FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS

TITLE OF INFORMATION COLLECTION: Focus Group Study of Adolescent and Young Adult Perceptions Related to Cigarette Smoking; 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, "Focus Group Study of Adolescent and Young Adult Perceptions Related to Cigarette Smoking, " to assess consumer perceptions about smoking.

2. **Intended use of information:**
   To inform the Agency's efforts to implement health education and communication messaging related to cigarette smoking initiation in the youth.

3. **Description of respondents:**
   The study will consist of 8 focus groups and 12 individual interviews (IDIs) representing a diverse population. The focus groups and interviews will be conducted in areas of the United States with relatively high rates of menthol smoking (Baltimore, New York City, Portland ME, and Indianapolis, IN). Four groups will be between 18 and 21 years of age, four groups between 22 and 25 years of age, and 12 IDIs will be conducted on adolescents age 15-17. The groups will be separated by gender and menthol preference. Attempts will be made to match groups according to race/ethnicity and education.

   For the 15-17 year old groups, 18 people will be recruited for the desired anticipated turnout of 12 participants. For the 18-21, 9 people will be recruited for the desired anticipated turnout of 6-7 participants and the 22-25 year old groups, 12 people will be recruited for the desired anticipated turnout of 8-9 participants.

   This project is designed to evaluate consumer use, knowledge, and perceptions about cigarette smoking. Focus groups and interviews will be conducted in person. Groups and participations will differ by gender and menthol preference. Information gleaned from the focus groups will inform FDA about first and current smoking experiences as well as potential messaging that can by used to help inform youth not to initiate cigarette smoking. Differences will be assessed between menthol and non-menthol smokers in order to determine if any unique messaging is needed for either group of smokers.

4. **Date(s) to be conducted and location(s):**
   The focus groups and individual interviews will begin in August 2012 and be completed by November 2012. The focus groups will be conducted in Baltimore, New York City, Portland ME, and Indianapolis, IN.

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 or a single adolescent for the individual interview. 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 and/or individual's answers and reactions to those questions.

Focus groups and individual 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 6 - 10 people who have characteristics similar to the target audience, or subgroups of the target audience. Both individual interviews and focus 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 and individual interviews are valuable in exploring consumer reactions to message concepts before additional resources are put into their development.

6. **Number of focus groups:**
There will be 8 focus groups and 12 individual interviews representing a diverse population.

7. Amount and justification for any proposed incentive:
As participants often have competing demands for time, incentives are used to encourage participation in focus groups and interviews. Incentives must be high enough to cover travel costs, time, and to provide enough incentive to attend the focus group rather than another activity. Additionally, incentives typically are higher for harder-to-recruit populations. If the incentive is not adequate enough, participants may agree to participate and then not show up for the group. 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).

Recruitment facilities consider youth (ages 15-17) and young adults (ages 18-25) who use tobacco products difficult-to-reach populations given their prevalence in the general population. In addition, youth are particularly difficult to recruit due to the sensitive nature of the topic—they must admit they are a current tobacco user or are susceptible to use. Thus, is it critical to this data collection that we are able to provide adequate incentives to encourage participation among the limited number of potential youth and young adults.

The amount of the proposed incentive for youth is $30, with an additional $25 offered to parents of these youth. We propose compensating parents of adolescent participants to facilitate participation of the youth. Young adults will be provided $50 for their participation.

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. Because questions are being asked of teenagers (ages 15 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. Assurance of Privacy Provided to Respondents

Before each group or interview begins, the moderator will obtain verbal consent from the participants to videotape the sessions. In the event consent is not given, the Contractor will refrain from videotaping the session.

The contractor will ensure that all sessions are audiotaped and videotaped, if consent is given. One copy of each session will be supplied in digital format that can be viewed on a computer. We will also produce transcriptions of the tapes to assist in report writing and to provide the FDA with a written record of the sessions. One paper and one electronic copy of the transcripts will be supplied. The audiotapes and transcripts for a given group or interview will be available to the FDA within two weeks of the completion of that data collection. To ensure participant privacy, the contractor will redact the recordings and transcripts.

All data will be collected with an assurance that the respondents' discussions will remain private to the extent provided by the law. The study moderator’s guide and consent form will contain a statement that no one will be able to link the respondent’s identity to their responses. Identifying information will not be included in the data files delivered by contractors to the agency.

Neither independent contractor nor focus group agencies will share personal information regarding panel members with any third party without the participant’s permission unless

it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in the transcripts and digital recordings delivered to the agency. Upon final delivery to FDA, transcripts and digital recordings will be destroyed. All data received by FDA will remain in a secured area. No data will contain identifying information.

10. **Description of Statistical Methods (I.E. Sample Size & Method of Selection):** Focus groups and interviews rely on qualitative methods and are not intended to yield results that are statistically projectable. Participants will be identified based on their age and smoking status. It is important for participants to represent a diverse race/ethnicity and education background. All respondents will be initially contacted by telephone or through the mail, and some over-recruiting will be done to compensate for non-responders.

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 (12 individuals 15 to 17 Years old)	12	96	19.2
Young Smokers (4 groups of 7; 18 to 21years old	28	96	44.8
Smokers (4 groups of 9; 22 to 25 years old)	36	96	57.6
Total	76	96	121.6

REQUESTED APPROVAL DATE: July 15, 2012

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