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

TITLE OF INFORMATION COLLECTION: Qualitative Research to Design Advertising to Encourage Quitting Among Adult Cigarette Smokers (SGM Population); OMB Control Number 0910-0796.

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

On June 22, 2009, the president signed the Family Smoking Prevention and Tobacco Control Act (TCA) (Public Law 111-31) into law. The TCA granted the FDA authority to regulate the manufacturing, 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.

Tobacco use is the leading preventable cause of disease, disability, and death in the United States. More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS Fact Sheet, 2014). Approximately 2 out of 3 adult smokers, that is more than 22 million people, say they would like to quit (CDC, 2017). The FDA Center for Tobacco Products (CTP) was created to carry out the authorities granted under the 2009 TCA, to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information.

In 2015, out of 55% of adult smokers who made a quit attempt, only 7.4% were successful (CDC, 2017). Research suggests that it often takes multiple quit attempts to achieve long-term cessation (USDHHS Fact Sheet, 2014). The goal of the *Every Try Counts* campaign is to change attitudes and beliefs about what it means to quit smoking, increase motivation to try quitting again, and encourage smokers to "practice the quit" as each attempt makes them more likely to succeed.

While *Every Try Counts* has historically sought to reach a general population of adult smokers, research over the past decade demonstrates that smoking is disproportionately high among sexual and gender minority (SGM) adults (Lee, Griffin & Melvin, 2009; Li, Haardörfer, Vu, Windle & Berg, 2018; McCabe et al., 2019). Researchers have proposed several factors that may contribute to elevated rates of tobacco use among SGM adults, including targeted marketing to the SGM community by the tobacco industry (Ling & Glantz, 2002; Stevens, Carlson, Hinman, 2004) and the use of smoking as a coping mechanism for feelings of stress associated with coming out, experiences of discrimination, and victimization (Matthews et al., 2018; Remafedi, 2007). However, recent reviews of the cessation landscape have revealed relatively few efforts focused on SGM adult cessation

(Baskerville et al., 2017; Berger & Mooney-Somers, 2017; Lee et al., 2014). This is despite evidence that SGM individuals report that tailored messages are more acceptable, salient and motivating than non-tailored messages (Matthews et al., 2018; Dickson-Spillman et al, 2014).

Part of the FDA's responsibility is to inform the public on health-related issues. In order to develop the appropriate messaging to support all populations in their quit attempts, it is important for the FDA to conduct this public health research to gain insight into SGM adult perceptions of tobacco cessation messaging. Information obtained will inform CTP's effort to target SGM adults with tobacco cessation messaging that will effectively support those aiming to quit smoking.

To develop appropriate messaging to encourage SGM cigarette smokers to quit, it is important for the FDA to conduct research to gain insight into SGM adult perceptions of cigarettes, the changing product landscape, SGM adult experiences with smoking and quitting, and reactions to draft advertising concepts. Information obtained through this study will be used to develop and refine messaging related to encouraging quitting among adult smokers.

The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance OMB Control No. 0910-0796 to conduct focus groups with adults aged 19 - 54 (n=240) who: (1) are interested in quitting smoking; (2) have tried to quit smoking within the past year but were unsuccessful and either currently smoke cigarettes or are dual users of cigarettes and other tobacco products; and (3) identify as sexual and gender minority. Adults will be diverse in terms of race/ethnicity, gender, and geographical location; we will ensure geographic diversity by conducting focus groups in several locations in the United States.

The purpose of these focus groups is to inform the development of appropriate messaging that will encourage SGM smokers to quit. We will ask participants about their experiences with smoking and quitting and their perceptions of the current tobacco landscape. These responses are then used to refine and develop strategic and creative concepts that will be used to develop ads that encourage smokers to quit.

2. Intended use of information:

Information obtained through this study will inform the development and implementation of FDA's public health campaign designed to encourage quitting among adult smokers. Specifically, focus group participants will answer questions regarding the changing product landscape, experiences with smoking and quitting, and reactions to strategic and creative

concepts. Study results indicate areas for refinement and development that will guide creation of effective advertisements.

3. Description of respondents:

The study will consist of up to 40 focus groups total, each with up to 6 adults aged 19 – 54 who: (1) are interested in quitting smoking; (2) have tried to quit smoking within the past year but were unsuccessful and either currently smoke cigarettes or are dual users of cigarettes and other tobacco products; and (3) who identify as sexual and gender minority. The total sample size will be no more than 240 participants. The groups may be held in-person or through an online platform. Groups will be segmented by age, gender, socio-economic status, and self-reported tobacco use. Groups will be otherwise diverse by other demographic variables (e.g., race/ethnicity).

4. Date(s) to be conducted:

The study is projected to occur between February 2020 and December 2020.

5. How the information is being collected:

The information will be collected through a combination of up to 40 virtual or in-person focus groups led by a professional moderator with experience leading focus groups with adults. Each group will be shown strategic (written statements) and/or creative concepts (animatic storyboards or finalized ad) and asked a series of questions using a semi-structured discussion guide to encourage participants' feedback around understanding, relevance, impact and motivation of the shared concepts and strategic concepts (see Attachment G: Stimuli and Attachment D: Discussion Guide). In each focus group, participants will be exposed to up to 9 concepts. The moderator will encourage participants to respond openly and spontaneously. Data will be collected in professional meeting rooms or focus group facilities and will be audio recorded. Each focus group will last no more than 95 minutes. The focus groups will also be observed by FDA and campaign contractor staff.

Strategic and Creative Concepts Focus Groups (95 minutes): After a study introduction (5 minutes), the first activity will consist of a discussion about "Smoking and Quitting Perceptions and Experiences" which will include questions about experiences and attitudes towards smoking and quitting (25 minutes). Next, participants will engage in a discussion focusing on "Reactions to Strategic/Creative Concepts" where they will be shown up to 9 concepts and will include questions regarding advertisements related to quitting smoking (30 minutes). See the stimuli attachment for examples. After each strategic and/or creative concept is shown, the moderator will ask a series of questions specific to the strategic and/or creative concept (such as feelings about the concept and perceived main message of the concept) to

obtain qualitative feedback from the group. Participants will then engage in a discussion focusing on "Potential Moments, Opportunities, and Message Optimization" which will include questions regarding quitting resources such as potential quit messages (30 minutes). Finally, the moderator will end the focus group and assist participants with collecting their incentives and checking out of the focus group (5 minutes).

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.

Qualifying focus group participants will be asked to provide verbal consent on the phone during screening. They will also be e-mailed a consent form to review and 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 consent from the participants to audiotape the session. In the event consent 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:

Virtual focus groups: CTP will be offering $50 to virtual focus groups participants as a token of appreciation, which will be offered in the form of reward points equivalent to $50 that are awarded through their affiliated research panel(s). The $50 token of appreciation for participants is provided as thanks for their entire burden time, which includes obtaining consent and participating in the 95-minute focus group session. As is customary with research conducted via panel sampling, panelists are incentivized to participate in this research opportunity with award points that are accrued and redeemable with their affiliated research panel for cash or other rewards. The reward points offered for participation in this study will be valued at no more than $50.

In-person focus groups: CTP will be offering $75 to in-person focus group participants as a token of appreciation, which will be offered in the form of a prepaid debit card. The $75 token of appreciation for participants is provided as thanks for their entire burden time, which includes obtaining consent, travel to and from the focus group facility, and participating in the 95-minute focus group session. 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; and (2) Any issues preventing participants from cashing a check (e.g., no bank account) are avoided.

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). 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 with adults. 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.

In previous studies, CTP has conducted with similar groups of adults (e.g. participants who are current 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 Strategic Concept Testing – Focus Groups with Current Adult Smokers (OMB Control No. 0910-0674); LGBT Campaign: Focus Group Study of Brand and Creative Concepts Designed to Prevent LGBT Young Adult Tobacco Use (OMB Control No. 0910-0674); and, 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 No. 0910-0796).

8. Questions of a sensitive nature:

Some studies require the inclusion of people who match selected characteristics of the target audience that the FDA is trying to reach. This may require asking questions about race/ethnicity, income, education, and/or health behaviors on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that the FDA speaks with the kinds 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, including those about sexual behavior or religious beliefs, for instance, will 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 recruitment procedures that employ screening questions about age; current, past and intended tobacco use; race and ethnicity; and gender. We estimate we will need to screen 2.5 times the number of participants to attain our sample number. 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:

Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Adult Participants (Ages 19-54)	Screener completion	600	1	600	0.08 (5 minutes)	50
	Consent Form	240	1	240	0.08 (5 minutes)	20
	Focus Group (includes study introduction, general discussion, and check out)	240	1	240	1.6 (95 minutes)	380
Total Annualized Hours						**450**

REQUESTED APPROVAL DATE: February 24, 2020

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