0910-0810
Supporting Statement Part A

Supporting Statement: Summary

- The goal of this study is to conduct a quantitative online survey of hookah users to support an ongoing project, the Hookah Purchase Journey (HPJ). The HPJ aims to elucidate the supply chain for waterpipe tobacco and charcoal, the waterpipe tobacco market size with growth trends over time, costs for smoking hookah tobacco in waterpipe establishments, and annual hookah unit sales. The online survey will support completed secondary analysis on the US waterpipe market. This research study aims to survey waterpipe/hookah smokers, individuals who purchase and smoke waterpipe/hookah products. The study will be conducted among adults, 18 and over, who have smoked hookah/waterpipe and have purchased hookah/waterpipe products in the last 12 months and live in the U.S.

- Participants will be recruited via email and screened and consented online. The study will be conducted using web-based surveys that are self-administered. The study will use an online survey to target 3,000 adults and have smoked and purchased hookah/waterpipe product in the past 12 months. The questionnaire will take approximately 20 minutes to complete, per respondent.

- The outcome of the study will be an understanding of overall hookah/waterpipe smoker behavior. Including where hookah/waterpipe is smoked, smoking session characteristics, and where waterpipe/hookah products are purchased.

- The resulting data will be analyzed using conventional techniques for quantitative data. Qualitative analysis of open-ended items will also be conducted. The study questions collect information of waterpipe/hookah product purchase and use behavior; they will also include questions to collect basic demographic information in order to understand whether and how these factors may influence individuals' responses.

Hookah Purchase Journey: Online Hookah User Survey

Supporting Statement: Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Tobacco use is the leading preventable cause of disease, disability, and death in the United States (USDHHS, 2014). More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS, 2014).

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (FSPTCA) was signed into law. This act gives authority to the Food and Drug Administration (FDA) to enact or facilitate tobacco product regulations, with the overall goals to (1) Prevent Americans—especially youth—from starting to use tobacco, (2) encourage current users to quit, and (3) decrease the harms of tobacco product use. Under the Act, FDA's Center for Tobacco Products (CTP) was created to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. In 2016, FDA finalized the Deeming Rule extending FDA's authority to include regulation of electronic nicotine delivery systems (such as e-cigarettes and vape pens), all cigars, hookah (waterpipe) tobacco, pipe tobacco, and nicotine gels, among others. The Deeming Rule went into effect on August 8, 2016.

CTP has contracted with a marketing consulting firm, Smart Analyst to understand and characterize the supply chain for the US waterpipe tobacco, to understand and characterize the supply chain of US waterpipe charcoal, to understand and characterize the size of the US waterpipe tobacco, steam stones, and charcoal markets, to understand and characterize waterpipe establishments in the US, include estimate of price ranges for consumer smoking sessions. Such information will assist CTP in understanding the marketplace effects of potential future regulatory actions.

This study is designed to gather information hookah smoker behavior. The study will recruit up to 3,000 adults (over 18), who have smoked hookah and purchased hookah products in the past 12 months in the U.S. Participants will be recruited in the spring and summer of 2019. They will be recruited and screened online.

Participants that pass screening (attachment B) and consent (Attachment A) to participate will participate in an online survey (Attachment C). The survey will collect information on types of hookah products purchased and smoked, the frequency of purchase and use, location of purchase (e.g. convenience store or specialty tobacco stores), and the location of smoking (e.g. home or friend's house).

It is anticipated that data collection will take approximately 12 weeks. The outcome of the survey will be an understanding hookah smoker use and purchase behavior.

2. Purpose and Use of the Information

This study is part of a project titled the Hookah Purchase journey. The information obtained from the proposed data collection activities will be collected from adults 18+ and will help in understanding the consumer side of the hookah market in the U.S. The study results will show the what and where consumers purchase hookah products and where hookah is smoked. This data will help:

- determine cost ranges for hookah tobacco material and

- price range estimates for consumer smoking sessions in waterpipe establishments, and

The information will be collected by a contractor, SmartAnalyst, using an online self-administered survey. The online quantitative research tasks will include direct responses about hooking smoking and purchase.

The study participants will consist of adults, over 18, who live in the U.S. and have smoked hookah and purchased hookah products in the last 12 months. Efforts will be made during recruitment to ensure that the participant pool represents a diverse population by region, race, age, and gender.

The survey will include a total of 3,000 participants who will be recruited online. Participants will self-identify as having smoked hookah and purchased hookah products. There are no exclusion criteria.

During screening, potential participant's personal email addresses will be used. However, no personable identifiers will be included with the data set. The final data set will not contain any personally identifiable information. Any personal identifiable information, such as personal email addresses, will be destroyed by deletion once the study is completed.

Participants can opt-out of the study anytime during the survey.

3. Use of Information Technology and Burden Reduction

Online recruitment methods offer benefits in terms of burden reduction and increased efficiencies. Further, the use of electronic questionnaire surveys offers a number of benefits. First, computerized administration permits the instrument designer to incorporate into the instruments routings that might be overly complex or not possible using a paper-based survey. For example, surveys can be programmed to implement skip patterns based on a participant's previous answers and/or assigned treatment group. Interviewer and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. Second, electronic administration increases the consistency of the data. The electronic questionnaire can be programmed to identify inconsistent or incomplete responses and attempt to resolve them through respondent prompts. This approach reduces the need for most manual and machine editing, thus saving time and money. In addition, it is likely that respondent-resolved inconsistencies will result in data that are more accurate than when inconsistencies are resolved using editing rules. Third, electronic data collection permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry, will be minimized). These efficiencies save time due to the speed and format of data transmission, as well as receipt in a format suitable for analysis. Fourth, this approach can increase participation rates by reducing drop off between the screener and questionnaire, because participants can complete the questionnaire on their own time and on their own devices, thus making study participation more convenient. This will also decrease time and costs related to recruitment. Finally, this technology permits participants to complete the instruments in private. Providing the participant with a methodology that improves

privacy makes reporting of potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) less threatening and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

The Hookah Purchase Journey is a contract original to FDA's CTP and the information has not been previously collected. As such, there are no existing datasets that can be used or modified to address FDA's need for information on hookah product purchase behavior and smoking behaviors. Therefore, the proposed information collection does not duplicate previous efforts.

5. Impact on Small Businesses or Other Small Entities

Participants in this study will be members of the general public, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden. Respondents to this collection of information will answer only once to ensure the participant burden is as low as possible. Without the information collection requested, it would be difficult to understand the hookah market in the U.S.

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). The online survey 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 the Agency

The following individuals inside the agency have been consulted on the design of the survey development:

Carolina Ramôa
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration
U.S. Food and Drug Administration
11785 Beltsville Drive
Calverton, MD 20705
Tel: 301-348-3988
carolina.ramoa@fda.hhs.gov

Priscilla Callahan-Lyon
Office of Science
Center for Tobacco Products

U.S. Food and Drug Administration
11785 Beltsville Drive
Calverton, MD 20705
Tel: 301-796-0973
priscilla.callahan-lyon@fda.hhs.gov

The following individuals outside of the agency have been consulted on questionnaire development.

Robin Gasloli
SmartAnalyst
9 E. 38th St. #12L
New York, NY 10016
rgasloli@smartanalyst.com
212-331-0010

Kristen Suozzo
SmartAnalyst
9 E. 38th St. #12L
New York, NY 10016
ksuozzo@smartanalyst.com
212-331-0010

Jeff George
SmartAnalyst
9 E. 38th St. #12L
New York, NY 10016
jgeorge@smartanalyst.com
212-331-0010

Jim Lustenader
SmartAnalyst
9 E. 38th St. #12L
New York, NY 10016
jlustenader@smartanalyst.com
212-331-0010

Avninder Srivastava
SmartAnalyst
14th Floor, Tower D, Cyber Green,
DLF City Phase-III,
Gurugram, Haryana 122002
asrivastava@smartanalyst.com
Phone: 91-124-4313800

Abhishek Pathak
SmartAnalyst
14th Floor, Tower D, Cyber Green,

DLF City Phase-III,
Gurugram, Haryana 122002
apathak@smartanalyst.com
Phone: 91-124-4313800

Meenal Bhat
SmartAnalyst
14th Floor, Tower D, Cyber Green,
DLF City Phase-III,
Gurugram, Haryana 122002
Meenal.bhat@smartanalyst.com
Phone: 91-124-4313800

9. Explanation of Any Payment or Gift to Respondents

A small incentive will be paid by the subcontractor, Rabin, to the participants. Through the website and database Rabin maintains, they can compensate participants that complete the study. When members join the panel maintained by Rabin, they have the option of having a point-based or monetary-based incentive system. This is user specific, incentive is paid in a variety of gift options on the subcontractor's website, from gift cards, magazines, to donations. The monetary value of this incentive system is estimated at approximately $6.00.

The accounts are password protected. A subject's specific answers to a particular questionnaire have no relationship to the incentive received, and there is no trail between an incentive and a subject's participation in a particular study. Because the individual incentives are aggregated when a subject goes to "cash them in" for a gift, there is also no link between the chosen gift and the subject's participation in various studies.

As participants often have competing demands for their time, incentives are used to encourage participation in research. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. When applied in a reasonable manner, incentives are not an unjust inducement, but are instead a way to acknowledge respondents for their participation (Halpern, et al., 2004).

Incentives must be high enough to equalize the burden placed on participants with respect to their time and cost of participation (Russell, Moralejo, & Burgess, 2000), as well as provide enough motivation for them to participate in the study rather than another activity. If the incentive is not adequate, participants may agree to participate and then drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with facility rental and costs with setting up the research (Morgan & Scannell, 1998).

Additionally, this can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research, both of which lead to increased costs. Incentives

are also necessary to ensure adequate representation among harder-to-recruit populations such as youth, low socio-economic groups, and high-risk populations (e.g., current or former tobacco users and those susceptible to tobacco use) (Groth, 2010).

10. Assurance of Confidentiality Provided to Respondents

CTP and FDA IRB reviewed and exempted the protocols and consent forms for this study. The letter of approval can be found in Attachment D. The IRBs' primary concern is protecting respondents' rights, one of which is maintaining the privacy of participant information to the fullest extent of the law.

Overview of Data Collection System and Data Security

All data will be collected with an assurance that the participants' responses will remain private to the extent allowable by law. Survey questions will not ask participants to provide other identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the agency. Additionally, IP addresses will not be collected by the online survey system, and survey links and access codes that are uniquely coded for each participant will not be used to identify participants or link them to the results. As noted above, no first- or third-party cookies will be stored during questionnaire completion and/or during the gift card distribution process.

All researchers handling data have completed training and obtained CITI human subjects protection (HSP) training certificates. These individuals will be the only staff with access to raw data files and will be responsible for keeping all data files secured. All data received by the FDA will be de-identified. Data will be kept on password-protected computer cabinets for a period of three years, and then will be destroyed by the permanent deletion of electronic information.

Overview of How Information will be Shared and for What Purposes

Information from this study will be used to inform FDA's knowledge of the hookah market in the U.S. Data will be used to gain insight into hookah smoking and purchase behavior in the U.S. Data from this study may also appear in professional journals or at scientific conferences. Participants' identifying information will not be included in any report or presentation. All analyses will be done in the aggregate and participant identifying information will not be appended to the data file used.

Neither contractors nor subcontractors associated with this project will share personal information regarding participants with any third party without the participant's written permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process.

Overview of Voluntary Participation and the Impact the Proposed Collection will have on the Respondent's Privacy

Participants will be informed that their participation in the study is voluntary and that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

The potential risks to participants' privacy in this study are minimal. As with any research study there is a chance that privacy could be compromised as a result of an accidental error or a security breach, however no other risks are anticipated. In the event a breach occurs, all participants will be contacted and notified as to the extent of the breach, any damages incurred, and future potential risks; contact information for additional inquiries will also be provided.

No personally identifiable information will be attached to respondents' answers. IP addresses will not be collected by the online survey system. There will be a respondent unique identifier associated with every response. A random system generated ID that will be used to track the respondent through the life cycle of this study and will effectively separate respondents from any personal information.

Data will be sent from Rabin to SmartAnalyst via secure email and will be stored on SmartAnalyst servers as well as an offsite server (without any PII). The server is secured by firewalls, antivirus and antispyware software. The data (without any PII) is held in a password protected folder, on a password protected computer. Data will be analyzed with no identifiers attached and implemented in a report for FDA.

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors, such as hookah smoking. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., hookah smoking behavior) and some demographic information, such as race/ethnicity, could be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- 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.
- The questionnaire is entirely self-administered and maximizes participant privacy by being conducted online, without the need to verbalize responses.

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 1,400 hours (Table 2). This includes the time burden associated with screening, consent, and the

questionnaire. The screening (3 minutes) and consent (3 minutes) will take approximately 6 minutes and the questionnaire will take approximately 20 minutes.

To obtain a final sample of 3,000 participants, it is estimated that approximately 100,000 potential respondents will need to be screened.

Table 2. 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
Screened Adults	Screener Completion	5,000	1	5,000	0.05	250
Consented Adults	Consent	3,000	1	3,000	0.05	150
Online Survey	Survey	3,000	1	3,000	0.33	990
Total Annualized Hours						**1,390**

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. The contractors have conducted many surveys of similar length and content among adults. To calculate estimated burden costs, the mean hourly wage of $7.25, national minimum wage, was used for adults. There are no direct costs to respondents associated with participation in this study. Thus, assuming an average hourly wage of $7.25, the estimated cost to participants will be $10,077.50. The estimated value of respondents' time for participating in the information collection is summarized in Table 3 below.

Table 3. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Screened Adult	Screener completion	250	$7.25	$1,812.50
Participants	Consent	150	$7.25	$1,087.50
	Survey completion	990	$7.25	$7,177.50
Total		**1390**		**$10,077.50**

13. Estimates of Other Total Annual Costs 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

This information collection is funded through a contract with SmartAnalyst. The total estimated costs attributable to this data collection are $66,200 (Table 4). There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA, data collection plan development, instrument development, reporting, IRB, and progress reporting and project management. This information collection will occur in 2019.

Table 4. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	10%	$96,970	$9,697
		Total Salary Costs	$9,697
		Contract Cost	$66,200
		Total	**$75,897**

15. Explanation for Program Changes or Adjustments

This is a new individual generic collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

The analysis will evaluate waterpipe smoking and purchase behaviors. Results will be aggregated and summarized. Demographic characteristics will also be analyzed. Findings from these analyses will be used to understand waterpipe consumer behavior in the U.S.

The reporting and dissemination mechanism will consist of one primary component: summary statistics (in the form of PowerPoint presentations and other briefings). The key events and reports to be prepared are listed in Table 5.

Table 5. Project Schedule

Project Activity	Date
Survey	August 2019 (Approximate)
Data analysis	September 2019 (Approximate)
Presentation of findings	October 2019 (Approximate)

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

An exemption to this requirement is not being requested. 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 Certificate for Paperwork Reduction Act Submissions.

References

Groth, S.W. (2010). Honorarium or coercion: Use of incentives for participants in clinical research. *Journal of the New York State Nurses Association, 41*(1), 11.

Halpern, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(7), 80l-803.

Morgan, D.L. & Scannell, A.N. (1998). *Planning Focus Groups.* Thousand Oaks, CA: Sage.

Russell, ML., Moralejo, DG., Burgess, ED. (2000). Paying research subjects: Participants' perspectives. *Journal of Medical Ethics, 26*(2), 126-130.

U.S. Department of Health and Human Services (HHS). (2014). *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.