FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS

TITLE OF INFORMATION COLLECTION:

Qualitative Study on Acute Nicotine Toxicity Warnings for E-Liquids: Knowledge, Beliefs, and Perceptions

OMB Control Number 0910-0796

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 exploratory focus groups, "Qualitative Study on Acute Nicotine Toxicity Warnings for E-Liquids: Knowledge, Beliefs, and Perceptions," to assess consumer reactions to draft acute nicotine toxicity warnings for e-liquids. To achieve this objective, a series of focus groups will be conducted with a wide-ranging sample of the population that covers various ages, races, and levels of educational attainment. The data collected during these focus groups will help finalize warnings that will be tested in future studies. The focus groups will be designed to answer the following questions:

1. What do adults and youth know about acute toxicity due to exposure to nicotine-containing e-liquids?
2. What are the best ways to present information about acute toxicity due to exposure to nicotine-containing e-liquids to consumers on electronic nicotine delivery system (ENDS) product packaging?
3. What are consumer reactions to draft acute nicotine toxicity warnings for e-liquids?
4. What information do people take away from the draft acute nicotine toxicity warnings for e-liquids? Are they learning any new information?
5. Do consumers find icons/symbols helpful in understanding the acute nicotine toxicity warnings for e-liquids (with and without textual warning statements)?
6. Do consumers believe that the use of colors in the acute nicotine toxicity warnings for e-liquids would help to increase the label's visibility?

Section 906(d)(1) of the FD&C Act provide FDA the authority to include restrictions on the access to, and the advertising and promotion of, the tobacco product, if FDA determines such restrictions would be appropriate for the protection of the public health. In order to meet the requirements under the Act, FDA is conducting consumer research to provide information and data needed to help guide the development of activities directed at the consumer. FDA's Center for Tobacco Products (CTP) will conduct a qualitative study to gain insight into consumer knowledge and perceptions surrounding risk of acute toxicity from nicotine exposure in electronic nicotine delivery systems (ENDS). In addition, consumers will be asked to view and react to draft acute nicotine toxicity warnings for e-liquids. Information gathered from this study will be used to improve the study stimuli (i.e., warning statements, icons/symbols, and formats) for a future quantitative study.

2. **Intended use of information:**

The study is intended to assess consumer reactions to draft acute nicotine toxicity warnings for e-liquids. Study findings will be used to refine the draft warnings to most effectively communicate the risk of acute toxicity from exposure to nicotine-containing e-liquids in ENDS and what to do in case of accidental contact.

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 12 focus groups. Focus groups will be conducted in two locations, tentatively planned for the following cities: Pensacola, Florida and Birmingham, Alabama. These locations were chosen for racial/ethnic diversity and rates of adult and youth ENDS use. Each group will include a mix of ages, sex, 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. Recruitment characteristics include respondent: age (youth, young adult, and adult) and ENDS device type: "open" ENDS devices that require users to refill a tank with e-liquid; and "closed" ENDS devices that require users to replace prefilled and sealed e-liquid cartridges. As is standard in focus group studies[1], groups will be segmented to achieve relative homogeneity within groups. Respondents are grouped together based on common characteristics (age and ENDS device type) to maximize compatibility and facilitate group discussions. Groups will be segmented as follows:

Youth: Four groups will be conducted exclusively with youth (ages 14-17 years) who have used any kind of ENDS device type (open or closed) in the last 60 days.

Adults: Eight groups will be conducted with adults (≥18 years old) who are current ENDS users (defined as use of ENDS every day or some days).

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
For each group, 14 individuals will be recruited, with the expectation of having 10 to 12 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 six 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 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 e-cigarette company;

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

- 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);
- Centers for Medicare & Medicaid Services (CMS).

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

Recruitment for focus groups will begin in April-May 2018. The focus groups will be tentatively conducted in two locations: Pensacola, Florida and Birmingham, Alabama

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 12 people who have characteristics similar to 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 guide, 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 60-minute focus group will be conducted at a local marketing research firm. With respondent consent, each group will be digitally audio-recorded. Focus groups may be monitored by FDA representatives from behind a one-way mirror. Focus groups will also be video-streamed such that FDA representatives can view them via a live webcast. Using a semi-structured moderator guide, a professional moderator will lead each group through a discussion about participants' reactions to draft acute nicotine toxicity warnings for e-liquids.

6. **Number of focus groups:**

There will be 12 focus groups representing a diverse population.

7. **Amount and justification for any proposed incentive:**

To ensure a high show rate, and to ensure that the data collected will be of a sufficiently high quality of data to allow FDA to have confidence in the findings to properly inform its efforts to continue development of draft acute nicotine toxicity warnings for e-liquids displayed on ENDS products, the amount of the proposed incentive is $40 for adults, $25 for adolescents, plus $15 for their parent/guardian.

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, establishing a market rate that makes recruitment more difficult. Additionally, incentives typically are higher for harder-to-recruit populations.[2]

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

Adults who use ENDS products are a difficult-to-reach population given the low prevalence of current ENDS use (5.5%) in the general population.[3] Similarly, youth who use ENDS are also a minority of the overall population. Additionally, participation in focus groups requires substantial commitment and investment of time on the part of the participant, in that they must make a commitment to attend the discussion at a certain time on a specific date. Participation also requires participants to travel to a designated location, with the average commute in the United States metropolitan areas estimated at about 25.1 minutes,[4] and may also require that the participant obtain child care for a fee. Thus, incentives have long been considered a standard practice in conducting qualitative research such as focus groups.

The proposed incentive amounts are in line with other federal information collections that use similar methods:

- OMB No. 0651-0080: Clearance for the Collection of Qualitative Feedback; DOC/PTO
- OMB No. 2010-0042: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery; EPA/OP
- OMB No. 3064-0198: Information Collection for Qualitative Research; FDIC
- OMB No. 0925-0648: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery; NIH
- OMB No. 0970-0401: Fast Track Generic Clearance for Collection of Qualitative Feedback on Agency Service Delivery; HHS/ACF

These standards also exist to provide fair compensation for costs incurred by participants while attending groups (i.e., travel and child care expenses). In addition to covering reasonable costs of participation, payment to participants is necessary to ensure that a sufficient number of respondents from the target populations participate in the study. Incentives to participants must encourage potential participants to agree to allocate their time to the focus group discussion and maintain that commitment on the day of the research ensuring high-quality data.

Offering no incentive or a smaller incentive could potentially exclude sections of the population who cannot attend the groups, either due to the cost of child care and/or travel or the cost of missing work. Excluding sections of the population would limit the quality of the information that would be gained through the focus group discussion and potentially bias the information needed to address the research questions of interest, thus negatively impacting data quality. An insufficient incentive level also 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. Given FDA's need to understand consumer reactions to draft acute nicotine toxicity warnings for e-liquids among varied populations, it is critical to this data collection that we provide adequate incentives to encourage participation among the limited number of eligible adult and youth ENDS users. Thus, to obtain the sample of participants required by our study, while also minimizing selection biases and balancing recruitment expenses, it is critical we offer a sufficient level of incentive.

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[3] Coleman, B.N., Rostron, B., Johnson, S.E., et al. (2017). Electronic cigarette use among US adults in the Population Assessment of Tobacco and Health (PATH). *Tobacco Control, 26,* e117-e16.

[4] McKenzie, B., & Rapino, M. (2011). *Commuting in the United States: 2009. Supplemental Table C. Mean travel time to work by means of transportation and selected characteristics*: 2009. Washington, DC: U.S. Census Bureau.

We anticipate that without the cash incentive, we would need to screen more people to achieve the desired cooperation rate and among those that agree to participate the quality of information collected would be lower. The current estimated burden for the participant screening is 216 hours. Without the incentive, we expect the burden to be approximately 302 hours, an increase of approximately 40%. The cost to respondents and the federal government would increase accordingly.

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 will 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 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 (62 FR 58782).

In this study, participants will be asked what acute nicotine toxicity warnings for e-liquids teach them about the risks of acute toxicity from exposure to nicotine-containing e-liquids in ENDS products; however, the questions could potentially 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 Respondents	Participation Time (minutes)	Burden (hours)
Youth (14-17 years old): 4 groups with 12 participants per group			
Initial Screener	720	6	72

Parent Permission Form	48	10	8
Adolescent Assent Form	48	10	8
Focus group discussion	48	60	48
Adults (≥18 years old): 8 groups with 12 participants per group			
Initial Screener	1440	6	144
Adult Consent Form	96	10	16
Focus group discussion - Adults	96	60	96
Total Screened	2,160		
Total Participants	144		392
Total	**2,304**		**392**

REQUESTED APPROVAL DATE: February 1, 2018

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FDA CENTER: Center for Tobacco Products (FDA/CTP)