

**FDA DOCUMENTATION FOR THE GENERAL CLEARANCE
OF PRETESTING COMMUNICATIONS ON TOBACCO PRODUCTS
(#0910-0796)**

TITLE OF INFORMATION COLLECTION: Nicotine Education Project: Qualitative Study to Gain Insights from Adult Current and Former Smokers to Educate the General Public about Changing Nicotine Standards; OMB Control Number 0910-0796.

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (TCA) (Public Law 111-31) was signed into law. The TCA granted to the Food and Drug Administration (FDA) important new authority to regulate the manufacture, marketing, and distribution of tobacco products; to inform the public on health-related issues; and to protect public health by reducing tobacco use and by preventing death and disease caused by tobacco use. FDA is considering the development of a tobacco product standard to set the maximum nicotine level for cigarettes. FDA is considering this action to lower nicotine levels in combustible tobacco products to a minimally or non-addictive level in an effort to decrease combustible tobacco product use and nicotine dependence.

Combustible tobacco use among adults is a critical public health concern. In 2017, 14% of adults (estimated 34.2 million) aged 18 or older in the U.S. were current cigarette smokers (CDC, 2017a), defined by the National Health Interview Survey as “an adult who has smoked 100 cigarettes in his or her lifetime and who currently smokes cigarettes” (CDC, 2017b). When broken out by age group, 16.5% of adults aged 45-64, 16.1% of adults aged 25-44, and 10.4% of adults 24 or younger reported smoking “every day” or “some days” (CDC, 2017a). These statistics show that adults of all ages are at-risk for use.

The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance OMB No. 0910-0796 to conduct a qualitative research study consisting of up to 30 focus groups to gain insights to inform how OHCE should message about this potential regulatory effort. Specifically, this study will use focus group discussions to explore the target audience’s thoughts around nicotine and tobacco products, as well as the potential regulatory effort. Approximately 30 focus groups with up to eight participants each will be conducted in various locations across the U.S. with a total sample of up to 240 adults. The research will be conducted with individuals aged 19 to 54 who either: 1) currently smoke cigarettes, 2) former cigarette smokers who currently use at least one nicotine product other than cigarettes (prioritizing other non-combustible tobacco products and/or nicotine replacement therapy); or 3) former cigarettes smokers who do not currently use any nicotine products. Individuals will be diverse in terms of race/ethnicity, gender, and geographical location; it is not our intention to come up with a nationally representative sample.

2. Intended use of information:

Information obtained through this study will inform communication strategies about this potential nicotine product standard. Specifically, this research study is designed to assess 1) general perceptions,

misperceptions and knowledge of nicotine in cigarettes, other tobacco products, and FDA-approved nicotine medications 2) knowledge and perceptions of comparative risk of harm of nicotine delivery products and, 3) related perceptions and understanding of the standard and of FDA authority. To address these objectives, researchers will conduct focus groups with current and former adult cigarette smokers.

3. Description of respondents:

This qualitative study will be composed of up to 30 focus groups, each with up to eight participants. Focus groups will take place in Indiana, Louisiana, Pennsylvania, North Carolina, and Atlanta. The research will be conducted with adults who are:

- Current smokers: Age 19-54 who have smoked at least 100 cigarettes in their lifetime and who currently smoke cigarettes (measured by past 30 day use of cigarettes)
- Former smokers: Age 25-54 who have smoked at least 100 cigarettes in their lifetime, quit smoking at least 6 months, but no longer than 5 years before the time of the focus groups, and are categorized as either:
 - Use Nicotine: Currently use at least one other nicotine product (prioritizing other non-combustible tobacco products and/or nicotine replacement therapy); or
 - Quit All Forms of Nicotine: Do not currently use any other nicotine products.

The total sample size will be no more than 240 participants. Groups will be segmented by age (young adult 19-24, adult 25-39, older adult 40-54) and by use status. Groups will be otherwise diverse by other demographic variables (e.g., gender, race/ethnicity).

4. Date(s) to be conducted:

The study is projected to occur between September 2019 and September 2020.

5. How the information is being collected:

The information will be collected through up to 30 in-person focus groups led by a professional moderator with experience leading focus groups on sensitive topics. Focus group moderators will administer a series of activities and ask questions using a semi-structured discussion guide, which is provided in the attachments. Moderators will encourage participants to respond openly and spontaneously. Focus groups will be audio recorded; they will be observed by FDA and research contractor staff. When possible, focus groups will be livestreamed, but not video recorded, to allow other members of the research team who are not in that location to remotely observe the sessions.

Check-In Survey: This questionnaire will be completed individually and includes several self-report items to assess additional demographics, tobacco-related behaviors, and knowledge attitudes and beliefs around tobacco. There will be 3 unique check-in surveys depending on smoking status (current smoker, former smoker - quit cigarettes, and former smoker - quit nicotine) because there is the need to ask different tobacco-related behavior questions depending on smoking status.

Study Introduction: Following the Check-In Survey, the moderator will explain the study purpose and provide general ground rules for participation in the focus group.

General Discussion: This segment will consist of a general discussion around tobacco use and norms, tobacco-related knowledge and product perceptions, and information and statements about potential nicotine-related regulatory action from the FDA. The moderator will pose open-ended questions to the group and allow for conversation to occur organically. The discussion is designed to glean insights from adult current and former smokers to inform how the FDA will communicate the new nicotine-related product standard to the public.

Once participants complete all activities, recruitment staff will instruct participants to sign out and give each participant their incentive. Individuals will be asked to initial a Check-Out Form certifying they received their incentive. Check-Out Forms are used for internal accounting purposes only; however, no identifying information such as participant Unique ID will be collected on the Check-Out Forms. Once data collection and internal accounting are complete, the Check-Out Forms will be destroyed. Approximately a week after data collection, data entry for individual surveys will be completed.

Data will be collected in professional meeting rooms or focus group facilities and will be audio recorded. Each focus group will last 90 minutes. The focus groups will also be observed by FDA and campaign contractor staff.

6. Confidentiality of respondents:

All data will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law.

All participants will complete a consent form prior to participation. Qualifying individuals will provide verbal consent on the phone, and then be e-mailed the consent information that they will review to either sign electronically or during the check-in process on the day of the focus group. Before each group begins, the moderator will obtain verbal assent from the participants to audiotape the session. In the event assent is not given, the contractor will refrain from audiotaping the session, although live notes/transcriptions may still be taken. The consent forms will also contain a statement notifying participants that audio recording will occur.

Neither independent contractors nor focus group agencies will share personal information regarding participants 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, a court order, or other legal process. Identifying information will not be included in the transcripts and digital recordings delivered to the agency. All data received by the FDA will remain in a secured area. No data will contain identifying information.

7. Amount and justification for any proposed incentive:

CTP will be offering a \$75 gift card to participants. The \$75 card for the participants is provided as thanks for their entire burden time, which includes obtaining consent, time needed to get to and from the

interview facility, and participating in the 90-minute focus group session, and any disruption to the normal routine that attending this focus group may result in.

As participants often have competing demands for their time, incentives are used to encourage participation in research. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation (Halpern, 2004). Incentives also help ensure adequate representation among harder-to-recruit populations such as youth, low socio-economic groups, and high-risk populations (current or former tobacco users and those susceptible to tobacco use) (Groth, 2010). If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with recruitment, facility rental, and moderator and observer time (Morgan, 1998).

Additionally, in the market research community, incentives are standard practice for all work conducted and are suggested by organizations that set the standards for conducting ethical market research among human subjects (CASRO Code of Standards and Ethics for Survey Research). The contractors conducting this research consistently use this type of incentive structure for studies conducted in schools with youth. An incentive less than the suggested amount per focus group will greatly inhibit the ability to successfully recruit participants who will show up for the focus group session. As a minimal intervention study with low burden, the incentive amount is considered appropriate.

The participation token of appreciation will be issued directly to the participant via a prepaid debit card (participants will not be required to pay any potential fees associated with activating the card). There are several benefits to paying participants with a debit card versus cash or check, including (1) Providing debit cards will prevent research staff from having to carry around large sums of cash, (2) Any sensitivity toward paying youth with cash is avoided (i.e., ability to use cash for illicit substances like drugs, alcohol or tobacco), and (3) Any issues preventing participants and/or their parent/guardian from cashing a check (e.g., no bank account) are avoided.

In previous studies, CTP has conducted with similar groups of adults (e.g. adult smokers) using similar protocols (e.g. 90 minute focus groups in focus group facilities), CTP has used tokens of appreciation of this amount and, with this token of appreciation, was successfully able to recruit and complete the focus groups within the relatively tight schedule for focus group research (4 geographic locations in 4 weeks).

The previous studies that CTP has successfully used tokens of appreciation for focus groups in focus group facilities are as follows: Point-of-Sale Creative Concept Testing – Focus Groups with Current Adult Smokers (OMB Control Number 0910-0674).

8. Questions of a sensitive nature:

It is important to include individuals with diverse characteristics. Potential participants are informed screening questions are asked to make sure that the FDA speaks with the variety of people for whom

its messages are intended. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (<http://www.whitehouse.gov/omb/fedreg/1997standards.html>).

FDA tobacco use communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, and 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, for instance, 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.

Raw data from data collections that include sensitive information (e.g., screening questionnaires and audiotapes) 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:

This research relies on qualitative methods and is not intended to yield results that are statistically projectable. Participants will be identified using standard telephone recruitment procedures that employ screening questions about age; current and past tobacco use; race and ethnicity; and gender. Recruitment will continue until a representative sample of the required number of participants for each group is obtained.

BURDEN HOUR COMPUTATION *Number of respondents (X) estimated response or participation time in minutes (/60) = annual burden hours:*

Estimated Burden Hours:

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Possible Participant	Screener completion	810	1	810	0.13 (8 minutes)	108
Participants	Consent	240	1	240	0.08 (5 minutes)	20
	Focus Group (includes check-in survey, study introduction, general discussion, and check out)	240	1	240	1.5 (90 minutes)	360
Total Annualized Hours						488

REQUESTED APPROVAL DATE: Sept 2, 2019

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