U.S. Food and Drug Administration
NATIONAL PANEL OF TOBACCO CONSUMER STUDIES
SUPPORTING STATEMENT PART A
OMB Control No. 0910-0815

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A. JUSTIFICATION

On June 22, 2009, the Tobacco Control Act (Pub. L.111–31) was signed into law. The Tobacco Control Act granted the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act, which amends Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), requires FDA to issue "regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)." FDA also can assert authority over other tobacco products and require similar label statements. In June 2016, the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) obtained clearance to establish a panel to conduct experimental and observational studies with a national sample of tobacco users designed to collect information from tobacco users from across the sociodemographic spectrum in order to assess consumers' responses to tobacco marketing warning statements, product labels, and other communications about tobacco products. The FDA CTP is seeking an extension for ongoing maintenance and replenishment of the national panel as well as the implementation of three experimental and observational studies.

A.1 Circumstances Making the Collection of Information Necessary

In June 2016, the U. S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) obtained clearance to establish a high-quality, national panel of about 4,000 tobacco users who agree to participate in up to 8 studies over a 3-year period to assess consumers' responses to tobacco marketing warning statements, product labels, and other communications about tobacco products CTP established the panel due to limitations with existing Web-based panels, including panel conditioning, lack of generalizability of study findings, and panel samples that are not designed to represent the sociodemographic spectrum of tobacco users. As a result, FDA established a primarily Web-based panel of tobacco users through in-person probability-based recruitment of eligible adults and limited the number of times individuals participate in tobacco-related studies to reduce the likelihood of bias in data collections. The collection of experimental and observational studies conducted with the panel are referred to as the National Panel of Tobacco Consumer Studies (TCS).

The currently approved information collection request obtained in June 2016 focused on the study design and data collection processes to recruit and maintain a national panel of about 4,000 tobacco users. The first of the TCS panel studies, Study A "Brands and Purchasing Behaviors," was included in the currently approved information collection request. The FDA CTP is seeking an extension for ongoing maintenance and replenishment of the TCS panel. Approval for Study B "Coupons and Free Samples" and Study C "Consumer Perceptions of Product Standards" is also included in this extension request. Data from these studies will be used to inform FDA's regulatory authority over tobacco products. Data collection activities under the extension information collection request include panel recruitment and maintenance, mail and in-person household screening, in-person recruitment of tobacco users, enrollment of selected household members, and administration of a baseline survey, following all required informed consent procedures for panel members. Panel members, who are asked to participate in up to 8 experimental and observational studies over the 3-year panel commitment period[1], will be invited to participate in the two observational and experimental studies. Approval for the remainder of the studies will be sought in future requests.

A.2 Purposes and Use of the Information Collection

A.2.1 Overview of the Design

The panel is designed to establish a primarily Web-based panel of about 4,000 adult tobacco users, aged 18 and older, in housing units and in non-institutionalized group quarters in the 50 states and the District of Columbia. The sample is designed to allow in-depth analysis of subgroups of interest and to the extent possible, provide insight into tobacco users more generally.

For this panel, the young adult population (aged 18-25) are oversampled, while tobacco users ages 26 and older are undersampled. This will allow us to achieve the target sample sizes in four domains formed by age group (18-25, 26+) and social economic status (SES) (low SES, non-low SES) and to conduct more in-depth study of these groups of tobacco users. The primary reason to oversample young adults is because they are at a point in their life when their tobacco use habits are not fully established and they may respond differently to tobacco regulation than

[1] Near the end of their 3-year panel commitment period, panel members will be asked to continue their participation in the TCS for up to 3 years through a web/mail re-consent process.

older, more established smokers. To better understand this population, we are oversampling 18-25 year-olds because the sample size of young adult smokers we would get for the panel would be relatively small otherwise. In addition to this oversample, smokeless tobacco users identified during screening are assigned higher probabilities of selection than other tobacco users. Supporting Statement Part B (***Section B.1)*** details the panel sample design. ***Exhibit B.1-1*** provides the sample sizes achieved in each of the sample domains of interest during panel establishment Panel recruitment and enrollment efforts during panel establishment, described below, also pertain to ongoing panel maintenance and replenishment.

Panel members were enrolled through in-person, probability-based screening of sampled households and recruitment of selected eligible adult household members. The panel methodology, including the panel recruitment, incentive, and maintenance protocols, were informed by focus group discussions and consultation with experts in Web survey methodology and Web panels during the study design phase. For panel establishment, in-person panel recruitment was competed in two field data collection phases. The initial implementation phase, conducted between August and October 2016, served as a small pilot test of the panel protocols and systems. Seventeen panel members were enrolled during this phase. The national implementation phase, conducted between January 2017 and August 2017, yielded an additional 3,876 enrollments, for a total of 3,893 panel members.

To minimize the potential for coverage and nonresponse bias, we implemented a multimodal design to maximize Web participation yet provide a means of participation for individuals who were unwilling or unable to do so online. Across both phases of panel recruitment, we enrolled 3,342 panel members (86%) to participate via Web mode using personal devices. We also offered selected adults the option to participate via mail mode or online using a study-provided tablet computer. The 546 panel members (14%) enrolled as mail mode participants were generally older, less educated adults, who did not use or were uncomfortable with computers and who did not regularly access the Internet. We offered the loan of the study-provided tablet computer to maximize the number of panel members who could participate in the planned studies online. We expected the tablet offer to encourage Web mode enrollment by individuals who did not have a readily available or reliable means of participating online but who would otherwise be capable Web participants. During panel recruitment,

however, we found very few eligible adults who were interested in the tablet loan offer, and only 5 panel members (0.1%) opted to participate via Web mode using study-provided tablets.

Following the initial and national implementation phases, four panel members were disenrolled, including two who passed away and two who were determined to be physically/mentally incapacitated and unable to continue participation. At their enrollment into the panel, the remaining 3,889 panel members represented a diverse group of tobacco users from across the sociodemographic spectrum, including 882 (22.7%) adults aged 18 to 25 and 3,007 (77.3%) adults aged 26 or older. These panel members also reflected a broad spectrum of tobacco use, including 2,160 (55.5%) cigarette-only users, 303 (7.8%) cigar-only users, 428 (11%) smokeless tobacco-only users, and 998 (25.7%) poly users of cigarettes, cigars, or smokeless tobacco products. The demographic profile of the established panel is presented in ***Appendix A***.

It is important to note that the sample selection is independent of the mode of data collection. That is, we first draw a random sample from all addresses on our address-based sample frame. In the process of recruitment we identify those who are either unable or unwilling to participate in an online panel and provide them with the option of an alternative mode to avoid biasing the panel. ***Section B.3.2*** provides additional details about the procedures for nonresponse bias assessment and the strategy used to weight results to address differences in mode of survey administration, oversampling of young adults, and adjust for deviations from the original design due to factors such as variable nonresponse.

A total of 3,889 panel members were invited to participate in the first TCS panel study (Study A “Brands and Purchasing Behaviors), including 3,344 (86%) web mode participants and 545 (14%) mail mode participants. Five of the 3,344 web mode participants enrolled using the loan of a study-provided tablet computer so they could participate in the panel studies online.

Of the 3,889 panel members invited to participate in Study A, a total of 1,626 elected to do so. Respondents included 292 (18.0%) adults aged 18 to 25 and 1334 (82%) adults aged 26 or older. Study A respondents also reflected a broad spectrum of tobacco use, including 959 (59.0%) cigarette-only users, 133 (8.2%) cigar-only users, 181 (11.1%) smokeless tobacco-only users, and 353 (21.7%) poly users of cigarettes, cigars, or smokeless tobacco products. The demographic profile of Study A respondents is presented in ***Appendix B.***

Attrition from the sample is expected, and the sample design provides for in-person panel replenishment, as needed, using the same sampling and data collection design described above, to replace panel members who choose to end their involvement in the panel.

A.2.2 Purpose of the Panel

The overall purpose of the data collection is to collect information from a national sample of tobacco users to provide data that may be used to develop and support FDA's policies related to tobacco products, including their labels, labeling, and advertising. Data are collected from the panel primarily through the use of randomized experimental designs. In the future FDA may submit ICRs under a separate clearance mechanism that use other methods, such as surveys, interviews, or online group discussions. As discussed in Section A.1, existing panels of tobacco users are not appropriate for this purpose for one or more reasons. The project establishes and maintains a panel of tobacco users who are asked to participate in up to 8 experimental and observational studies over a 3-year period. Oversampling of young adults (18-25) is another key feature of this study. Smoking initiation has increased among young adults (Lanz, 2003), and this age group has the highest smoking prevalence rate in the United States (Schiller, Lucas, & Peregoy, 2012). As a result, information about how proposed regulations might impact them is essential to continued decreases in tobacco use among Americans. Another key feature of this study is the oversampling of adults who use smokeless tobacco products and the inclusion of panelists who use cigars.

A nationally representative sample is not necessary for conducting the experiments; rather the need is for a sample that is sufficiently varied with respect to the major sociodemographic characteristics of tobacco users. Although we use probability methods to recruit the panel of tobacco users, the final panel may not be able to produce results that are representative for the population of tobacco users in the U.S. Of particular concern are the complex relationships among tobacco use, age, income, race/ethnicity, education, and geography (both location and urban/rural). As such, whenever the results are presented, CTP will clearly describe the sociodemographic and geographic characteristics of the sample that responded to a given survey, explicitly characterizing potential limitations in generalizability. It is likely that, for at least some studies, we may be limited to describing the results as sufficiently varied to reflect the general characteristics of smokers in the U.S. Such a description should be sufficient

for documenting the trends and patterns of interest to CTP in the context of this information collection. Consistent with obligations under HHS' and OMB's Information Quality Guidelines, CTP will assess the quality of the information generated for each regulatory or policy purpose under consideration.

A.2.3 Information Elements and Data Sources

The data elements in the initial set of surveys used for establishing the panel was driven primarily by the need for quality baseline data to benchmark future experimental and observational studies and to accurately characterize the tobacco use of panel members. The surveys also took into account the methodological and administrative factors relevant to collecting data in a cost effective manner that does not burden respondents unduly, and that adequately deals with the requirements of a diverse multicultural population of interest. Relevant factors taken into account included the overall length and complexity of each survey and the presentation of individual questions, response sets, and respondent instructions in both Web and paper self-administration environments (e.g., minimizing use of grids or other complex question formats). All surveys were also translated into Spanish.

Instrument Development Process

Four questionnaires—a mail screening questionnaire, field screening questionnaire, enrollment questionnaire, and baseline questionnaire—were developed to support screening and recruitment of the panel and collection and maintenance of participant contact information, demographic data, and other background information pertinent to panel management and analysis. The questionnaires were drafted using existing survey items from the National Health Interview Survey (NHIS) and the Tobacco Use Supplement in the Current Population Survey (TUS-CPS) as the source for items on tobacco use. Use of previously tested and fielded survey items mitigates the need for extensive pretesting of the questionnaires. In addition, an interviewer observation questionnaire was developed. Study A was included in the currently approved information collection request in order to engage panel members in their first substantive study within the first few months of their panel enrollment. Studies B and C are included in this extension request. The panel instruments, including Studies B and C questionnaires, are described in detail in the sections that follow. Further details are provided in ***Section B.2.3***.

Baseline Questionnaire

The baseline survey collects a detailed history of the panel member's use of cigarettes, cigars or little cigars, and smokeless tobacco products. Panel members are asked how frequently they use each tobacco product and whether they intend to quit within the next 30 days. They are also asked questions to assess their level of addiction to nicotine, their general health status, and use of other tobacco products, including electronic cigarettes, pipes, and water pipes.

At the conclusion of the baseline survey, and upon leaving the panel member's home, the interviewer completes a brief interviewer observation questionnaire on his/her tablet computer to document perceptions about the panel member recruitment process, comfort level with the Web baseline survey and computers in general, and his/her likelihood of remaining in the panel. This information, coupled with the baseline survey items on comfort with the computer, is used to identify panel members at greater risk of attrition or who may need increased levels of technical support while in the panel. These panelists receive more targeted or more frequent support while in the panel, and in particular during the initial weeks and months following enrollment. The interviewer observation questionnaire is also used to capture information collected by interviewers during their post-enrollment follow-up call to those panelists using a loaned tablet.

Experimental and Observational Studies

Periodic self-administered Web (or mail) surveys will be the mechanism for collecting experimental and observational data desired by FDA. As noted above, up to 8 studies will be conducted with TCS panel members during the initial 3-year panel period. The first TCS panel study, Study A "Brands and Purchasing Behaviors," was included in the currently approved information collection request in order to engage panel members in their first substantive study within the first few months of their panel enrollment. Studies B and C are included in this extension request. The remaining studies will be handled in separate clearance requests. To minimize burden, each of these studies will require no more than 20 minutes for panel members to complete.

The first panel study, Study A, was an observational study offered to all TCS panelists focused on purchasing behavior, tobacco brands, and use of coupons and price promotions for tobacco products. The goal of this study was to collect information about participants' tobacco product brand loyalty and more accurate measures of their tobacco product consumption. It was

important to quantify the brand loyalty of panel participants in order to examine how it affects panelist choices in planned experimental studies. Study A was completed in June 2018, and therefore will be mentioned minimally in this extension.

Study B: Study B will be an observational study offered to all panelists that will provide a more in-depth examination of tobacco product promotions, namely free samples and coupons, after the ban on distribution of free samples of tobacco products (with the exception of certain smokeless tobacco exemptions) that went into effect when FDA finalized the "Deeming Rule" on August 8, 2016 (published May 10, 2016 (81 FR 28973)) that extended FDA's regulatory authority to all tobacco products. This extended the free samples ban to all types of tobacco products except smokeless tobacco, which remained exempted from this rule. The free samples ban went into effect immediately.

A common industry marketing practice is to offer price promotions in the form of coupons that are directly sent to consumers that allow them to reduce the costs of their tobacco products. This legal marketing practice offers the tobacco industry opportunities to introduce new products to current or potential tobacco users, and also retain current tobacco users with discounts on their usual products. While CTP does not have authority to regulate the prices/taxes associated with tobacco products, CTP does have the authority to regulate industry marketing practices.

Study Design: Study B will explore whether tobacco users report receiving free samples of prohibited tobacco products. This will help CTP understand the occurrence of free sample distribution despite the ban on distribution of free samples of tobacco products (with the exception of certain smokeless tobacco exemptions). It will also explore the frequency of receipt and use of smokeless tobacco free samples among tobacco users as well as, if feasible, the associations between receipt and product liking, health perceptions, and quit intentions. This will help CTP better understand the current impact of smokeless tobacco free sample receipt on tobacco users. In addition, this study will explore the intentions, motivations, and behaviors of regular tobacco users who seek and/or receive coupons (as part of industry marketing) to reduce the costs of tobacco products. This study will also explore coupon use among tobacco users and its associated impact, including product experimentation, subsequent product liking, and associated health perceptions and quit intentions; and the receipt of samples that are close to free.

This information will help CTP understand manufacturers' price-related marketing strategies and target populations. Specifically, this study will examine prevalence of free sample and coupon receipt for tobacco products, where and how consumers are receiving free samples and coupons, and how free sample and coupon receipt may be associated with tobacco product perceptions, use intentions, and behavior. The questionnaire includes items from national surveys including the NHIS, PATH Study, and CPS-TUS.

Study C: FDA was granted authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health. Some of the Agency's responsibilities include setting product standards that would regulate the levels of certain harmful and potential harmful constituents (HPHCs). To understand the potential impact of a product standard, we should first determine whether consumers are aware of potential tobacco regulations. Second, we should better understand how product standards may influence perceptions and intentions to use tobacco, both constructs that have been shown to predict future tobacco use (Ajzen, 1991).

Study Design: Study C will be an experimental study examining how a hypothetical tobacco product standard may impact consumers' perceptions, attitudes, and intentions to use tobacco. Specifically, this study will use an experimental design where treatment group participants are exposed to a stimulus that describes a hypothetical product standard that reduces 'a chemical' in cigarettes or smokeless tobacco and then respond to questions about perceptions and intentions. Comparison group participants will respond to questions about perceptions and intentions before stimulus exposure. The survey will assess whether consumers are aware of potential tobacco regulations and product standards; consumers' perceptions of FDA's credibility; consumers' knowledge and awareness of HPHCs in tobacco products; consumers' harm perceptions of HPHCs; consumers' attitudes about tobacco product standards; how consumer attitudes toward tobacco product standards are related to perceptions, tobacco use, and intentions; and how a hypothetical product standard may change tobacco product perceptions and use intentions. The questionnaire includes items from the Health Information National Trends Survey and peer-reviewed literature. This design enables a comparison of outcomes between the treatment group (i.e., those exposed to the product standard statement in the middle of the survey instrument), and the comparison group (i.e., those exposed to the product standard statement later in the survey instrument).

We will randomly assign respondents to one of 8 conditions with variation in timing of exposure to the stimulus, product type described in the stimulus, and health outcome described in the stimulus. ***Exhibit A.2-1*** illustrates the study design.

Exhibit A.2-1. Study Design

Timing of Exposure to Stimulus	**Product Type Described in Stimulus**	**Health Outcome Described in Stimulus**	
		Cancer (a)	**Heart Attack and Stroke (b)**
Treatment (T): stimulus shown before assessment of perceptions and intentions	Cigarettes (1)	T_A1	T_B1
	Dip (2)	T_A2	T_B2
Comparison (C): stimulus shown after assessment of perceptions and intentions	Cigarettes (1)	C_A1	C_B1
	Dip (2)	C_A2	C_B2

Survey flow will vary for *Treatment* and *Comparison* groups. ***Exhibit A.2-2*** illustrates the survey flow for each group. In Section X (Stimuli Exposure), respondents will be shown a statement with piped text that varies according to *product type* and *health outcome*.

Exhibit A.2-2. Survey Flow, by Study Condition

Treatment (T)	**Comparison (C)**
Section A: Awareness of FDA Authority	Section A: Awareness of FDA Authority
Section B: FDA Credibility	Section B: FDA Credibility
Section C: Current Tobacco Use	Section C: Current Tobacco Use
Section D: HPHC Knowledge And Awareness	Section F: HPHC Knowledge And Awareness
Section E: Demographics	Section E: Demographics
Section X: Stimuli Exposure	Section G: Future Tobacco Behavior Intentions
Section F: Attitudes About Product Standard	Section H: Product Harm Perceptions
Section G: Future Tobacco Behavior Intentions	Section J: HPHC Harm Perceptions
Section H: Product Harm Perceptions	Section X: Stimuli Exposure
Section J: HPHC Harm Perceptions	Section F: Attitudes About Product Standard

A.3 Use of Improved Information Technology and Burden Reduction

The panel instruments, including the field screener, enrollment survey, baseline survey, and experimental and observation study instruments, are programmed for computer-assisted data collection. Computer-assisted interviewing (CAI) technology affords well-known improvements and efficiencies in the collection of survey data. The technology permits more complex routings compared to a paper-and-pencil mode of data collection. It allows for on-screen cueing of respondents, delivery of media images, and consistency checks during self-administration or by the field interviewer, and produces quality backend data that saves costs associated with data-cleaning and data analysis.

The contractor uses its mobile field system (via interviewer tablet computers) to conduct all counting and listing and field screening operations. This includes identification of dwelling units that were not part of the sampling frame using Check for Housing Units Missed (CHUM) protocols. The mobile field system is also used for the administration of the enrollment survey and interviewer observation survey that are deployed on the interviewer's tablet computer. This system enables the ready creation of instruments for deployment and the easy output of codebooks and data at the backend. Use of mobile technology enhances the quality of data, for example allowing behind-the-scenes GPS capture to verify sampled addresses, while improving the efficiency of the doorstep screening operation. Survey data on the tablet are encrypted and both the tablet and the mobile field system are password protected. An integrated field management system supports field staff data transmissions, time reporting, and assignment of cases.

The contractor's *Hatteras* Web authoring system is used for the panel member's baseline and Study A instruments. Like the mobile field system, the *Hatteras* survey engine supports all aspects of survey deployment, data output, and codebook generation. A *Hatteras* Web page can display a wide array of fonts, colors, and images, including videos with superior resolution. Use of both systems reduces user burden and creates efficiencies, both for project staff and panel members. *Hatteras* is also used to support the collection of panel member survey data in alternative modes, including entry of completed mail questionnaires. Additionally, any in-person or telephone data collection undertaken as part of nonresponse follow-up efforts for Study A or

subsequent experimental and observational studies can also be supported by the mobile field system and/or *Hatteras*.

Access to the panel member Web surveys is controlled through a project Web portal hosted by the contractor. A two-tiered security approach is used for accessing the surveys and transmitting the data. An ID and password is required for a panel member to enter a Web survey; Secure Socket Layer (SSL) certification ensures that only encrypted data flow over the Internet.

A control system is the central component of all the activities that take place with the panel. Data maintained in the control system database provides a record of the panel operations, including sampling, screening and recruiting, data collection, panel member communications (mailings, e-mailings, text messaging, automated telephone prompting), panel member tracing, fulfillment operations (incentive and questionnaire mailings, mail survey receipt and data entry), helpdesk operations, and data processing. This centralized repository of information creates efficiencies in the generation of reports on sample disposition, data quality monitoring and the flow of information between the contractor, self-administered interviews, and field operations.

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

Three commercial Web-based panels include smokers, but none of these panels meet the rigorous requirements needed to inform FDA's regulatory authority over tobacco products. For example, Harris Interactive includes smokers, but there is limited participation by disadvantaged populations that may be of interest to FDA. Many tobacco control investigators use the GfK Knowledge Networks panel for survey research, as it is built from an address-based sample and includes many difficult to reach populations such as young adults, cell-phone only households, and ethnic/racial minorities. However, there are significant concerns that the smokers in this panel may be biased by conditioning effects because they participate in a relatively high number of tobacco-related studies. These effects may be particularly pronounced among the small number of disadvantaged populations due to the gap in smoking-related information about them which places them in high demand for surveys. Of particulate note, however, is that in our own experience we have found that these commercial panels cannot easily recruit the number of cigar smokers or smokeless tobacco users that the planned studies may require.

Existing longitudinal surveillance studies of tobacco users, such as FDA's Population Assessment of Tobacco and Health (PATH), are not appropriate for the planned experimental or observational studies. PATH is intended to understand the natural history of tobacco use uptake, cessation, and relapse and associated health consequence without conducting experiments that may influence their behavior. Therefore, subjecting PATH participants to experiments may influence their behavior and then the PATH study would not be able to claim that it is a representative picture of tobacco use and health for the U.S.

The survey items in the panel instruments are standard measures used to characterize participant demographics, smoking status, and level of addiction to tobacco products. These items are included in many national surveillance systems to monitor trends in tobacco use. However, their inclusion in the panel questionnaires is nonduplicative of these surveys; rather, they are included to identify tobacco users to be recruited to the panel and to measure potential covariates that may be needed to account for nonresponse in future studies.

A.5 Impact on Small Businesses or Other Small Entities

There is no impact on small business or other entities. No small businesses are involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

By design, the panel has been established to support up to 8 experimental and observational studies of adult tobacco users over a 3-year period to assess consumers' responses to tobacco marketing, warning statements, product labels, and other communications about tobacco products. Given the length of commitment, it is critical to the overall success of the panel, especially in minimizing attrition, to maintain frequent contact with panelists to ensure their continued interest and participation, address technical or other issues they may have, and to maintain accurate locator information that will facilitate longitudinal contact and tracking of movers. Thus, other contacts, involving other forms of communication with panel members are planned for this purpose.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR1320.5

None.

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

A.8.1 Federal Register Announcements and Comments

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 10/23/2018 (83 FR 53485). FDA received ten comments, however only one was PRA related. Within those submissions, FDA received one comment which the agency has addressed.

(Comment) One commenter supports FDA's establishment of a tobacco user panel, adding that high-quality research is critical to successful implementation of many provisions of tobacco policy. The commenter further stated that the research panel can provide the FDA with critical information on how adult tobacco users respond to tobacco marketing, product labels, warning statements and other communications about tobacco products. The commenter also noted the ability to have its own panel of tobacco users will allow the FDA to gather more reliable information in a more efficient manner.

(Response) FDA agrees with this comment and believes the panel will be a valuable tool for conducting new observational and experimental studies.

A.8.2 Consultation Within the Research Community

To inform the design of the panel recruitment and retention strategies, the contractor engaged the services of a Web survey panel expert in the research community. The consultant participated in discussions with the contractor to review focus group findings (Focus groups conducted under OMB Control No. 0910-0497) and provide feedback on strategies for recruiting and engaging panel members long-term. This included guidance on 1) the feasibility of providing tablet computers to panelists as part of a study incentive protocol rather than a loan, and potential challenges with this approach; 2) panelist use of personal computing devices to complete Web surveys; 3) cash-based incentive options both at enrollment and throughout the panel period; 4) the need for Internet service provision by the study to enroll some panelists; 5) length of the panel commitment period; and 6) panel maintenance strategies, including short surveys and other forms of contact with the panel. The consultant also provided feedback on the most significant challenges in Web-enabling survey respondents and keeping them engaged long-term, and the

need for alternative survey modes for panel members who will not participate online in order to minimize coverage and nonresponse bias.

Consultant contact information is provided below.

Scott Crawford Founder, Chief Executive Officer	**Survey Sciences Group, LLC** 950 Victors Way, Suite 50 Ann Arbor, Michigan 48108 Ph. 734-527-2150

A.9 Explanation of Any Payment or Gift to Respondents

The multi-year longitudinal design with multiple surveys can pose a burden to respondents, while the self-administered modes of data collection and relatively sensitive topic limit the ability to motivate sample members and encourage participation. Along with other features of the study, these factors create a substantial risk of nonresponse and attrition bias in estimates of tobacco use (e.g., Seltzer, Bosse and Garvey, 1974; Vestbo and Rasmussen, 1992; Cunradi et al., 2005), if left unaddressed. A comprehensive incentive strategy was implemented to recruit and maintain the 4,000-member panel, given the length of the panel commitment, the need for panelists to have frequent yet easy access to the Web survey application, and the planned frequency of contacts (up to 8 experimental and observational studies) during their time in the panel.

Two key concerns in longitudinal panel maintenance are panel attrition and panel conditioning. To combat panel attrition and increase the likelihood of participation at each survey request during the life of the panel, panel members are offered incentives contingent on survey completion (Baker et al., 2010). Furthermore, minimum burden through limited number of survey requests can ensure panel retainment and at the same time minimize panel conditioning, associated with repeated measurement on the same topic and frequency of the survey request. However, the limited number of survey requests can also induce nonresponse due to lack of engagement. Given the significant investment made during the recruitment stage and the high cost of replacing panel members (due to in-person recruitment and screening), we have developed a sound incentive strategy to keep recruited panelists engaged throughout the life of the panel.

We conducted a review of the existing longitudinal surveys in terms of panel maintenance strategies, and specifically, incentives (see ***Attachment 6***). The incentive protocol, based on findings in the survey literature, focus groups (OMB Control No. 0910-0497), and discussions with survey researchers outside of the study team, includes the following:

- to minimize the initial screening cost, we mail a paper screener to all sampled households to determine if there is an eligible tobacco user in the household. A $2 prepaid incentive is enclosed with this initial mailing to maximize response rates and reduce the number of households requiring a more expensive in-person screening visit.[2] This approach is consistent with other large federal surveys (e.g., National Household Education Survey, U.S. Department of Education (as part of the transition from a telephone to a mail mode of administration); The National Survey of Early Care and Education, Administration for Children and Families) that have experimented with a mail screener that includes a small prepaid incentive (typically, $2 or $5) and have reported on their effectiveness in increasing screener response rates.
- provision of a one-time $35 enrollment incentive, paid by the interviewer upon the panelists' completion of both the enrollment and baseline surveys. The goal of this incentive is to engage the potential panelist, provide a token of appreciation for his/her participation in the enrollment and baseline surveys (an estimated interview burden of 20 minutes, plus interviewer training on website login) and serve as a proof that future promised incentives are paid upon survey completion.
- a $15 promised incentive, payable upon completion of each experimental and observational study. The goal of this incentive is to maximize participation in each study. Each study instrument is expected to take approximately 20 minutes to complete, on average.

We believe the existing incentive strategy, summarized in ***Exhibit A.9-1***, is reasonable for recruiting, maintaining, and replenishing a 4,000 member panel of tobacco users for the 3-year period, maintaining their interest and active participation long-term, thereby minimizing attrition, and achieving the necessary response rates to support the planned analyses for each of the 8 experimental and observational studies. Additional documentation in support of the incentive strategy is provided in ***Attachment 6***.

[2] The design provides for screening all nonresponding households in a face-to-face mode and selecting a 10% random sample of those who report ineligibility to be screened by an interviewer during a face-to-face visit.

Exhibit A.9-1. Incentive Type and Amount

Type of Incentive	Participant	Amount/Value
Mail screener incentive	All sample members	$2 one time
Enrollment incentive	All panel members	$35 one time
Experimental and observational study cash or digital gift card incentive	All panel members	$15/study; Up to $120 total, covering 8 studies

Over the 3-year panel period, panel members have the opportunity to receive a maximum of $155 in incentives if they enroll and complete all planned studies (8).

A.10 Assurance of Privacy Provided to Respondents

The contractor's Institutional Review Board (IRB) has reviewed and approved the panel protocols and consent forms (see Attachments 3-25, 3-26, 3-55, 4-25, 4-26, and 4-55). The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law and in accordance with 45 CFR 46.103(f). The IRB will review any amendments to the study protocol before the requested changes are implemented, and conduct annual continuing reviews.

This data collection is not covered by the Privacy Act and does not require a SORN because the federal government will never have access to any personally identifiable information received during the establishment and implementation of the panel. Instead, the government will only receive de-identified datasets. All personally identifiable information is handled by the contractor that establishes and maintains the panel. The contractor assigns a unique 8-digit identification number to each sample member and the contractor uses this number to maintain linkages between the survey data files and control system files that the contractor maintains. The contractor removes the following sensitive data to produce the datasets to be delivered to the government: a) names, addresses, telephone numbers, and email addresses for panel members, b) names of all household members, and c) names, addresses, telephone numbers, and email addresses of contact persons.

All data collection activities are conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of

human research subjects as contained in their regulations. Respondents receive information about privacy protections as part of the informed consent process.

A.10.1 Procedures for Protecting Data Collected from Participants

PRIVACY ANALYSIS & DESIGN

In developing this study, FDA-CTP consulted the agency Privacy Officer to identify potential risks to the privacy of survey participants and panel members whose information may be handled on behalf of FDA in the performance of this study. FDA designed the study to minimize privacy risks in keeping with the Fair Information Practice Principles (FIPPs) and applying controls selected from the National Institute of Standards and Technology (NIST), Special Publication 800-53, Security and Privacy Controls for Federal Information Systems and Organizations. CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in the CTP satisfy all in accordance with law and policy.

PII Collection

As part of this study, CTP's contractor, acting on behalf of FDA, collects and maintains personally identifiable information (PII) about potential survey participants, household screening respondents, enrollment survey respondents, and enrolled panel members. The PII about potential survey respondents consists of the addresses selected via address-based sampling for household screening in 80 primary sampling units (PSUs) across the nation. The PII about household screening respondents consists of respondent and household member names and address of households, and is collected directly from the adult household screening respondent. The PII about enrollment survey respondents consists of name, address, telephone numbers, email addresses, and contact person information for the eligible adult selected for the panel, and is collected directly from the enrollment survey respondent. Updated contact information (name, address, telephone numbers, email addresses, and contact person information) may be provided directly by the panel member or updated through panel tracing and/or nonresponse prompting activities. An estimated 74,165 household screening respondents and 9,000[3] enrollment/baseline

[3] Includes 4,000 respondents from the initial/national implementation phase and an additional 5,000 from annual replenishment efforts (1,400 for each of 3 years, plus an additional 800 respondents should attrition be greater than expected.)

survey respondents are expected to provide PII. FDA does not receive PII data. All PII data is handled by the contractor that establishes and maintains the panel.

Privacy Act Applicability

The information collection is not subject to the Privacy Act of 1974. Hence, no Privacy Act Statement is required to be displayed on the form, website, mobile application or other point at which information is collected.

Data Minimization

The PII collected or used for this study is limited to the minimum necessary to achieve the authorized purpose and produce a valid study. The purpose of the TCS is to assess consumers' responses to tobacco marketing, warning statements, product labels, and other communications about tobacco products to inform FDA's regulatory authority over tobacco products. The study is authorized under the Tobacco Control Act (Pub. L.111–31). The PII is necessary to screen sampled households, select eligible adult tobacco users for the panel, achieve the desired sample sizes across age and SES domains, and maintain contact with panel members for the experimentational and observational studies.

FDA has minimized the risk of unnecessary access, disclosure, use or proliferation of PII about respondents. All PII subjects are provided notice regarding the collection and use of the information they submit. FDA does not receive IP addresses. FDA and its contractors will notify participants if IP addresses are recorded. FDA's contractor will maintain study records containing PII only as long as required to maintain and replenish the TCS panel and conduct the planned experimental and observational studies. PII will be deleted and/or securely shredded at the conclusion of all panel activities. Sample and panel member names, addresses, telephone numbers, and email addresses will not be included on any data file delivered to FDA by the contractor. All open-ended survey text responses included on the files will be reviewed by the contractor for the presence of PII. If found, PII will be masked in the text string by replacing it with generic terminology, such as "[NAME]". All contractor personnel involved in the project will sign Commitment to Protect Non-Public Information agreement forms, and access to PII will be limited to authorized project staff involved in data processing, data delivery, and panel data collection and panel maintenance activities. Contractors and subcontractors that collect data on behalf of CTP never pass along any PII, and at the most we receive ID numbers. For these

collections, we don't have any systems where we maintain or retrieve PII. In most if not all our contracts we even specify that contractors cannot send FDA any PII.

FDA's contractor only shares collected PII for (1) the secure printing of some respondent materials (e.g., personalized letters, mailing envelopes), (2) database tracing of panel members who may have moved, (3) fulfillment activities, (4) telephone verification interviews, tracing, and prompting, and (5) field screening, recruitment, tracing, and prompting. The contractor's print vendor, who does not access the panel systems, works in accordance with a detailed Data Security Plan governing submission of print jobs via their secure web portal, which uses SSL encryption and automated deletion of files following order receipt. Printing is done in a controlled access environment. PII shared for printing purposes is limited to sample and panel member names and addresses and contact person information. The contractor only uses tracing vendors with whom it has executed Data Use Agreements (DUAs). The primary purpose of the DUA is to protect PII when it is determined that the existing contact information is incorrect and needs to be updated through tracing. PII shared for tracing purposes is limited to the names, addresses, and telephone numbers of panel members whose contact information needs to be updated to facilitate ongoing study activities. The contractor also uses three subcontractors to provide staff recruiting, human resources, and payroll services for fulfillment staff, telephone interviewers, and field interviewers who support panel data collection activities. PII may be shared with these staff to prepare study mailings, receipt and process mail survey forms, conduct telephone verification interviews, or conduct telephone or field tracing, prompting, or data collection activities. All fulfillment and interviewing staff are required to sign confidentiality agreements when hired. They are also trained on project-specific protocols for the protection of physical and electronic PII and are required to sign Commitment to Protect Non-Public Information agreement forms. The contractor's Research Operations Center, which houses its Call Center, tracing, and fulfillment operations, is a controlled access facility. The Center complies with the confidentiality and data security guidelines set forth by the National Institute of Standards and Technology (NIST) in *Recommended Security Controls for Federal Information Systems and Organizations*, and can accommodate both low- and moderate-risk projects, as defined by NIST's Federal Information Processing Standards Publication 199, *Standards for Security Categorization of Federal Information and Information Systems*.

Notice and Transparency

All PII subjects are provided notice regarding the collection and use of the information they submit. This is communicated through the survey descriptions that are read to or by the participant at the beginning of each survey, the informed consent statements/forms associated with the study, the TCS study brochure provided to panel members, and in the Frequently Asked Questions pages of the study website. The panel data collection forms, website pages, and other study materials are clearly branded as FDA-sponsored products.

The privacy compliance documentation materials such as Privacy Impact Assessments are typically posted on HHS.gov and linked on FDA.gov to provide further notice and transparency regarding this collection.

FDA and its contractor identified certain privacy risks entailed in this study. Study participants have control over the information they submit and may choose to submit PII about other individuals who have not been provided notice or an opportunity to object or consent. To mitigate this risk, panel enrollment questionnaires and documents limit the amount of collected PII to that information needed for household eligibility screening and panel member contact during planned studies and panel maintenance activities. The use of open-ended text fields to gather information is also avoided when possible. Access to the contact information section of the study website, as well as the online experimental and observational studies launched through the study website, requires the entry of panel member unique login credentials.

Individual Participation and Control

Participation in all TCS surveys is voluntary and respondents can skip any question they do not want to answer. Household screening respondents are read an informed consent statement as part of the questionnaire introduction and verbally consent to participate in the interview. Enrollment survey respondents are read and required to sign a written informed consent form as part of their panel enrollment process; the enrollment process includes completing both the enrollment and baseline survey components. Panel members who agree to participate using a study-provided tablet also sign an equipment agreement form acknowledging their use of the loaned device while participating in the panel and the steps to be taken by the contractor to clean and restore the device to factory settings upon its return. Panel members who respond to the experimental and observational studies are provided an informed consent statement as part of their web and mail survey questionnaires. Web participants to the studies indicate their

agreement to complete the online surveys by answering a yes/no consent question at the beginning of the online survey. Mail participants to the studies indicate their agreement to participate by completing and returning the paper survey form to the contractor. Subjects can refuse to participate in any study and can opt out of the panel entirely. Panel members will be disenrolled from the panel at their request. Near the end of their 3-year panel commitment period, panel members may be invited to continue their participation in the TCS for up to 3 years through a web/mail re-consent process. Web re-consent would involve reading the re-consent script and actively consenting (answering "yes" or "no") to continue participation in the panel. Mail re-consent would involve signing and returning the re-consent form to the contractor. As part of their panel enrollment consent, and the re-consent process (if implemented), panel members will be informed that a Certificate of Confidentiality exists for this research. Panel members will also be informed that TCS researchers may use, share, or release their deidentified panel data for similar research in the future without obtaining additional informed consent.

Data Security

A detailed description of the steps to protect the privacy of information collected in-person, online, by mail, and through the use of study-provided tablets are summarized in Sections A.10.2 to A.10.5, respectively. This includes protections for both electronic and physical (hardcopy) data, and the use of encryption protocols for electronic information submitted online or through secure transmissions from contractor field data collection personnel.

The contractor's Institutional Review Board reviewed and approved all study protocols and respondent materials, including provisions for protection of private information. The contractor's IRB was also consulted on privacy and human subjects protections during the study design phase. This included reviewing preliminary plans for obtaining informed consent, collecting data using various modes, protecting the privacy of data to be collected, and provisions for loaning study-provided tablets to panel members. The contractor's IRB required minor modifications to the study consent forms specific to panel participation requirements, and respondent materials associated with the loan of the study-provided tablets. This included adding language to the equipment agreement specifying that the contractor would wipe the device clean and restore it to factory default settings upon return by the panel member, with no attempt made to access any data that may have been stored locally on the device. The IRB also consulted on

the protocols for secure access to the study website by panel members, including the protocol for establishing a security question at panel enrollment and the 2-step process for resetting passwords. Copies of all study protocols and respondent materials were also provided to CTP's RIHSC.

A.10.2 Privacy Procedures for In-Person Data Collection

The procedures that are used to maintain privacy for the panel in-person data collection are summarized below:

- All project staff, including fulfillment personnel, sign a privacy pledge that emphasizes the importance of nondisclosure and describes their obligations.
- All field data collectors are trained on privacy procedures and are prepared to describe them in full detail, if necessary, or to answer any related questions raised by sample members. Training includes procedures for safeguarding sample member information in the field, including securing hardcopy case materials and tablet computers in the field, while traveling, and in respondent homes, and protecting the identity of sample members.
- Hardcopy documents containing personally identifying information (PII) are stored in locked files and cabinets. Discarded hard copy material containing PII are securely shredded.
- Hardcopy consent forms and case folders for completed field cases are receipted and securely stored at the contractor's Research Operations Center (ROC), which uses a keyless card-controlled entry system for controlled access.
- Responses to all screening, CHUM, enrollment, and interviewer observation surveys are entered directly into the Android tablet computing device provided to each field interviewer. The data entered are encrypted before being written to the local database on each tablet. In the unlikely event the tablet is stolen or otherwise compromised, the tables holding the survey data would be unreadable.
- GPS data collected on the field interviewer's tablet during the screening and enrollment process are used for quality control purposes only to verify the interviewer's location in relation to the sampled address. These data are not used in analyses of the substantive data or included on deliverable data files.
- Both the Android tablet, the contractor's MOBILE FS system on the tablet, and any field supervisor laptops used for administrative tasks are password protected with unique user logins.
- Field supervisor laptops have whole disk encryption to protect the hard drive. The associated Checkpoint FDE software is FIPS 140 compliant. File transfers are done through an FTP site using secure socket layer (SSL) to protect data in transit. The FTP

site is specific to the project and requires credentials specific to the project. Data files are encrypted using FIPS 140 certified libraries prior to sending.

- All data transferred to the contractor's servers from field staff Android tablets including CARI files, media files such as audio, photo and video and survey data are encrypted on-the-fly using AES-256 with a 'secure random' public key hashed using SHA-256 and a private key. These files are transmitted back to the contractor using secure socket layer (SSL) over HTTPS. A batch process decrypts these files after receipt on the contractor's private network where they are stored on secure contractor servers. The survey data are stored in SQL Server databases on those servers. Only authorized project staff members are able to access them on the secure network share or databases. Access requires passwords and the enabling of user access by contractor IT security personnel.
- Respondents receive information about privacy protections as part of the informed consent process.
- A unique 8-digit identification number is assigned to each sample member and used to maintain linkages between survey data files and control system files.
- Following receipt from the field, PII is stored only on contractor password protected, secured servers. Only authorized project members have access to PII for research sample members.
- Reports and data files provided to the research community will not include any individually identifying information.
- As noted above, all precautions are taken against inadvertent disclosure. Project directories and files containing data, and files of identifiers and contacting data, are protected through the use of encryption and passwords.

A.10.3 Additional Privacy Concerns Associated with On-line Data Collection

Panel member privacy concerns regarding use of the Internet for participation will typically be related to three issues:

- Disclosure of subjects' PII by the researchers to others outside the study;
- Use of electronic information to gather additional PII without the subject's knowledge or consent, and;
- Electronic breach of security allowing access of subjects' PII to unrelated third parties.

Plans to minimize potential for risk and addressing these three issues are described below, respectively.

All study consent forms provide participants with advance notice of what data are collected and the measures that are taken to protect their privacy. These methods include: using

approved encryption and other methods to physically and electronically secure data, collecting only the minimum amount of information necessary to conduct the study, not disclosing this information to anyone outside the research team, and destroying data as soon as possible after the study has been completed. The data are collected only for the stated purpose and not used subsequently for any other purposes.

Panelists access the panel website using their unique 8-digit identification code. They are required to create a unique password to access their Web surveys, and in the event of a break-off, to resume surveys at a later date. At their initial log in, panelists are also required to select and answer one of 5 security questions that is used in the event the panel member requests a password reset during the course of the panel period. Responses entered through the Web-based survey are encrypted as the responses are on the panel website with an SSL certificate applied. Like the mobile instrument survey data, the Web survey data reside on secure contractor servers on SQL Server databases. Only authorized project staff have access.

The type of Web browser and operating system used by a panel member cannot be used to identify an individual. Panel member access to the Web survey system requires a unique panel member identifier and password, as noted above. In addition, the panel member is reassured that the researchers do not gather any other information aside from the survey answers and electronic information already described. The Web site does not place session cookies, persistent cookies, or any other type of tracking or monitoring software on panel members' computers, tablets, or smartphones to track or monitor. There is no tracking or monitoring of panel members' internet behavior in this information collection.

A.10.4 Privacy Procedures for Mail Survey Participants

The privacy of responses from mail survey participants is treated in the same manner as Web survey participants.

- Project staff take all necessary precautions to ensure the secure transport of study materials to participants and to ensure the secure transport, processing, and storage of participant data.
- All study materials, while in possession of the contractor, are assembled, processed, and stored at the contractor's ROC, a controlled-access facility equipped to support sensitive, large-scale mail survey efforts. Access to the building is by keyless card-controlled entry.

- All staff who come in contact with private project materials have signed privacy pledges and have been trained on all project security procedures.
- Electronic files containing sensitive data created in the process of preparing printed materials for mailouts (e.g., mail-merge data files, print files) are deleted by staff as soon as all associated mailings or printings have been completed.
- Any printed sensitive materials not used, such as test printouts or batches of materials with printing problems for which reprinting is required, are securely shredded immediately.
- Mailings for mail survey participants are assembled by project staff that have signed privacy pledges.
- After participants complete a mail survey, they return the completed form, identified only by the Case ID, to the contractor in a standard Business Reply Envelope. All returned mailings and forms received by the contractor are sent directly to the Survey Support Department (SSD) at the ROC and stored in a secure area at all times. The SSD area is locked at all times. A supervisor is present at all times when work is being performed in the SSD area. At SSD, a Document Control Clerk is assigned the responsibility of processing, filing, and maintaining all project materials. Incoming materials are stored in a locked file cabinet after processing and then shredded at the end of the project.
- After receipt by the contractor, completed mail survey forms are scanned using Teleform. Panel member names are not printed on paper survey forms; instead, forms are labeled with the panelist's study ID.
- Re-consent forms (if implemented) for mail mode panelists are not returned to the contractor with completed survey forms.
- Completed mail survey forms are security shredded at the end of the project, following data delivery to FDA.

A.10.5 Privacy Concerns for Participants Using Loaned Tablet Computers

The privacy of responses from panel members using the loaned tablet computer is treated in the same manner as Web survey participants. In addition:

- The Web-enabled tablet computer loaned to a subset of panel members is provided as a tool for accessing the panel website to participate in panel surveys online. No survey data are collected or stored locally on the device. Additionally, the device is not used to track the panel member's location or to collect data from the device about non-study usage.
- Panel members receive detailed written instructions by mail for the packaging and return of loaned tablets to the contractor when their panel participation ends. This includes shipping boxes and overnight postage-paid shipping labels.

- Upon return, loaned devices are inventoried and receipted, wiped clean of any data that might have been stored on them, and restored to their factory settings. Panel members are reassured that no attempts are made to gather any other information from the device aside from the survey answers and electronic information already described.

A.11 Justification for Sensitive Questions

The panel field screener and enrollment surveys contain items about current employment status and basic demographic information including age, gender, birth month and year, race/ethnicity, educational attainment, and marital status. Federal regulations governing the administration of these questions, which might be viewed as sensitive due to personal or private information, require (a) clear documentation of the need for such information as it relates to the primary purpose of the study, (b) provisions to respondents that clearly inform them of the voluntary nature of participation in the study, and (c) assurances that responses may be used only for statistical purposes, except as required by law (20 U.S.C. § 9573).

The collection of data related to current employment status and basic demographic information is essential for subsequent analyses, which includes examination of demographic characteristics of survey nonrespondents and panel members who leave the study over time. These data are used to accurately characterize and/or subset panel members for inclusion in the experimental and observational studies, and for descriptive and other analyses described in ***Section A.16.***

Respondents are advised of the voluntary nature of participation and their right to refuse to answer any question during the informed consent process.

A.12 Estimates of Annualized Burden Hours and Costs

A.12.1 Annualized Hour Burden Estimate

Exhibit A.12-1 contains the estimated interview times for each member of the panel. Burden was estimated using data from timed-readings of each instrument, including the mail and field screeners, enrollment survey, baseline survey, and Study B and C questionnaires. To compute the total estimated annual cost, the total burden hours were multiplied by the average hourly wage for each adult participant, according to the Bureau of Labor Statistics, Current Employment Statistics Survey, 2011. Estimates are presented in ***Exhibit A.12-2***.

Exhibit A.12-1. Estimated Annual Reporting Burden

Activity/Respondent	Number Of Respondents	Number Of Responses Per Respondent*	Total Annual Responses+	Avg. Burden Hours Per Response**	Total Hours+
Study B	4,000	.33	1,320	.33	436
Study C		.33	1,320	.33	436
Panel Replenishment Household Screening Respondent[1]	38,280	.33	12,632	.13	1,642
Panel Replenishment Enrollment Survey[2]	5,000	.33	1,650	.25	413
Panel Replenishment Baseline Survey[2]		.33	1,650	.25	413
TOTAL	51,280				3,340

* Assumes respondents will participate once over a 3-year period, or .33 responses annually.
** Reflects estimated average burden hours per response from currently approved clearance request. The actual average hours per response from panel establishment are: .15 for household screening, .30 for enrollment survey, and .10 for baseline survey.

+ Amounts are rounded to the nearest whole number.

[1] Includes both mail and field screening. Of the total screening respondents, we expect 25% will respond only in the mail screening (household deemed ineligible), 65% will respond only in the field screening (mail screening nonrespondents), and the remaining 10% will respond in both the mail screening and the field screening. The latter includes eligible households from the mail screening that are subsequently field-screened to sample the panel member, and the 10% quality control sample of households whose mail screening ineligibility is verified through in-person screening. Assumes an estimated 11,385 household screening respondents during yearly panel replenishment and allows for an additional 1,375 household screening respondents during each replenishment should annual attrition rates be higher than expected (38,280 total).
[2] Assumes 1,400 additional panel members will be recruited annually (4,200 total) as part of the panel replenishment effort. Allows for an additional 800 panel replenishment enrollment and baseline survey respondents should annual attrition rates be higher than expected (5,000 total).Replenishment panel members replace original panel members and become part of the 4,000-member panel that receives experimental/observational and panel maintenance surveys.

A.12.2 Annualized Cost Burden Estimate

Exhibit A.12-2. Estimated Annualized Response Burden for Panel Members

Activity/Respondent	Avg. Annual Burden Hours+	Hourly Wage Rate	Total Respondent Costs
Study B	436	$22.88	$9,975.68
Study C	436	$22.88	$9,975.68
Panel Replenishment Household Screening Respondent[1]	1,642	$22.88	$37,568.96
Panel Replenishment Enrollment Survey[3]	413	$22.88	$9,449.44
Panel Replenishment Baseline Survey[3]	413	$22.88	$9,449.44
TOTAL	3,340	$22.88	76,419.20

+ Amounts are rounded to the nearest whole number.

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital or operating and maintenance costs associated with this collection. There are no direct monetary costs to individual participants other than their time to participate in the study.

A.14 Annualized Cost to the Federal Government

The estimated annual cost to the government for each year of the panel maintenance contract is $3,265,966.80. This figure is based on a total cost to the Federal government for maintaining and replenishing the panel under the terms of the 3-year, $9,797,900.40 contract to RTI International and their subcontractors. These costs include design and implementation of the panel replenishment samples over the 3-year period, screening and recruitment of additional panel members annually as part of the panel replenishment effort, tracing and prompting of study nonrespondents, data processing and analysis, and preparation of reports and data files. Panel member incentive costs associated with panel replenishment are included in this estimate.

A.15 Explanation for Program Changes or Adjustments

FDA is requesting an extension on the currently approved information collection request for remaining planned studies, panel maintenance and replenishment activities and non-

substantive changes to update the estimated burden for an additional year of panel replenishment. The average annual burden hours will decrease by 1,095 hours, from 4,435 to 3,340 hours.

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

A.16.1 Study Schedule

Exhibit A.16-1 provides a schedule of the major activities for the panel project. A 3-year extension of the currently approved information collection is requested given the long-term nature of the Panel and the plan to enroll replenishment panel members for a 3-year period.

A.16.2 Analysis, Publication and Reporting Plans

The key findings of the TCS panel experimental and observational studies will be summarized in presentations and/or written reports and disseminated to target audiences within the public health community (including researchers and policymakers) within approximately one year after the completion of data collection. As described in Section A.2.3, Study A focused on purchasing behavior, tobacco brands, and the use of coupons and price promotions for tobacco products. Data collection for Study A was completed in June 2018, and data analysis was completed in September 2018. The analysis and reporting of the key findings of Study A consists of descriptive and bivariate analyses to describe participants' tobacco product brand preferences by demographic characteristics and to identify factors associated with brand loyalty for tobacco products.

In Study B, the focus of this evaluation study, and the analysis, will be on describing the receipt and use of free samples of tobacco products after the prohibition of free samples of tobacco products (with the adults-only exception for smokeless tobacco) that became effective with the Deeming Rule. The intervention or "independent variable" is the free sample prohibition itself. Therefore, descriptive and bivariate analyses will be used to assess the prevalence of coupon and free sample receipt and use as well as details surrounding the receipt and use context, e.g. demographics, product type/brands, locations, etc. Further analyses using inferential statistical methods, as feasible and appropriate, may explore the relationships of free samples and coupons receipt with use behaviors, quit intentions, and harm perceptions. For the qualitative questions, we will assess the quality of the responses utilizing a team of at least two coders to independently code each response and come to agreements where there is disagreement on responses.

In Study C, bivariate and multivariate analyses will examine the association between stimulus exposure to the hypothetical product standard and tobacco product use intentions and tobacco product harm perceptions. Sub-group analyses will be conducted with exclusive cigarette, smokeless tobacco, and cigars, as well as among respondents with any dual use. A sub-group analysis among respondents whose dual use includes the product they were exposed to in the stimuli will also be considered.

When communicating or publishing research outcomes associated with this clearance, CTP will present: a) the unweighted distribution of sociodemographic and geographic characteristics of the sample that responded to a given survey, and b) study results based on both weighted and unweighted data. CTP will assess the quality of the information generated by collections conducted under this clearance for each regulatory or policy purpose under consideration.

Analysis, Publication and Reporting Plans for each subsequent observational or experimental study will be described in the information collection request for that study.

Exhibit A.16-1. Panel Project Schedule

Activity	Time frame	
	Start date	**End date**
Select address sample for panel implementation	June 2016	July 2016
Recruit and train field staff for panel implementation	August 2016	January 2017
Conduct field enumeration activities in selected areas	November 2016	December 2016
Recruit and enroll initial cohort of panel members	September 2016	August 2017
Conduct nonresponse follow-up and troubleshooting (flow basis)	October 2016	End of Panel
Provide reports of panel recruitment and maintenance activities (flow basis, during active recruiting phases)	October 2016	End of Panel
Conduct Study A, first experimental or observational study	April 2018	June 2018
Conduct panel replenishment (as needed)	April 2018	End of Panel
Conduct analysis and reporting of Study A findings	July 2018	September 2018
Conduct Studies B and C and reporting of findings	March 2020	September 2020

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

The OMB number and expiration date is displayed on the survey website where questionnaires are launched, all mail survey instruments, and on the consent forms.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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APPENDIX A. DEMOGRAPHIC PROFILE OF ESTABLISHED PANEL

Characteristic[a]	N	Percentage
Total Enrolled in Panel[b]	3,893	100.0%
Age		
18–25	883	22.7%
26–34	724	18.6%
35–49	1,002	25.7%
50–74	1,200	30.8%
75 or older	84	2.2%
Race		
White	2,682	68.9%
Black or African American	790	20.3%
American Indian/Alaska Native	81	2.1%
Asian	34	0.9%
Native Hawaiian, Other Pacific Islander	6	0,2%
More than one race selected	156	4.0%
Missing	144	3.7%
Ethnicity		
Hispanic or Latino	453	11.6%
Not Hispanic or Latino	3.428	88.1%
Missing	12	0.3%
Gender		
Male	2,341	60.1%
Female	1,551	39.8%
Missing	1	0.0%
Education		
Less than high school	644	16.5%
High school/GED	1,524	39.1%
Some college/voc tech	856	22.0%
2-year college degree	420	10.8%
4-year college degree	448	11.5%
Missing	1	0.0%

(continued)

APPENDIX A. DEMOGRAPHIC PROFILE OF ESTABLISHED PANEL (CONTINUED)

Characteristic[a]	N	Percentage
Household Income		
Less than $30,000	1,727	44.4%
$30,000 to $49,999	901	23.1%
$50,000 to $74,999	486	12.5%
$75,000 to $99,999	269	6.9%
$100,000 to $124,999	141	3.6%
$125,000 to $149,999	52	1.3%
$150,000 or more	97	2.5%
$30,000 or more (if other not available)	144	3.7%
Missing	76	2.0%
Tobacco Use for Enrollment[c]		
Cigarettes only	2,163	55.5%
Cigars only	303	7.8%
Smokeless tobacco only	428	11.0%
Two of the three tobacco products	852	21.9%
All three tobacco products	147	3.8%
Current Tobacco Use[d]		
Cigarettes	3,088	79.3%
Cigars	1,127	28.9%
Smokeless tobacco	824	21.2%
Poly use of cigarettes, cigars, and or smokeless	999	25.7%
E-cigarettes	544	14.0%
Pipe	188	4.8%
Water pipe or hookah	306	7.9%
Other tobacco products	159	4.1%
Panel Participation Mode		
Web, using personal device	3,342	85.8%
Mail mode	546	14.0%
Web, using study-provided tablet	5	0.1%
Enrollment Language		
English	3,789	97.3%
Spanish	104	2.7%

[a] Missing includes Don't Know, Refused, and Not Available categories.
[b] Includes one panel member from the national implementation phase who passed away after enrollment.
[c] Indicates current use of the tobacco products that determined panel eligibility.
[d] Count of panel members who reported using these products at enrollment. Does not sum to number of panel members because of poly use.

APPENDIX B. DEMOGRAPHIC PROFILE OF STUDY A RESPONDENTS

Characteristic[a]	N	Percentage
Total Study A Respondents	1,626	100.0%
Age		
18–25	292	18.0%
26–34	275	16.9%
35–49	430	26.4%
50–74	591	36.3%
75 or older	38	2.3%
Race		
White	1,159	71.3%
Black or African American	295	18.1%
American Indian/Alaska Native	32	2.0%
Asian	12	0.7%
Native Hawaiian, Other Pacific Islander	2	0.1%
More than one race selected	61	3.8%
Missing	65	4.0%
Ethnicity		
Hispanic or Latino	161	9.9%
Not Hispanic or Latino	1,464	90.0%
Missing	1	0.1%
Gender		
Male	877	53.9%
Female	748	46.0%
Missing	1	0.1%
Education		
Less than high school	197	12.1%
High school/GED	589	36.2%
Some college/voc tech	402	24.7%
2-year college degree	190	11.7%
4-year college degree	248	15.3%
Missing	0	0.0%

(continued)

APPENDIX B. DEMOGRAPHIC PROFILE OF STUDY A RESPONDENTS (CONTINUED)

Characteristic[a]	N	Percentage
Household Income		
Less than $30,000	699	43.0%
$30,000 to $49,999	356	21.9%
$50,000 to $74,999	216	13.3%
$75,000 to $99,999	132	8.1%
$100,000 to $124,999	69	4.2%
$125,000 to $149,999	28	1.7%
$150,000 or more	44	2.7%
$30,000 or more (if other not available)	53	3.3%
Missing	29	1.8%
Tobacco Use for Enrollment[b]		
Cigarettes only	959	59.0%
Cigars only	133	8.2%
Smokeless tobacco only	181	11.1%
Two of the three tobacco products	297	18.3%
All three tobacco products	56	3.4%
Panel Participation Mode		
Web, using personal device	1,312	80.7%
Mail mode	309	19.0%
Web, using study-provided tablet	5	0.3%
Enrollment Language		
English	1,606	98.8%
Spanish	20	1.2%

[a] Missing includes Don't Know, Refused, and Not Available categories.
[b] Indicates current use of the tobacco products that determined panel eligibility.