobacco constituents.

3. **Description of respondents:**
   Respondents to this collection will be part of 16 focus groups representing a diverse population. The focus groups will be conducted in areas of the United States with relatively high rates of smoking (Metropolitan Washington, DC; Nashville, TN; Baton Rouge, LA; and Miami, FL). At least eight of the groups will be comprised of young smokers (four groups between 13 and 17 years of age and four groups between 18 and 24 years of age). The remaining groups will consist of four groups between 25 and 34 years of age and four groups between 35 and 65 years of age. The groups will be separated by gender and will also vary by race, income, and/or smoking status (e.g., regular users, occasional users, those planning to quit, ect.). At least half of the groups will be comprised of smokers with lower literacy levels. The contractor will recruit 12 individuals for each focus group discussion, with the expectation of have 8 to 10 participants per group.

4. **Date(s) to be conducted and location(s):**
   The focus group research will begin in January 2011 and be completed by April 2011. The focus groups will be conducted in Metropolitan Washington, DC; Nashville, TN; Baton Rouge, LA; and Miami, FL;

5. **How the Information is being collected:**
   The information is being collected by a contractor who will conduct a session in a room containing one of the focus groups. The session will be live, face-to-face, and may be videotaped if consent is given from everyone in the group. The contractor will ask a series of questions, and record the group's answers and reactions to those questions. Participants are also given a package of questions to which they are asked to respond. The questions will be collected at the end of the focus group session, and the data collected in these focus groups will be used to inform the design of a follow-up qualitative-quantitative comprehension study and a quantitative experimental survey to access the ability of consumers to use and understand the publicly available information on H-PH constituents.

   Focus groups, or group interviews, 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.) Focus groups are usually composed of 8 - 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 their development.

   The information is being collected by the moderator, and the session will be live, face-to-face, and may be videotaped if consent is given from everyone in the group. The moderator will ask a series of questions, and record the group's answers and reactions to those questions. Participants are also given a package of questions to which they are asked to respond. The questions will be collected at the end of the focus group session, and the data collected in these focus groups will be used to inform the design of a follow-up qualitative-quantitative comprehension study and a quantitative experimental survey to access the ability of consumers to use and understand the publicly available information on H-PH constituents.

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 $75 per respondent. 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.

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, income, education 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 FDA speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information 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, while not 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 the interview situation and are more at ease with the interviewer/moderator. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

FDA tobacco communications may also be concerned with discouraging tobacco use by adolescents before they start. FDA acknowledges the sensitivity of questions about the purchase and use of tobacco, which is illegal for minors in some states. In the event that questions are asked of teenagers (ages 13 to 17), interviews will be conducted by moderators specifically trained for interaction with adolescents.

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):

Pretesting for potential respondents to this collection includes various methods and approaches. 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 on cancer and other negative tobacco-related health outcomes among professional, patient, and public audiences.

In general, pretesting relies on qualitative methods and is not intended to yield results that are statistically projectable. However, tobacco communication messages will be designed and marketed with specific audiences in mind (e.g., 13-17 year olds, 18-24 year olds, tobacco users who intend to quit, non-users, health care professionals, and tobacco retailers). 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 which is not representative of the population. For this focus group, all respondents will be initially contacted by telephone or through the mail, and some over-recruiting may be done to compensate for not following up with non-respondents.

For the quantitative methods used in this group study, information collection activities will target these particular audiences with statistical sampling procedures employed to identify potential survey respondents, such as smokers in a particular age group. Mail, telephone, and Internet surveys will seek a convenience sample that nonetheless has a reasonable degree of diversity in key demographic characteristics such as age, gender, education, and race/ethnicity. FDA does not intend to generate nationally representative results or precise estimates of population parameters using these surveys.

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)
Young Smokers (4 groups of 12; 13 to 17 Years old)	48	96	76.8
Young Smokers (4 groups of 12; 18 to 24 years old	48	96	76.8
Smokers (4 groups of 12; 25 to 34 years old)	48	96	76.8
Older Smokers (4 groups of 12; 35 to 65 years old)	48	96	76.8
Total	192	96	307.2

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