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. Thus, 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 they 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: Qualitative Study on Nicotine: Knowledge, Beliefs, and Perceptions; 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, "Qualitative Study on Nicotine: Knowledge, Beliefs, and Perceptions," to assess consumers' understanding and awareness of the chemical nicotine, as it relates to the use of tobacco products. 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) by understanding how people think about nicotine.

   Section 1003(d)(2)(D) of the Food, Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) and Sections 2, 3, 105, 201, 204, 904, and 908 of the FD&C Act support the development and implementation of FDA communications and education related to tobacco use. Effective communication requires an understanding of consumer knowledge and beliefs.

2. **Intended use of information:**
   Nicotine is the primary reason that people continue to use tobacco products—even after they decide they no longer want to.[1] At the same time, the relationships between nicotine, addiction, and tobacco use are complex and it is unclear the extent to which the public—particularly tobacco users—understand these relationships. Survey evidence suggests that the majority of smokers understand that nicotine is addictive; however, also prevalent is the (inaccurate) belief that nicotine is the primary reason cigarettes cause cancer.[2]

   Communicating to the public about the harms of tobacco products is becoming increasingly complex in the context of the growing diversity of tobacco products and other nicotine-containing products. Given the wide variety of nicotine-containing products under FDA jurisdiction, understanding how consumers view nicotine across products is critical for effective communication. For example, beliefs such as these may be one reason smokers are sometimes resistant to using the FDA-approved cessation products, Nicotine Replacement Therapies (NRT), believing incorrectly that they are just as harmful as tobacco products.[2,3,4] While several national surveys, including PATH, provide data on the perceived addictiveness of nicotine and beliefs about role of nicotine

[1] U.S. Department of Health and Human Services (1988). *The Health Consequences of Smoking: Nicotine Addiction: A report of the Surgeon General* Rockville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health.

[2] Bansal, M. A., Cummings, K. M., Hyland, A., & Giovino, G. A. (2004). Stop-smoking medications: Who uses them, who misuses them, and who is misinformed about them? *Nicotine & Tobacco Research, 6,* S303-S310.

in causing cancer, little else is known about people's knowledge and beliefs about nicotine more broadly, how people understand nicotine and its role in addiction (including satisfying craving) and harm across products, and where people get information about nicotine. By exploring these issues qualitatively, FDA can understand what and how people are thinking about nicotine and addiction in more depth than can be provided through existing surveillance measures.

This study is intended to qualitatively explore knowledge and beliefs about nicotine and addiction. Findings from this formative research will allow FDA to: 1) identify potential communication messages; and 2) determine whether there may be a need to assess the prevalence of additional nicotine-related beliefs or to better understand the relationship between beliefs and tobacco behaviors. Any further work done to create communication messages or develop items for inclusion on national surveys would require additional research prior to execution. Research conducted to inform such efforts will seek OMB approval.

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.

3. Description of respondents:

Respondent Characteristics and Group Segmentation

Respondents will participate in one of 16 focus groups. Four focus groups will be conducted in Washington, D.C. or Baltimore, MD. Eight focus groups will be conducted in Columbus, OH. Four focus groups will be conducted in New Orleans, LA. These locations were chosen because they 1) have relatively high rates of tobacco use overall; 2) have relatively high rates of youth cigarette use; 3) have relatively high rates of smokeless tobacco use; and/or 4) have a relatively large African American population (proxy for high rates of menthol cigarette use). Geographic diversity is achieved by selecting one site on the east coast, one in the mid-west/west and one in the south. Each group will include a mix of ages, races/ethnicities, and education levels.

Because this study is exploratory, it is important to capture a full range of responses from a variety of people. Respondents will be recruited based on characteristics related to differences in smoking behavior and addiction. Recruitment characteristics include: age (adolescent, young adult, adult) smoking status (e.g., current user, susceptible to smoking), and cigarette type (e.g., menthol, non-menthol). As is standard in focus group studies[5], 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: Four groups will be conducted exclusively with adolescents (ages 16-17). The adolescent groups will be segmented by gender (2 male groups and 2

[3] Kaufman, A. R., Waters, E. A., Parascandola, M., Augustson, E. M., Bansal-Travers, M., Hyland, A. et al. (2011). Food and Drug Administration Evaluation and Cigarette Smoking Risk Perceptions. *American Journal of Health Behavior, 35,* 766-776.

[4] Mooney, M. E., Leventhal, A. M., & Hatsukami, D. K. (2006). Attitudes and knowledge about nicotine and nicotine replacement therapy. *Nicotine & Tobacco Research, 8,* 435-446.

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

female groups) and smoking status: current users (smoked a cigarette in the past 30 days) and susceptible to smoking (based on a 3-item screener).

Young Adults: Three groups will be with young adults (18-25 years old) who are current, daily smokers. The young adult groups will each contain equal numbers of males and females and will include two groups that typically smoke menthol cigarettes.

Adults: Nine groups will be conducted with adults (≥26 years old). Of these nine groups, two groups will consist of current, daily smokers, three groups will consist of intermittent smokers (currently smoke "some days"), two groups will consist of dual users (currently use any other tobacco product in addition to smoking cigarettes, at least intermittently), and two groups will consist of daily smokers who typically smoke menthol cigarettes. Each group will contain an equal number of males and females.

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 6 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 adult 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); and/or
- Centers for Medicare & Medicaid Services (CMS).

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

The focus groups will be conducted in summer 2014. The focus groups will be conducted in Washington, D.C. or Baltimore, MD, Columbus, OH, and New Orleans, LA.

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 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 in the Washington, D.C. or Baltimore area will be monitored by FDA representatives from behind a one-way mirror. The other focus groups will 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 knowledge, beliefs and perceptions about the chemical nicotine, as it relates to the use of 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.[6]

   The amount of the proposed incentive is $30 for adolescents, plus $25 for a parent/guardian that accompanies them to the study facility; and $75 for adults. 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 population.

   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[7]. 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 eligible adult tobacco users. Thus, in order to obtain the sample of participants required by our study, while also

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

[7] Morgan, D.L. & Scanell, A.U. (1998) *Planning Focus Groups.* Thousand Oaks, CA: Sage Publications.

minimizing biases in self-selection and balancing recruitment expenses, it is critical we offer a sufficient level of incentive.

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. In this study, participants will be asked in general terms about what, if anything, nicotine does to the body and brain, however the questions could 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	Participation	Burden

	Respondents	Time (minutes)	(minutes)
Adolescents (16-17 years old): 4 groups with 12 participants per group			
Initial Screener	720	6	4,320
Parental Assent	**48**	5	240
Adolescent Assent	48	5	240
Focus group discussion	48	90	4,320
Young adults (18-25 years old): 3 groups with 12 participants per group			
Initial Screener	324	6	1,944
Consent	**36**	5	180
Focus group discussion	36	90	3,240
Adults (≥26 years old): 9 groups with 12 participants per group			
Initial Screener	972	6	5,832
Consent	**108**	5	540
Focus group discussion - Adults	108	90	9,720
Total	**192**		30,576
Total Burden	30,576 minutes = 509.6 hours		

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