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 group 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: Other Tobacco Products (OTP): A 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, "Other Tobacco Products (OTP): A Focus Group Study," to assess consumer perceptions of non-cigarette 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) related to educating the public about the harms of tobacco use.

   The aim of the proposed study is to inform the design of future experimental studies and surveys related to other tobacco products. The study is designed to ascertain the diversity of knowledge, attitudes, and awareness related to these other tobacco products held by a variety of people. Accordingly, the current study design employs a number of focus groups with diverse types of tobacco users, as well as former users. This research will explore knowledge, beliefs, and risk perceptions of cigars, e-cigarettes, and hookah.

   This study complements another study that is seeking approval to be conducted under the Generic Clearance Cognitive Testing of Instrumentation and Materials in the Population Assessment of Tobacco and Health (PATH) Study (ICR 201209-0925-001). The primary aim of the complementary study is to inform the development of appropriate survey questions for inclusion in PATH that relate to the use of hookah and e-cigarettes by exploring how products are used and the terminology used by consumers to describe both the products and use behaviors. To best address these issues, this study will recruit highly experienced users of these products.

   Both studies examine aspects of emerging non-cigarette tobacco products, including e-cigarettes and hookah. As such, researchers in both studies are working closely with each other to ensure that the contributions from each study are unique and complementary. The current study, as it is more formative in nature, addresses several issues not addressed by the PATH study. In particular, unlike the PATH study, the current study will examine, in-depth, consumers' attitudes and beliefs about these products including: their reasons for use, perceptions of how the products compare to other (conventional) tobacco products, knowledge and beliefs about health effects and addictiveness. In addition, discussions in the current study will explore perceived social norms regarding these products, including use and attitudes among friends and family, and other sources of information about the products.

2. **Intended use of information:**
The Family Smoking Prevention and Tobacco Control Act directs the FDA to educate the public regarding the harms associated with tobacco use. In order to maximize the efficacy of these communication and education efforts, it is imperative that the FDA have a complete understanding of the full landscape of current tobacco use: this entails understanding consumers' perceptions, attitudes, and behaviors related to tobacco products currently regulated by the FDA (cigarettes, roll-your-own tobacco, and smokeless tobacco products), as well as those products not currently regulated by the FDA. The current project examines a set of these "other tobacco products" not currently regulated by FDA: cigars (including regular cigars, little cigars and cigarillos) e-cigarettes, and hookah. Moreover, this requires speaking to a range of types of users in different parts of the country in order to sample the full diversity of public perceptions and attitudes.

Currently, the research literature on cigars, e-cigarettes, and hookah is limited. Surveillance of the use of these products is incomplete and these efforts are challenged by a lack of understanding about how best to ask questions about use of these products[1]. Even less is known about how consumers talk about these products, what they know and believe about them in terms of health effects, and how and when they use them.

FDA has indicated its intention to exert jurisdiction over these products. Thus, in addition to informing communication and education efforts, it is in FDA's interest to begin building the knowledge base related to consumer understanding of these products, so that we will be better equipped to design future research that will inform our understanding of the public health impact of these products.

The purpose of these focus groups is to explore consumers' perceptions, knowledge and use patterns around this set of other tobacco products. The study findings will inform future research efforts.

3. **Description of respondents:**
A set of focus groups will be dedicated to each product type: Cigars, Little Cigars, and Cigarillos (16 groups), E-cigarettes (12 groups), and Hookah (12 groups) for a total of 40 focus groups. Groups will be conducted in each of the following five locations, which were selected based on prevalence rates of use of the products of interest: Orlando, FL; Los Angeles, CA; Providence, RI; Richmond, VA; and Washington DC. Respondents will participate in one focus group. So that the groups are homogeneous in terms of familiarity with the product of interest, respondents will be segmented in terms of experience with the product (current or ever use; exclusive vs. dual-use). Groups will be conducted with young adults (18-24 years) and adults (25+). In addition, in some cases, groups will be segmented by race/ethnicity and gender. Otherwise, groups will include a mix of ages, races/ethnicities, and education levels. The table below provides the segmentation for the 40 groups.

FOCUS GROUP SEGMENTATION

[1] Trapl. E.S., Terchek, J.T., Danosky, L., Cofie, L., Brooks-Russell, A., & Frank, S.H. (2011). Complexity of measuring "Cigar use" in adolescents: Results from a split sample experiment. *Nicotine and Tobacco Research, 13,* 291-295.

	Cigars	E-cigarette	Hookah
Orlando	2 adult (1 African American male; 1 White/Other Male) 2 young adult (1 Female; 1 White/Other Male)	1 adult mix* 2 young adult mix*	3 young adult mix*
Los Angeles	2 adult (1 Female; 1 Hispanic Male) 2 young adult (1 Female; 1 Hispanic Male)	1 adult mix* 2 young adult mix*	3 young adult mix
Providence	2 adult (1 Female; 1 Hispanic Male) 1 young adult (1 Hispanic Male)	1 adult mix* 1 young adult mix*	3 young adult mix*
Richmond	2 adult (1 African American male; 1 White/Other Male) 2 young adult (1 African American male; 1 White/Other Male)	2 adult mix* 1 young adult mix*	
Washington, D.C.	1 young adult (African American Male)	1 adult mix*	3 young adult mix*

Mix* = mix of gender, race/ethnicity, 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 February 2014. The focus groups will be conducted in Orlando, FL; Los Angeles, CA; Providence, RI; Richmond, VA; and Washington, DC.

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-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 focused on one of the three tobacco product types of interest.

6. Number of focus groups:

There will be 40 focus groups representing a diverse population and range of other tobacco products.

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.[2]

The amount of the proposed incentive is $75. Adults who use tobacco products are a difficult-to-reach population given the low prevalence of tobacco use in the general population. Further difficulties in recruitment of participants will result from the current study's need for participants who use one of several low-prevalence tobacco products (e.g., current prevalence of ever use of e-cigarettes is estimated to be between 3%-6%).

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[3]. 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

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

[3] 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. 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. 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)
Cigar, Cigarillo, Little Cigar user (16 groups)	192	66	211.2

E-cigarette user (12 groups)	144	66	158.4
Hookah user (12 groups)	144	66	158.4
Total	480		528

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