FDA CTP E-Blast Survey Audience Analysis Study
0910-0810

Supporting Statement: Part A

Supporting Statement: Summary

- The goal of the FDA Center for Tobacco Products (CTP) E-blast Survey Audience Analysis Study is to learn more about the CTP email subscriber base across its three email communications (i.e., CTP Connect, CTP News, and Spotlight on Science).
- The study will be conducted using a web-based anonymous survey, using Qualtrics software, which is self-administered on personal computers. The study will use an online survey to target up to 1,500 CTP email subscribers. The study will take approximately 5 minutes to complete per respondent.
- The outcome of the survey will be to guide CTP in content development, stakeholder engagement, and public affairs activities.
- The study questions collect information on respondents' level of satisfaction with CTP email communications and suggestions for better meeting respondent needs. To assess how demographic and other variables and survey items may be associated, the survey also asks respondents a few basic demographic questions.

- Attachment A: CTP E-Blast Survey Invitation Recruitment Email [Includes Reminders]
- Attachment B: CTP E-Blast Informed Consent Information
- Attachment C: CTP E-Blast Online Survey Instrument
- Attachment D: IRB Approval

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Supporting Statement: Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Food and Drug Administration (FDA) was granted new authority to regulate the manufacture, marketing, and distribution of tobacco products and educate the public about the dangers of tobacco use. Section 1003(d)(2)(D) of the Food, Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) and Sections 2, 3, 105, 201, 204, 904, and 908 of the Tobacco Control Act support the development and implementation of FDA public education campaigns and information related to tobacco use.

The FDA Center for Tobacco Products (CTP) was created to carry out the authorities granted under the 2009 Tobacco Control Act, educate the public about the dangers of tobacco use, and serve as a public health resource for tobacco and health information.

Through CTP, FDA researches, develops, and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels.

The goal of the FDA CTP E-blast Survey Audience Analysis Study is to learn more about the CTP email subscriber base across its three email communications:

1. CTP Connect
    - This newsletter serves as a digest on the latest announcements and stories out of CTP as they happen, including information about regulations, guidance, enforcement actions, and other compliance-related announcements.
2. CTP News
    - This newsletter offers messages from CTP leadership, a regulatory news roundup, feature articles on current tobacco issues, and educational resources.
3. Spotlight on Science
    - This newsletter offers updates on CTP's tobacco regulatory science and research efforts, tobacco scientific publications and study findings, and CTP grants.

The objectives of the proposed data collection is to determine the following:

- Who are CTP's subscribers?
    - Who is currently engaging with CTP?
    - What are the demographic characteristics and job descriptions of CTP subscribers?
- How well are CTP's intended audiences being reached?

- How satisfied are CTP's intended audiences with CTP's emails?
- How can CTP improve what it does to better serve subscribers?

This study will be conducted using a web-based survey that is self-administered on personal computers and electronic devices. The study will use the online survey to target up to 1,500 CTP email subscribers.

The CTP research team will send a recruitment email to its approximately 40,000 E-blast subscriber base inviting subscribers to complete the FDA CTP E-blast Survey (see Attachment A). If a recipient of the email invitation is interested in taking the survey, they will click on a link URL provided to them in the electronic invitation. IQ Solutions (CTP's contractor) will send two reminders to complete the survey. Respondents may complete the survey on a desktop computer, tablet, or mobile phone. To reduce the potential for any one individual completing the survey more than once, IQ Solutions will program the survey to limit one survey completion per device.

The first page of the online survey (see Attachment C) will include informed consent information explaining the purpose of the study, the risks and benefits of the study, and the voluntary and anonymous nature of the study, as well as the contact information of the study's Principal Investigator should a respondent wish to contact a study team member for any reason (see Attachment B).

We anticipate data collection to take approximately three weeks. The outcome of the survey will be guide CTP in content development, stakeholder engagement, and public affairs activities.

2. Purpose and Use of the Information

The information obtained from the proposed research activity will be collected from the CTP email subscribers. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- To understand the current information and content area gaps so that CTP can address those gaps.
- To provide insights into opportunities for leveraging stakeholders' communication channels and engaging stakeholders in CTP's activities.
- To assess the reach and impact of CTP messaging, news, and research.

To achieve the above, data collection will consist of one, one-time online anonymous survey completed by up to 1,200 CTP email subscribers (three percent of the approximately 40,000 total CTP email subscribers). The survey dissemination will occur over a three-week period. Respondents will receive two reminders to complete the survey during this three-week period.

All tracking of surveys will be conducted by IQ Solutions.

3. Use of Information Technology and Burden Reduction

This study will rely on web-based survey data collection on opinions about CTP email communications, aspects of CTP communications that can be improved, and characteristics of CTP email subscribers. Using an anonymous survey allows respondents to be more candid with their responses. An anonymous study approach allows for more accurate data collected compared with other types of research methodologies because respondents provide more honest responses. In addition, using a survey will allow for a higher number of respondents to respond in a cost-effective and timely manner. Also, the self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically immediately to cloud storage, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. Finally, as noted above, this technology permits respondents to complete the survey in privacy. Providing respondents with a methodology that assures privacy makes reporting of potentially uncomfortable comments less threatening and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

FDA CTP's three email communications (i.e., CTP Connect, CTP News, Spotlight on Science) are relatively new, and therefore it is important to assess who makes up the target audience. In addition, it is important to test what is working well and areas for improvement to best meet target audience needs and sustain target audience interest.

To date, there have been no data collection activities for the purpose of describing the CTP email subscriber base and measuring satisfaction levels with various aspects of CTP's email communications. This study therefore does not duplicate any existing efforts.

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be public health professionals, healthcare professionals, tobacco industry representatives, media professionals, and members of the general public. Within the "tobacco industry representative" respondent category, retailers, manufacturers, wholesalers or distributors, importers, and/or growers would be welcome to take the survey. While there is potential for such small businesses to complete a survey, no impact on small businesses or other small entities is anticipated.

6. Consequence of Collecting the Information Less Frequently

To ensure that the participant burden is as low as possible, respondents to this collection of information will answer only once. Without the information collection requested for this evaluation study, it would be difficult to describe the CTP email subscriber base and measure satisfaction levels with various aspects of CTP's email communications. Failure to collect

these data could reduce effectiveness of CTP's email communications and therefore reduce the benefit of CTP's email communications to CTP's target audiences.

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

There are no special circumstances for this collection of information that require the data collection to be conducted in a manner inconsistent with 5 CRF 1320.5(d)(2). This study's data collection activities fully comply with the guidelines in 5 CFR 1320.5.

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

Not applicable.

9. Explanation of Any Payment or Gift to Respondents

Since engagement in the study is minimal, no respondents will be paid an incentive to participate in the online survey. All participation in this study is voluntary.

10. Privacy Impact Assessment Information

FDA's Research Involving Human Subjects Committee (RIHSC) will review and approve the protocols and consent forms for the survey prior to any respondent contact. The RIHSC's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

Overview of Data Collection System

All information will be collected electronically through a self-administered anonymous survey instrument hosted in a secure, online, web-based data collection system. Respondents will be recruited through an existing CTP email subscriber database.

The survey begins with initial information that provides potential respondents with informed consent information, including the purpose of the study and the benefits and risks of the study, as well as informs respondents about the anonymous nature of the study. (The survey is classified as anonymous as no Personally Identifiable Information [PII] is asked of respondents.) IP addresses are also masked and not included in collection. The survey item immediately following the informed consent information invites the potential respondent to click "Start survey now" or "Exit survey" to assure that those respondents who complete the survey are doing so voluntarily.

Each respondent will offer his or her opinions on CTP email communications and give basic demographic information (i.e., age cohort, country of residence, the state of employment [if in the United States], and education level). The respondent will participate at the time of his or her choosing. None of the study team members will

have direct contact with the respondents, nor will the study team have access to any respondent PII.

Overview of How Information will be Shared and for What Purposes

The CTP research team will program the online survey of the CTP E-blast Survey Audience Analysis Study using Qualtrics software. The survey includes 14 questions, including three multi-part questions. Except for one open-ended question, the survey questions include closed-ended response categories where the respondent must select one of various options. For the multi-part questions, respondents who answer a specific way on one question will receive other specific questions afterwards.

To analyze the quantitative data collected from the online survey's closed-ended questions, the CTP research team will summarize the descriptive statistics, such as means, standard deviations, and percentages, generated by the Qualtrics software as well as create cross-tabs, using statistical software, to assess how demographic and other variables and survey items may be associated.

Although demographic information (i.e., age cohort, country of residence, the state of employment [if in the United States], and education level) will be gathered, no direct personal identifiers (e.g., full name, phone number, social security number, etc.) will be collected or maintained as part of the survey (Attachment C). As such, because Personally Identifiable Information (PII) does not exist, no individually identifiable information or PII is being collected, and thus, the Privacy Act does not apply.

Overview of Voluntary Participation

When potential respondents click on the online survey link, they will be advised of the nature of the survey and length of time it will require to complete the survey, as well as that participation is voluntary. Respondents will be assured that they will incur no penalties if they wish not to respond to the information collection as a whole or to any specific questions. Respondents on the web-based survey will have the option to decline to respond to any item in the survey for any reason and may drop out of the survey at any time. These procedures conform to ethical practices for collecting data from human participants.

Overview of Data Security

All web-based respondents will use a link to enter the survey and the Qualtrics software will assign them a unique ID and the responses will be anonymous. No Personally Identifiable Information (PII) will be linked to the survey data. All those who handle or analyze data will be required to adhere to standard data security policies. All data will be reported in the aggregate only. During data collection, all data will be stored on password-protected databases to which only IQ Solutions employees working on this project have access. IQ Solutions will keep the data for three years after data collection has been completed, and then the data will be deleted from the password-protected databases. All data will be sent to IQ Solutions using a password protected, encrypted file. IQ Solutions will limit access to this portion of the share drive by limiting the personnel with access to this share drive to appropriate project staff.

11. Justification for Sensitive Questions

Almost all, if not all, of the questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN) or IP address. Demographic questions (i.e., age cohort, country of residence, the state of employment [if in the United States], and education level) could be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise respondents that these topics will be covered during the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

- Should respondents have any questions or concerns about the study or their rights as a study participant, respondents will be provided with the telephone number of the study's Principal Investigator.

- This survey is anonymous and no Personally Identifiable Information (PII) will be collected.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection will be approximately 169 hours (Table 1). This includes the time burden associated with reading the email invitation to take the survey.

Based on experience from previous surveys, with other satisfaction surveys, we anticipate that about one percent to three percent of the approximately 40,000 total current CTP email subscribers will participate in the study—that is, we expect to receive between 400 and 1,200 completed surveys. To be conservative for the purposes of calculating the estimated annual reporting burden, we will assume that the total sample size is 1,500.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
CTP email subscriber	Review email invitation to take survey	1,500	1	1,500	0.0125	**19**
CTP email subscriber	Review and complete informed consent form	1,500	1	1,500	0.017	**26**
CTP email subscriber	Complete survey	1,500	1	1,500	0.083	**125**
Total Annualized Hours						**170**

12b. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. IQ Solutions has conducted many online surveys of similar length and five IQ Solutions staff and two CTP staff members took the survey for this study, with an average completion time of five minutes.

To calculate the cost, the mean hourly wage of $22.33 was used for the respondents. This cost represents the Department of Labor estimated mean for state, local, and private industry earnings (Bureau of Labor Statistics, National Compensation Survey–Wages https://www.bls.gov/ncs/ncswage2008.htm#Wage_Tables) . There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of $22.33, the estimated one-year annualized cost to participants will be $3,796.10. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
CTP email subscriber	Review email invitation to take survey	19	$ 22.33	$ 424.27
CTP email subscriber	Review and complete informed consent form	26	$22.33	$580.58
CTP email subscriber	Complete survey	125	$22.33	$2,791.25
Total				0

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-12	10%	$79,720	$7,972
GS-13	5%	$95,217	$4,761
		Total Salary Costs	$12,733
		Contract Cost	$34,921
		Total	**$47,654**

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

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To analyze the quantitative data collected from the online survey's closed-ended questions, the CTP research team will summarize the descriptive statistics, such as means, standard deviations, and percentages, generated by the Qualtrics software as well as create cross-tabs, using statistical software, to assess how demographic and other variables and survey items may be associated.

This study's aims are to: (1) obtain demographic information about the CTP email subscriber base; (2) determine the current information gaps that exist for CTP email subscribers; (3) assess the opportunities that exist to engage subscribers in CTP activities; and (4) identify the reach and impact of CTP email communications. The findings from this study will help guide CTP in developing content, engaging stakeholders, and tailoring effective public affairs activities.

Reporting

The reporting and dissemination mechanism for this study's findings will consist of two primary components: (1) summary statistics in the form of a PowerPoint presentation and other briefings and (2) a comprehensive evaluation report summarizing findings from this information collection. The key events and reports to be prepared are listed in Table 4.

Table 4. Project Schedule

Project Activity	Projected Schedule
Survey	3 weeks (Approximate)
Data Analysis	2 weeks (Approximate)
Report Writing and Dissemination	4 weeks (Approximate)

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

We are not requesting an exemption to this requirement. The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.