SUPPORTING STATEMENT FOR THE

Parents' Perceptions of Public Service Announcement Concepts on Electronic Nicotine Delivery Systems

(OMB No. 0920-0910, Exp. Date 03/31/2018)

PART A: JUSTIFICATION

November 20, 2015

Submitted by:

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TABLE OF CONTENTS

LIST OF ATTACHMENTS

1. Screener
2. Informed Consent
3. ICF Institutional Review Board Approval
4. Moderator's Guide
5. Educational material for distribution at the conclusion of each focus group: CDC's Factsheet "Electronic Nicotine Delivery Systems: Key Facts"
6. Confirmation Reminder Script
7. Educational material for distribution at the conclusion of each focus group: Smoker Cessation Fact Sheet

Notes on Excluded Attachments

In this GenIC, the Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) outlines a plan to test 3 draft concepts, as demonstrated through a storyboard, with content that may be considered sensitive. The draft materials are not included in the attachments for this GenIC because:

- Publically releasing the Public Service Announcement (PSA) concepts can contaminate the feedback from participants, compromising the ability to get unbiased information.
- The PSAs have not been approved for public distribution by HHS/Assistant Secretary for Public Affairs (ASPA).
- The untested PSAs could be perceived by the public as ineffective or offensive (testing is designed to identify potential problems).
- Release of the PSAs must be coordinated with the launch of the Surgeon General's Call to Action on Electronic Nicotine Delivery Systems (ENDS) Among Youth and Youth Adults. The specific contents of the Surgeon General's Call to Action on ENDS Among Youth and Young Adults is proprietary and release of the PSA concepts may compromise its development.

To support adequate review of this GenIC by OMB, CDC requests permission to provide OMB with a secure link to the draft materials.

Goal of the Study: To assess attitudes and perceptions of three concepts for a Public Service Announcement (PSA) about Electronic Nicotine Delivery Systems (ENDS) that will be released as part of the Surgeon General's Call to Action on ENDS Among Youth and Young Adults. The goal of the study is to collect information needed to provide creative direction for the PSA targeted to adults who are 30-60 years of age who are parents or guardians of children ages 12-17 years.

Intended use of the resulting data: The resulting data will be used to determine which concept should be developed into a final PSA to support the release of the Surgeon General's Call to Action on ENDS Among Youth and Young Adults.

Methods to be used to collect data: Information will be collected through nine focus groups total in three cities: New Orleans, LA; Cleveland, OH; and Tulsa, OK. Each focus group will be approximately 1.5 hours. Ninety participants (i.e., 10 per group) will be recruited through a convenience sample.

Subpopulation to be studied: Adults who are 30-60 years of age who are parents or guardians of children ages 12-17 years. Respondents will be segmented into 3 groups according to their use of conventional cigarettes and/or ENDS. Segment 1 will consist of respondents who do not use conventional cigarettes or ENDS (conventional cigarettes = No, ENDS = No). Segment 2 will consist of respondents who use conventional cigarettes only (conventional cigarettes only = Yes, ENDS = No). Segment 3 will consist of respondents who use ENDS exclusively or in combination with conventional cigarettes (Conventional Cigarettes = Yes or No, ENDS = Yes).

How data will be analyzed: The resulting qualitative data will be analyzed using thematic analysis. The data will be read thoroughly and initial codes will be created manually, identifying themes and patterns of responses.

A.1 Circumstances Making the Collection of Information Necessary

Research suggests that teens rely mainly on parents (55%); health classes in school (32%); and doctors and nurses for their health information (29%), (Northwestern University, School of Communication, 2015). Parents, adolescents, and young adults have not previously been fully informed by public health agencies about many of the dangers of nicotine exposure for youth. Parents of youth and youth themselves may not understand that electronic nicotine delivery systems (ENDS) are tobacco products or that they typically contain nicotine. There is no safe level of nicotine exposure for youth. The Surgeon General has previously concluded that nicotine is highly addictive and may be dangerous for adolescent brain development. Adolescence is a critical window for brain development, and during that time youth are uniquely vulnerable to nicotine. Because the adolescent brain is still developing, nicotine use during adolescence can disrupt the formation of brain circuits that control attention, learning, and susceptibility to addiction (Leventhal, Strong, Kirkpatrick, et al., 2015). In addition, an emerging body of research has linked e-cigarette use with initiation of conventional cigarettes (Primack, Soneji, Stoolmiller, Fine, Sargent, 2015).

As of 2014, ENDS have surpassed cigarettes to become the most common form of tobacco product used by U.S. adolescents. From 2011 to 2014, past 30-day use of e-cigarettes has increased nine-fold for high school students (1.5% to 13.4%) and more than six-fold for middle school students (0.6% to 3.9%) in the United States (Arrazola, 2015). According to a study conducted in California, "Psychosocial Factors Associated with Adolescent Electronic Cigarette and Cigarette Use", almost half of current users reported that they did not believe there were health risks associated with e-cigarette use (Barrington-Trimis, 2015).

CDC Office on Smoking and Health (OSH) is currently developing a public service announcement (PSA) to support the launch of the Surgeon General's Call to Action on ENDS Among Youth and Young Adults. The PSA will be designed to increase knowledge and raise awareness among adults who are 30-60 years of age who are parents or guardians of children ages 12-17 years and other adults about the health effects of ENDS. In addition, the PSA will be designed to raise awareness among parents that their conventional cigarette or ENDS use may influence their children's use of the products. Therefore, the primary target of this PSA will be adult sources of health information.

The concepts focus on:

- Constituents of ENDS and ENDS aerosol, including nicotine and other potentially harmful chemicals;
- Effects of nicotine, from any tobacco product, on the developing brain;
- Explosive growth in youth use of ENDS; and
- Unfettered marketing of ENDS that reaches youth using tactics that the Surgeon General has previously found to increase youth use of conventional cigarettes.

The PSA's call to action will point parents and other adults to additional messages and materials to help them communicate with youth and young adults in their lives about the potential dangers of using ENDS and exposure to ENDS aerosol.

As part of the PSA development process, OSH, through a contract with ICF International (ICF), will conduct nine in-person focus groups to pre-test the concepts and guide the creation of the PSA. The focus groups with take place in New Orleans, LA; Cleveland, OH; and Tulsa, OK with adult who are 30-60 years of age who are parents or guardians of children ages 12-17 years. Respondents will be segmented into 3 groups according to their use of conventional cigarettes and/or ENDS (see table A.1 below). Cities were selected based on prevalence rates of adult and youth smokers by state, as well as ENDS use by region. The cities represent moderate to high conventional cigarette smoking prevalence and are cities are in the regions seeing highest growth in ENDS use among adults, the Midwest and South.

A.1 Respondent Segmentation

Respondent Segment	Products Used	
	Conventional Cigarettes	ENDS
1	No	No
2	Yes	No
3	Yes or No	Yes

A.2 Purpose and Use of Information Collection

This information will be used to develop an educational PSA and other communication strategies to help parents inform their 12-17 year-old children about the harms of ENDS usage. The information to be collected will allow CDC to assess attitudes and perceptions of concepts for a PSA about ENDS that will be released as part of the Surgeon General's Call to Action on ENDS Among Youth and Young Adults. If this data collection is not performed, CDC will not have data needed to support the development of messages that credibly and effectively educate adults who are parents or guardians of children ages 12-17 years about the harms of these products.

To test the proposed PSAs concepts, individuals will be asked about their opinions of the messages. Conventional cigarette smokers, ENDS users and nonsmokers may have different beliefs and behaviors related to tobacco use, secondhand smoke, and secondhand aerosol exposure, and thus may respond differently to certain types of messages. Therefore, the target audiences will be segmented into 3 groups according to their use of conventional cigarettes and/or ENDS. In addition to collecting information about respondents' reactions to the draft advertisements, basic demographic and tobacco use information will be collected at screening in order to understand whether and how these factors may influence individuals' responses to these messages.

Each concept, as demonstrated through a storyboard, will be tested in all focus groups. The order of concepts will be rotated between groups. The focus groups will be designed to test concepts

for, among other aspects, message strength, emotional appeal, and "shareability" (i.e., likelihood to tell someone this message).

A.3 Use of Improved Information Technology and Burden Reduction

Due to the qualitative nature and scope of this project, incorporating improved information technology (e.g., web-based technology or electronic submission of responses) for the purpose of data collection is not feasible. Only the minimum amount of data needed to inform PSA development will be collected. Upon consent from the participants, we will audio record the discussions and later transcribe the discussion into an electronic document to capture all information and assist with the preparation of reports.

A.4 Efforts to Identify Duplication and Use of Similar Information

This ICR is designed to test new, draft PSA concepts to support the launch of the Surgeon General's Call to Action on ENDS Among Youth and Young Adults. Prior to conducting any data collection, CDC reviews existing published literature and unpublished qualitative pretesting reports when they are available. Additionally, CDC consults with outside experts to identify information that could facilitate message development.

There are no similar data available specific to the PSA concepts proposed for testing in this ICR. CDC/OSH conducts focus group among adults to perform formative testing of Tips from Former Smokers ad concepts. CDC/OSH collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the Food and Drug Administration Center for Tobacco Products (CTP). These affiliations serve as information channels, help prevent redundancy and promote use of consistent measures of effectiveness. Coordination activities include the review of proposed messages for advertisements; review of moderator's guide for testing purposes; and sharing data. FDA is not currently developing a PSA to support the Surgeon General's Call to Action on ENDS Among Youth and Young Adults.

CDC will share the findings from this collection of information with CTP. CDC and FDA are developing complementary but distinct messages to educate the public about the harmful effects of tobacco products. Staff members in OSH's Health Communications Branch work closely with staff in FDA's Health Communication and Education unit. Regularly scheduled conference calls are held to review plans and share research findings of mutual interest. Staff members in OSH's Health Communications Branch are thus working closely with staff in FDA's Health Communication and Education unit as appropriate. It was determined that message testing proposed in this GenIC does not duplicate FDA efforts.

Points of contact for this coordination are:

CDC: Diane Beistle, Chief, Health Communication Branch, telephone (770) 488-5066, email zgv1@cdc.gov

CDC: Michelle O'Hegarty, Health Communications Specialist, Campaign Development, Health Communication Branch, telephone (770) 488-5582, email mohegarty@cdc.gov

FDA: Tesfa Alexander, Health Communication Specialist, Office of Health Communication and Education, telephone (301) 796-9335, email Tesfa.Alexander@fda.hhs.gov

[Pending] HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) has reviewed this proposed collection of information, and has determined that it does not duplicate other collections.

A.5 Impact on Small Business or Other Small Entities

This data collection will not involve small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time information collection request.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require data collection to be conducted in a manner inconsistent with 5 CRF 1320.5 (d) (2). The information collection fully complies with the guidelines in 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A.8.a Federal Register Announcement

A Notice was published in the *Federal Register* on August 11, 2014, volume 79, number 154, pp.46829-46830). One public comment was received and addressed.

A.8.b Consultations

CDC has been working with its contractor ICF International, a leading communications firm, since June 2015 on the development of creative concepts for the PSA. One of the first steps in the process was to develop a creative brief that includes the goal, background information, target audience/s, messages, and tone to guide the creation of concepts for the PSA. Several CDC experts weighed in on the content of the creative brief. The creative brief was then sent to HHS's Office of the Assistant Secretary for Health (OASH) and the Office of the Surgeon General for review and input. We received some feedback from OASH and the Office of the Surgeon General, which helped guide the direction of the PSA concepts. Next, ICF used the creative brief to develop about 15 creative concepts. CDC experts reviewed the concepts and winnowed them down to three of the strongest concepts that best meet the goals for the PSA.

Next, ICF developed storyboards for each of the three concepts that were chosen, which included six sketches (frames) and scripts. These storyboards were reviewed by internal CDC experts and were shared during a few briefings with the Office of the Surgeon General. The Surgeon General and his staff provided feedback on the storyboards and approved them to move forward for testing.

A.9 Explanation of Any Payments or Gift to Respondents

We will give participants in the focus groups a monetary gift to show appreciation for their participation. It is assumed that many of these participants will have to travel to the focus group. Further, participants will have children, and the gift may also serve to offset childcare costs related to participating in the study. The amount is $75.00 for participation in a 1.5 hour focus group. This proposed gift of $75.00/participant is intended to recognize the travel time and cost, childcare costs, and to convey appreciation for contributing to this important activity. Numerous

empirical studies have shown that a monetary gift can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000).

The firms that will recruit the parents for the focus groups recommend a minimum gift of $75.00 per participant for this population. In their experience, they find a reduction in respondent commitment with any lower amount. In response to offering this level, respondents are much more likely to honor their commitment of participating in the focus group. Lower amounts could actually result in higher recruiting costs and burden to the public due to the need for additional recruitment (Krueger & Casey, 2009).

A.10 Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by staff in CDC's National Center for Chronic Disease Prevention and Health Promotion, who determined that the Privacy Act does not apply.

Overview of the data collection system

CDC contracts with ICF for this information collection. Focus groups will be moderated by trained facilitators from ICF, with recruitment support from professional recruitment firms in each city. All information collection responses will be through in-person focus groups. CDC will not have direct contact with participants nor will CDC have access to any personal identifying information about the participants. CDC staff will attend each group, watching through the observation room window, while others will be observing the groups via a password-protected web stream.

Professional recruitment firms will conduct the screening process. Potential respondents will be advised of the nature of the activity, the length of time it will require, and that participation is voluntary. The appropriate advisements on voluntary participation are included in the screener (Attachment 1) as well as the informed consent form (Attachment 2). Prior to beginning the focus group, all participants will be required to submit a signed consent form. If any participants have not signed the consent form, they will need to sign it prior to beginning the group and hand it in. Respondents will be assured that they will incur no penalties if they wish not to participate in the focus group. These procedures conform to ethical practices for collecting information from human participants.

Identifying information (name, address, telephone number) will be used by the professional recruitment firms to make contact and send reminder calls to respondents. This information will be kept by the recruiting firms separately from any information collected in the groups (i.e., participant responses will not be connected to any identifiable information). Screeners will be kept in a locked file cabinet at the recruitment firm or in password-protected computer files. The recruiter will only provide ICF and CDC a summary of participant information on the recruitment grids, which will be stripped of identifiable information, such as the last names, addresses, and telephone numbers of the participants. No directly identifying information will be transmitted to CDC/OSH, and thus, the Privacy Act does not apply. The professional recruiting firms will be instructed to destroy their project-related records July 1, 2016.

Data Security

All findings will be reported in the aggregate only. CDC and ICF will take many precautions to

secure participants' identifiable information (see Privacy section of Consent Form – Attachment 2). The information participants provide during the focus groups will not be linked to their identifying information. Participants will use only first names or pseudonyms during the discussions. Transcripts and notes will not include participants' names. Audio files of the groups will be stored by ICF on a secure share drive and password-protected computers. Transcripts and reports will not include any identifiable information. Transcripts and reports will be stored on a secure share drive and password-protected computers. Computers used for this project are stored at the ICF Rockville, MD office. It is ICF policy for each staff member to keep his/her computer locked to his/her desk at all times.

A. 10.1. Access Controls

Technical Controls	Physical Controls	Administrative Controls
• User identification • Passwords • Firewall • Virtual Private Network (VPN)	• Guards/Security Officers • Identification badges • Key Cards	1. The system security plan for the information collection is that survey data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study. 2. The contingency plan for this information collection is that the screeners will be kept in a locked file cabinet at the recruitment firm or in password-protected computer files. The recruiter will only provide ICF and CDC a summary of participant information on the recruitment grids, which will be stripped of identifiable information. No directly identifying information will be transmitted to CDC/OSH (thus, the Privacy Act does not apply). 3. The files will be saved in a secure folder that is backed up every night. Shared drives are backed up multiple times during a 24 hour period. 4. Backup file storage: Audio files of the groups will be stored by ICF on a secure share drive and password-protected computers. Transcripts and reports will not include any identifiable information. 5. There will not be user manuals for this information collection. 6. Personnel who use the system will be trained to protect the information

		being collected and maintained by adhering to a procedure that removes identifiers from response data. Identifying information will be used by the professional recruitment firms to make contact with respondents. This information will be kept by the recruiting firms separately from any information collected in the groups. 7. Contractors who are operating/using the system will include clauses in the contracts that adhere to privacy provisions and practices. 8. Methods will be in place to ensure least privilege. Data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study. 9. There are policies/guidelines in place with regard to the retention and destruction of IIF: IIF will not be transmitted to CDC, and IIF will not be linked to response data.

The precautions taken by CDC and ICF have been evaluated by the Institutional Review Board of ICF and found to be acceptable (see ICF IRB approval – Attachment 3). CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

All procedures have been developed in accordance with federal, state, and local guidelines to ensure that the rights and privacy of participants are protected and maintained. The ICF Institutional Review Board (IRB) reviewed and approved all instruments, informed consent materials, and data collection and management procedures (see ICF IRB approval notice in Attachment 3)**.**

Sensitive Questions

The majority of questions asked will not be of a sensitive nature (see Attachments 1 and 4). There will be no requests for a respondent's Social Security Number (SSN). Questions asked during screening about cigarette or ENDS use and some demographic information (e.g., race or ethnicity) could be considered sensitive, although these items would not generally be considered highly

sensitive. A subset of questions about tobacco use are necessary for audience segmentation and to collect information integral to the purpose of this study, but are not highly sensitive.

During the focus groups potentially sensitive information will only be requested when necessary for specific project objectives and steps to avoid negative reactions will be taken, including:

- Participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards.

A.12 Estimates of Annualized Burden Hours and Costs

Screening (Attachment 1) of the audience with up to 180 people will be conducted to determine qualification status for participating in the research. Nine focus groups will be conducted with up to 90 adults who are 30-60 years of age and who are parents or guardians of children ages 12-17 years. The estimated burden to respondents is 5 minutes for screening and 1.5 hours for a focus group. The total estimated burden for all responses is 150 hours.

Table A.12.A. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Adults ages 30-60 years who are parents or guardians of children ages 12-17 years	Screener	180	1	5/60	15
	Moderator's Guide	90	1	90/60	135
				Total	**150**

The estimated cost of the time devoted to this information collection by respondents is $3,450 as summarized in Table A.12.B. To calculate this cost, we used the mean hourly wage of $23, which represents the Department of Labor estimated mean for state, local, and private industry earnings (U.S. Bureau of Labor Statistics, 2015). There are no direct costs to respondents associated with participation in this information collection.

Table A.12.B Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden (in hours)	Hour Wage Rate	Total Cost
	Screener	180	1	15	$23	$345

Adults ages 30-60 years who are parents or guardians of children ages 12-17 years	Moderator's Guide	90	1	135	$23	$3,105
Total						$3,450

A.13 Estimates of Other Annual Cost Burden to Respondents and Record Keepers

There will be no respondent capital and maintenance costs.

A.14 Annualized Cost to the Government

Approximately 18% each of two full time equivalents (FTE) will be required to oversee the information collection activities. Responsibilities will include internal coordination and review of materials and reports and maintaining proper accounting of burden hours. The agency estimates that it will take a GS-14, at a wage rate of $48.41/hour, approximately 335 hours/annually to manage the project, totaling about $16,217. It is estimated to take a GS-13, at a wage rate of $46.43 an hour, approximately 327 hours annually to assist in managing the project, totaling $15,182. The total average annualized cost to the government for CDC oversight is $31,376.

Government Personnel	**Time Commitment**	**Hourly Basic Rate**	**Total**
GS-14 step 1	18.17%	$48.41	$16,217
GS-13 step 5	17.0%	$46.43	$15,182
Total			$31,399

The majority of data collection activities will be conducted by contractors on CDC's behalf. The total cost of the data collection contractors is $82,571, which includes consultation, instrument design and development, recruitment, data collection, analyses, and reporting. The total cost for the project, including government and contractor cost, is $113,970.

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Data Tabulation Plans

The information will be used to inform the development of a PSA for the Surgeon General's Call to Action on ENDS Among Youth and Young Adults. The estimated OMB approval date is January 8, 2016, with an anticipated information collection to begin on February 1, 2016. A PSA

will be selected among the three tested, revised and finalized by April 8, 2016 with an anticipated release by mid-April. The resulting qualitative data will be analyzed using thematic analysis. The data will be read thoroughly and initial codes will be created manually, identifying themes and patterns of responses.

Publication and Dissemination Plans

This information will be used to inform the development of a PSA and other communication strategies regarding ENDS use. CDC will also use this information to better understand parents' perceptions of ENDS usage by minors.

Project Time Schedule

Activity	**Date**
Information Collection Form Submitted to OMB for approval (appx.)	12/11/15
Milestone: OMB approves Request	1/8/16
Recruitment for focus groups begins	2-3 weeks after OMB approval
Information Collection Activity for focus groups begins	3-4 weeks after OMB approval
Begin modifying selected PSA concept based on the results of focus groups	5 weeks after OMB approval
Launch of PSA	13 weeks after OMB approval

A.17 Reason(s) Display of OMB Expiration is Inappropriate

The expiration date of OMB approval will be displayed on all information collection instruments.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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