FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF COLLECTION OF QUALITATIVE DATA ON TOBACCO PRODUCTS AND COMMUNICATIONS (0910-0796)

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: Focus Groups on ENDS: Device Types, User Experiences, and Product Appeal

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 0910-0796 to conduct focus groups with users of electronic nicotine delivery systems (ENDS) with a study titled "Focus Groups on ENDS: Device Types, User Experiences, and Product Appeal," to assess consumer perceptions of electronic nicotine 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 informing future research efforts and development of plans for educating the public about the harms of tobacco use.

   The aim of the proposed study is to understand how device characteristics of ENDS, such as e-cigarettes, influence users' experience; and how these experiences shape use behavior, beliefs, and attitudes about ENDS. The study is designed to ascertain the diversity of knowledge and attitudes related to these electronic nicotine products held by a variety of people. Accordingly, the current study design employs a number of focus groups with diverse types of users, including: those who primarily use "cigalikes" (non-customizable devices that have a similar appearance to cigarettes), and those who use "tank systems" (or, advanced-generation, customizable devices).

   This study is a follow-up to one conducted in 2014 under generic clearance 0910-0497, titled "Other Tobacco Products (OTP): A Focus Group Study". That study involved focus groups with current users of e-cigarettes, hookah, and cigars and explored 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. Findings from this study were informative and useful to CTP as well as FDA's sister agencies: Study investigators presented the findings to audiences from multiple offices in CTP and FDA, as well as to the interagency HHS Tobacco Workgroup. Additionally, four manuscripts have been developed from these study findings for peer-reviewed publication; two of which are currently in press[1,2]. For more information on this study, a copy of this presentation is included as an Appendix.

[1] Coleman, B.N. et al., "It's not smoke. It's not tar. It's not 4,000 chemicals. Case closed": Exploring attitudes, beliefs, and perceived social norms of e-cigarette use among adult users. *Drug and Alcohol Dependence.* doi:10.1016/j.drugalcdep.2015.11.028

[2] Dickinson, D. et al. (in press). The language of cigar use: Focus group findings on cigar product terminology. *Nicotine & Tobacco Research*.

The current study will build on the knowledge gained in the e-cigarette portion of the prior study by exploring use of specific ENDS device types in order to understand how device characteristics influence users' experience; and how these experiences shape use behavior, beliefs, and attitudes about ENDS.

2. **Intended use of information:**
FDA has proposed to assert jurisdiction over all products that meet the definition of tobacco products in Chapter IX of the Food, Drug and Cosmetic Act, including ENDS. In order to maximize the efficacy of FDA's surveillance activities and communication and education efforts, it is imperative that FDA have a complete understanding of the full landscape of ENDS products for which FDA has proposed to extend its jurisdiction. Once such products are deemed under the authority of FDA, CTP will require a deep understanding of consumers' perceptions, attitudes, and behaviors related to ENDS. Owing to the diversity of this product category, this understanding 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.

Findings from the initial set of e-cigarette groups raised additional questions which this study aims to address. In particular, the OTP study findings revealed a great diversity among e-cigarette users in terms of their attitudes, knowledge, and beliefs. A salient dimension that seemed to distinguish between users was their familiarity and use of different types of e-cigarette devices. For instance, users of cigalikes vs. users of more sophisticated 'later-generation' products seemed to vary greatly in their experiences and attitudes. Indeed, evidence from the literature suggests these devices are associated with different experiences for the user[3], including in nicotine delivery[4]. Moreover, individuals differ in their preference for each type of product[5] and some evidence suggests that many users start with cigalikes and then many of those users progress to more advanced, customizable, devices[6]. Device preference, then, is a meaningful category that distinguishes between user groups. Because the differences in the device technology can affect the user experience, we hypothesize that users' knowledge, attitudes and beliefs, are likely to differ as well.

Although the scientific literature on ENDS is growing at a rapid pace, there remain significant gaps in our knowledge related to consumers' language, knowledge, attitudes and beliefs, and how they relate to or may be affected by device type. National surveillance of ENDS use is critical for monitoring the emerging phenomenon of this product category. Surveillance is challenged, however, by gaps in knowledge about which behaviors should be asked about, and how best to ask those questions. This study contributes to our ongoing research designed to uncover the salient and relevant topics to

[3] Hitchman, S.C. et al. (2015). Associations between e-cigarette type, frequency of use, and quitting smoking: Findings from a longitudinal online panel survey in Great Britain. *Nicotine & Tobacco Research, 1-8*.
Lechner, W.V. et al. (2015). The comparative efficacy of 1st vs. 2nd generation electronic cigarettes in reducing symptoms of nicotine withdrawal. *Addiction, 110,* 862-7.
[4] Shihadeh, A. & Eissenberg, T. (2015). Electronic cigarette effectiveness and abuse liability: Predicting and regulating nicotine flux. *Nicotine & Tobacco Research, 158-162.*
[5] Dawkins, L. et al. (2014). First- versus second-generation electronic cigarettes: Predictors of choice and effects on urge to smoke and withdrawal symptoms. *Addiction, 110,* 669-677.
[6] Yingst, J., et al. (2015). Factors associated with electronic cigarette users' device preferences and transitions from first generation to advanced generation devices. *Nicotine & Tobacco Research, 17,* 1242-1246.

be addressed by national surveillance efforts. Moreover, an ongoing challenge for ENDS research is determining the appropriate terms, labels, and language to use. Findings for this study will inform the development of survey items to most effectively capture the experience of ENDS users.

As stated above, FDA has indicated its intention to assert jurisdiction over ENDS products. Thus, in addition to informing surveillance efforts, this research will also enable FDA to build the knowledge base about these products in order to inform future communication and education efforts.

3. **Description of respondents:**

A total of 24 focus groups will be conducted with users of e-cigarettes. Groups will be conducted in four locations, which were selected based on prevalence rates of use of the products of interest, need for geographic diversity, as well as ability to reach both rural and urban participants: New York, NY; Chicago, IL; Memphis, TN; and Denver, CO. Respondents will participate in one focus group. So that the groups are homogeneous in terms of familiarity with the characteristics of interest, respondents will be segmented in terms of experience with one of two types of products (cigalikes vs. tank systems). Groups will be conducted with young adults (18-29 years) and adults (30+) and with those who live in urban and rural zip codes. Groups will include a mix of ages, sex, races/ethnicities, and education levels. The table below provides the segmentation for the 24 groups.

FOCUS GROUP SEGMENTATION

Segment	Northeast (NYC)	Midwest (Chicago)	South (Memphis)	South Rural (Memphis)	West (Denver)	West Rural (Denver)	TOTAL
Young Adult Cigalike	2			2		2	**6**
Adult Cigalike		2	2		2		**6**
Young Adult Tank System	2		2	2			**6**
Adult Tank System		2			2	2	**6**
TOTAL	**4**	**4**	**4**	**4**	**4**	**4**	**24**

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 winter/ early spring, 2016. The focus groups will be conducted in New York, NY; Chicago, IL; Memphis, TN; and Denver, CO.

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.

   In reporting qualitative findings, it is customary to report the summary sociodemographic characteristics of the overall sample based on information collected at screening. To keep the screening questions to a minimum, some background questions will be asked once participants arrive to participate, prior to the focus group discussion. In particular, a brief Background Assessment will be administered prior to the focus group discussion to assess behavioral characteristics of the sample not ascertained in screening.

   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 e-cigarette product types of interest.

6. **Number of focus groups:**
   There will be 24 focus groups representing a diverse population and range of e-cigarette users.

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 sufficient 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 offered in government studies (Fieldwork Denver, personal communication, March 22, 2012), establishing a competitive market rate. Additionally, incentives typically are higher for harder-to-recruit populations.[7]

The amount of the proposed incentive is $75.

The current study's need for participants who use e-cigarettes regularly presents an additional challenge because current e-cigarette users represent a very small minority of the overall population the US. Data from the 2014 the National Health Interview Survey reported prevalence of every day or some day e-cigarette use among adults is only 3.7%[8],. Additionally, this study seeks to recruit users of different e-cigarette device types, including the more common cigalike devices as well as less common advanced, customizable devices. A 2014 report on electronic cigarettes sales found that market share is 65% cigalike devices and 35% advanced, customizable devices[9], which may pose additional recruitment challenges for users of advanced e-cigarette products.

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[10]. Given FDA's need to understand consumer perceptions of tobacco products 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 users. Thus, in order to obtain the sample of participants required by our study, while also 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 to the extent allowable by law. 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).

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

[8] Agaku, I.T. et al. (2014). Tobacco Product Use Among Adults—United States, 2012-2013. *Morbidity and Mortality Weekly Report (MMWR), 63*(25), 542-547.

[89] Schoenborn, C & Gindi, R.M. Electronic Cigarette Use Among Adults: United States, 2014. NCHS Data Brief, no. 217. Hyattsville, MD: National Center for Health Statistics, 2015.

[910] Herzog, B. Gerberi, J. & Scott, A. *Equity Research—Tobacco: Vapor Work Expo—Key Takeaways.* Wells Fargo Securities, May 12, 2014.

[1011] Morgan, D.L. & Scanell, A.U. (1998) *Planning Focus Groups.* Thousand Oaks, CA: Sage Publications.

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 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 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 Respondents	Participation Time (minutes)	Burden (hours)
Young adult e-cigarette users (18-29 years old): 12 groups with 12 participants per group			
Initial Screener	2,160	6	216
Consent	144	5	12
Background Assessment	144	5	12
Focus group discussion	144	90	216
Subtotal			**456**
Adult e-cigarette users (30+ years old): 12 groups with 12 participants per group			
Initial Screener	2,160	6	216
Consent	144	5	12
Background Assessment	144	5	12

Focus group discussion	144	90	216
Total Screened	**4,320**		456
Total Participants	**288**		**912**

[1] **The total universe (number of respondents) for this individual generic collection of information is 4,320. The 288 represents the total number of participants in this study. The total number of participants (4,320) will be pre-screened for participation in the study, and only 288 will actually partake in the study after screening.**

REQUESTED APPROVAL DATE: March 1, 2016

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