U.S. Food and Drug Administration
Experimental Study on Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products and Tobacco Smoke

OMB Control Number 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Tobacco Control Act (Pub. L. 111-31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 904(e) of the FD&C Act requires FDA to establish, and periodically revise as appropriate, "a list of harmful and potentially harmful constituents (HPHCs), including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand." Section 904(d)(1) of the Act further requires that the list be published in a format that is understandable and not misleading to laypersons.

The study proposed here is an effort by FDA to collect data on the public's comprehension and perception of misleadingness of informational displays of Harmful and Potentially Harmful Constituents (HPHCs). HPHCs are chemicals or chemical compounds in a tobacco product or tobacco smoke that cause, or could cause, harm. Examples of HPHCs include toxicants, carcinogens, and addictive chemicals and chemical compounds. FDA's Center for Tobacco Products (CTP) seeks data on how the public comprehends and responds to displays of HPHC information to inform an appropriate set of displays that are understandable and not misleading to laypersons. The results from the proposed study will inform the Agency's broader efforts to finalize the development of informational displays of HPHCs to be tested in future studies and ultimately to implement the informational HPHC display as required by section 904 of the Tobacco Control Act.

2. Purpose and Use of the Information Collection

Section 904(d)(1) of the Tobacco Control Act states "the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful and potentially harmful constituents] established under subsection (e)." Information obtained through this quantitative study will inform the best way to convey HPHC information that is understandable and not misleading to a layperson. Participants will be asked to answer questions regarding their comprehension and perception of misleadingness of different displays of presenting HPHC information. The purpose of the current study is to test the effectiveness of sample formats to ensure they meet the statutory requirements to communicate HPHC information. Results will be used to inform strategies to effectively communicate about HPHC information that is understandable and not misleading to a layperson.

FDA has undertaken a rigorous science-based research approach to help with the development of the sample formats to ensure that the content of the formats is based on accurate and reliable science. In the past, FDA conducted preliminary research including focus groups and an experimental study that tested a format of a list of HPHCs in tobacco. This research found significant gaps in consumer understanding of tobacco constituents and their health effects. Further, it was concluded that the formats tested did not present HPHC information in a manner that was understandable and not misleading as required by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

Below we summarize additional work that informed this proposed study.

- FDA used data from the past HPHC research to launch new research specifically designed to gain insight on gaps identified in the first phase. FDA conducted in-depth interview research: *Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products* (OMB Control Number 0910-0796, approved by OMB on December 12, 2016). This set of 54 in-depth interviews was conducted with adult cigarette users, adult smokeless tobacco users, adult former cigarette or smokeless tobacco users, youth cigarette and/or smokeless tobacco users, or youth who are susceptible to using tobacco products. The goal was to gain a better understanding of the best way to convey HPHC information that is understandable and not misleading to a layperson. Feedback from those interviews were used to create the sample formats that will be tested in the current study [1].
- Additionally, to inform the design of the current study, FDA funded four administrative supplements to existing grants. The administrative supplements included research to define and operationalize what constitutes public display of HPHC information by brand and by quantity in each brand and subbrand in a format that is "understandable and not misleading" to a lay person. The supplements also included the design of a format by which to put on public display information by brand and by quantity in each brand and subbrand, to increase the likelihood that when such information is put on public display is understandable and not misleading to lay persons. FDA also consulted with experts who were special government employees to inform areas of research to support implementation of section 904 of the Tobacco Control Act. Recommendations from these experts informed the operationalization of “understandable and not misleading” to a layperson.

FDA proposes to conduct this experimental study to explore consumer comprehension and perceptions of misleadingness of displays of HPHC information. In the study, data collection will consist of a one-time, web-based survey of youth and adult participants from an online consumer panel. The survey will be randomized to one of six conditions. In all conditions, participants will respond to a set of questions about their current tobacco use and prior knowledge and perceptions about HPHCs. Then, in all conditions, participants will view one of six formats. While viewing the format, participants will respond to a set of questions about their knowledge and understanding about HPHCs and perceptions of the format. These formats also include information about the known health effects associated with each constituent in concordance with the established list of the HPHCs in Tobacco Products and Tobacco Smoke published in the Federal Register on April 3, 2012.

Survey questions will be designed to answer the following research questions:

- After viewing the sample format, what do adults and youth know about HPHCs in tobacco products?
- After viewing the sample format, what do adults and youth perceive about HPHCs in tobacco products?
- After viewing the sample format, what formats do adults and youth prefer when receiving information regarding HPHCs?
- After viewing the sample format, is the information presented misleading?
- Are participants able to understand the information presented about HPHCs?

3. Use of Improved Information Technology and Burden Reduction

Because this is a web-based study, 100% of the respondents will submit the information in an electronic format. Respondents will be shown a sample HPHC format and respond to questions using a web-based survey on their personal computers. Web-based surveys reduce respondent burden, minimize possible administration errors, and expedite the timeliness of data processing. Furthermore, web-based surveys are less intrusive and less costly compared with face-to-face interviews and mail and telephone surveys. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative collection of this information. No comparable data have been collected by any other entities. Earlier HPHC research found significant gaps between consumer understanding of tobacco constituents and their health effects. Further, it was concluded that the formats tested did not present HPHC information in a manner that was understandable and not misleading as required by the Tobacco Control Act. In-depth interviews were then conducted to better understand gaps in consumer comprehension that were discovered in the initial research, and FDA consulted with experts to operationalize the concept of "understandable and not misleading" to a layperson in HPHC research. This proposed information collection is to study how the public comprehends and responds to displays of HPHC information. While informed by the earlier research, this study does not duplicate it. In addition, we have reviewed the existing data sets and determined that they are not sufficiently similar or cannot be modified to address FDA's need for information on consumer comprehension of displays of HPHC information.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection of information.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. The collection of information will provide important data needed for FDA to implement the mandatory publicly available list of HPHCs required by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

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

This information collection fully complies with 5 CFR 1320.5(d)(2). No special circumstances are associated with this information collection that would be inconsistent with the regulation.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of February 11, 2019 (84 FR 3188). FDA received comments from six individuals or organizations, 3 of which were PRA related.

(Comment) One comment recommended that FDA make the study design, sample formats, and all study measures available for public comment.

(Response) FDA notes that the study protocol, list formats, and the survey questionnaire are available for review upon request and are described in detail as part of the overall information collection request submitted to OMB for review.

(Comment) One comment suggested that FDA add a control group that does not view a sample format to our study design.

(Response) FDA considered the utility of adding a no-exposure control group to this study. However, FDA determined that this is not in line with the study aims. The aims of the study are derived from section 904(e) of The Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 387d(e)) which requires FDA to publish a list of harmful and potentially harmful constituents (HPHCs) in each brand and sub-brand of tobacco product, in a way that people find understandable and not misleading. Therefore, the proposed study will test different formats of HPHC lists to meet this statutory requirement. A condition in which people do not see a list of HPHCs in a tobacco product does not approximate real-life conditions.

(Comment) One comment suggested that FDA should clarify whether the HPHC sample formats will include smokeless brands since items in the draft survey are exclusive to cigarettes. The comment also noted that FDA should clarify whether smokeless tobacco and exclusive cigarette users will only view HPHC lists in their respective categories.

(Response) HPHC sample formats will not include smokeless brands because HPHC lists for cigarettes are the focus of the proposed study. All participants will view HPHC lists for cigarettes only to allow for a parsimonious and focused design that is adequately powered to detect effects.

(Comment) One comment suggested that FDA should use validated survey measures, establish the validity of other metrics prior to use, and consider using validated risk perception metrics.

(Response) FDA agrees that validated items should be used whenever possible. FDA engaged in a multi-step process to select validated survey items for this study. First, FDA conducted a literature review and used available validated survey measures, including measures from past HPHC research (e.g., Byron et al., 2018). However, for some outcomes (e.g., knowledge about the tested format), validated measures do not exist because questions are

specific to the stimuli. Second, FDA conducted qualitative research to inform our measures. Based on insights uncovered during this research, we created and modified survey items. Third, FDA conducted cognitive testing to refine the measures. It should be noted that there are many ways to measure these constructs, including harm perceptions. The harm perceptions items that FDA used are based on a systematic review that identified the most commonly measured tobacco-related health consequences in the literature (O'Brien, Persoskie, & Tam, 2019).

(Comment) One comment suggested that FDA should get end-user input into the development and refinement of the survey items. The comment suggested that survey items should be subject to cognitive testing, with individuals representing end-users until the point of saturation is reached.

(Response) FDA agrees that it is important to test a survey before collecting responses. As part of the research program, FDA conducted 54 in-depth interviews, "Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products" (OMB # 0910-0796), as a first step to develop items. Based on the findings from that study and a literature review to uncover validated measures, FDA developed a draft survey. Next, FDA cognitively tested the draft survey and stimuli and refined each by reducing redundant content and editing any confusing items. FDA reached saturation in both qualitative studies.

(Comment) One comment suggested that including a mid-point on some of the scales (e.g. "neutral" and "neither agree nor disagree") may be difficult for some respondents to understand. The comment suggested that FDA incorporate a "don't know" response option for some items including the HPHC general knowledge questions.

(Response). The inclusion of a "don't know" response on the knowledge items was made in order to best match the source of those items (Brewer et al., 2016; Byron et al., 2018). That is, FDA included a "don't know" option when the source item did so.

Although it is true that individuals interpret middle options like "neutral" in different ways, these personal interpretations should be randomly distributed across condition and thus not affect the comparisons among the stimuli (Nadler, Weston, & Voyles, 2015).

(Comment) One comment recommended that FDA ask several of the post-test items (e.g. items 33, 34, 38) during the pre-test so that we can obtain a baseline estimate of misperceptions and determine whether there was any change in respondents' incorrect beliefs following exposure to the stimulus.

(Response) The primary purpose of this study is to test formats to see if they are understandable and not misleading. This can be achieved by comparing post-test measures of understanding and misleading across conditions and does not require a pre-test. Further, as these items are part of a validated scale if FDA selects only a few items to ask in the pre-test, this may lead to data that is not reliable or valid. As these items are part of a larger scale that has been used and tested in previous research, only selecting a few questions may alter how participants respond to these and other questions in the survey. Also, these items have not been tested to be used alone.

(Comment) One comment suggested that FDA add an attention check and measures of believability, truthfulness, or skepticism to provide additional context for the study results.

(Response) The knowledge items in the survey are inherently an attention check because the participant can use the information in the stimulus to answer questions. Adding an attention check will not provide any additional benefit. Adding additional measures about believability, truthfulness or skepticism are outside of the scope and purpose of this study.

(Comment) One comment suggested that FDA oversample vulnerable populations including youth, minorities and those with low levels of education in our survey. An additional comment commended FDA for including youth aged 13 to 17 in this study as it is critically important because most tobacco consumers begin using tobacco before the age of 18. Further, including youth in the sample underscores FDA's recognition that it is possible to survey youth about the comprehension of information about tobacco without violating ethical standards.

(Response) FDA agrees about the need to survey youth, minorities, and those with low levels of education.

This study will use a convenience sample because generating a representative sample of the size necessary for this study (using random digital dialing or another similar method) would be cost prohibitive. In order to ensure that the convenience sample includes sufficient representation of vulnerable populations, we have established quotas in the recruitment so that the sample is comprised of at least 20% of low socioeconomic participants (income of less than $25,000 year) and at least 20% of adults without a high school diploma or GED. These proportions are not exclusive because low education and low socioeconomic status are strongly correlated. Further, the study sample will include approximately 1500 adolescent tobacco users and adolescents at risk for using tobacco (ages 13 to 17).

(Comment) One comment suggested that FDA collect demographic information pertaining to race/ethnicity, age, and education level.

(Response) FDA agrees. We already plan to collect this demographic information as part of the screening procedures. These data will be used to describe the make-up of the sample and to check that participants were successfully randomized to experimental condition. FDA can also conduct subgroup analyses, such as examining whether participant understanding of HPHC information is similar across education levels.

(Comment) One comment suggested that FDA ask participants where they would look for information about tobacco constituents.

(Response) FDA appreciates the suggestion. As previously mentioned in our comment responses FDA conducted 54 in-depth interviews where this was assessed. There is also an item on the survey that asks, "Where would you most like to see information on chemicals in cigarettes and cigarette smoke?" The response options are "on cigarette packs," "in stores," and "online." Between this item and the in-depth interviews FDA conducted, this will provide FDA with adequate information on where participants would look for information about tobacco constituents.

(Comment) One comment suggested that FDA add "to the best of your knowledge" at the beginning of questions 6 through 10.

(Response) FDA does not believe this is necessary as these questions include a "don't know" response option. Further, these questions were used in previous research (Byron et al., 2018).

(Comment) There were a few comments about the "understanding" section of the survey. One comment suggested that FDA add nicotine, acetone, and carbon monoxide to this section. Another comment suggested that FDA expand the "Understanding" section to include a section on addiction. The comment suggested that the section list specific constituents and ask participants if they cause addiction. One comment suggested that FDA modify the question that asks, "does smoking cause addiction" and change it to "does smoking cigarettes cause addiction."

(Response) FDA appreciates these suggestions. FDA declines to add additional items or modify items in the "understanding" section as it is consistent with prior research. Further, these items were part of cognitive testing and did not cause confusion. Prior research deliberately selected two chemicals that would be familiar to respondents (ammonia and lead) and three that would be unfamiliar (1-aminonaphthalene, acrylonitrile, and isoprene) (Byron et al., 2018). Further, even though there is not a specific question about the link between certain chemicals and addiction, FDA assesses participants' understanding of whether smoking causes addiction in items 11-24.

(Comment) There were two comments that asked FDA to add additional items measuring participants behavior. One comment suggested that FDA should add additional questions so that the survey could also determine how likely someone is to not only switch brands but also whether they are likely to quit or switch to a different product. Another comment suggested that FDA add questions to the post-test to measure the behavioral impacts of these formats including cessation intentions.

(Response) Although measuring these behavioral intentions and outcomes are interesting, these questions are outside the scope of this study. The focus of this study is to assess whether displays of HPHC information are understandable and not misleading per the statutory requirement.

(Comment) FDA received two comments that supported the collection of this information. One comment urged FDA to move forward promptly with this study.

(Response) FDA appreciates this comment and intends to move forward with the study promptly. We note that data collection will occur within two months following OMB approval.

(Comment) One comment noted that FDA was required to publish a list of constituents in a format that is understandable and not misleading to a lay person by June 2012. However, no such list has been published. The comment also noted that it is important for the FDA to ensure that information is disclosed in a way that is not misleading.

(Response) FDA agrees that the proposed study is important to help FDA fulfill its statutory requirement. FDA has undertaken an extensive program of research to ensure that we not only publish a list of constituents in a manner that is understandable and not misleading, but also avoid any unintended consequences of such a list.

(Comment) One comment noted that FDA should make it clear that characterizations of information on the list by tobacco product manufacturers in advertising or promotional material are subject to the requirements of the provisions of Section 911 of the Tobacco Control Act regarding modified risk claims.

(Response) Thank you for this suggestion. However, this comment is outside the scope of the present study as it is about the implementation of the public displays of HPHCs and not about testing the display.

9. Explanation of Any Payment or Gift to Respondents

HPHC survey respondents will be members of Lightspeed's (formerly GMI) web-based research panel. Lightspeed will provide 100 nonmonetary "LifePoints" valued at approximately $1.25 to panel members who complete the study. LifePoints are a routine part of Lightspeed's panel maintenance strategy and can be accrued and traded for material items with Lightspeed partner vendors (e.g., Amazon.com, Starbucks) or for cash. Panel members customarily receive LifePoints for each survey completed in recognition of time spent and to encourage cooperation in future panel surveys.

Among young adults (aged 18 to 24), 19.6% report current cigarette smoking, among older adults (aged 25 or older) 17.9% report current smoking. Among youth, the numbers are substantially lower, among 12- to 17-year-olds, 4.6% report past 30-day smoking[1] and 28.6% are susceptible to smoking.[2] Recruiting adolescent smokers may be more difficult because use of tobacco is illegal in a few states for those under 18 and sales to adolescents under age 18 is illegal in nearly every state. Previous research has shown that recruiting and retaining adolescents into studies about tobacco is challenging.[3]

10. Assurance of Confidentiality Provided to Respondents

Concern for privacy and protection of respondents' rights will play a central role in the study implementation, storage and handling of data, and data analysis and reporting. The Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection, as well as FDA's IRB, the Research Involving Human Subjects Committee (RIHSC), will review and approve the protocols for the surveys before any data collection. The primary concern of both IRBs is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

Information provided by respondents will be maintained in a secure manner and will be used only for the purpose of this research. Private information is protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the Agency's regulations (21 CFR part 20). CTP consulted with FDA's Privacy office, which conducted a Privacy Threshold Analysis, and concluded that the Privacy Act does not apply to this information collection. The collection was assigned PIA unique identifier (P-3042816-919564)

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[1] Kasza KA et al. (2017). Tobacco-product use by adults and youths in the United States in 2013 and 2014. N England J Med. 376(4), 342-53.

[2] Trinidad DR et al. (2017). Susceptibility to tobacco product use among youth in Wave 1 of the Population Assessment of Tobacco and Health (PATH) study. Prev Med. 101, 8-14.

[3] Diviak KR et al. (2006). Recruitment and retention of adolescents in a smoking trajectory study: Who participates and lessons learned. Subst Use Misuse. 41, 175-182; McCormick LK et al. (1999). Recruiting adolescents into qualitative tobacco research studies: experiences and lessons learned. J Sch Health. 69, 95-99.

As part of the informed consent/assent process, participants will be provided with an assurance of privacy to the extent allowable by law and the technology used. Privacy for survey respondents will be ensured in a number of ways:

- The survey will not include any personally identifying information (PII), nor will any PII be requested. Though Lightspeed, the organization that manages the web-based research panel, maintains a database of names and email addresses of potential participants as part of its normal operations, neither FDA nor RTI will receive this information or any other PII from Lightspeed. Each respondent will be known to FDA and RTI only by a unique alphanumeric variable provided by Lightspeed.
- Lightspeed will contact panel members directly and ask them to complete the survey through an email invitation.
- Lightspeed will invite adolescent children of adult panel participants to complete the survey through an email invitation to their parent or guardian asking for their consent to have their child's opinions, which is fully compliant with the Children's Online Privacy Protection Act's revised standards. If consent is provided, parents will be asked to allow their child to complete the screener and survey in private, so they cannot see the responses. Youth participants will also be informed that their answers will not be shared with their parents.
- All respondents will log onto Lightspeed's secure server using a link provided by Lightspeed to complete the screener and survey.
- The information obtained from all the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.
- The online survey is self-administered, and respondents will participate on a voluntary basis. All respondents will have the option to decline to respond to any item in the survey for any reason. The voluntary nature of the information collection is described in the consent/assent forms.

Implementation of data security systems and processes will occur as part of the survey data collection. Data security provisions involve the following:

- All RTI project staff are required to adhere to strict standards and to sign a nondisclosure agreement as a condition of employment on this project. RTI maintains restricted access to all data preparation areas (i.e., receipt, coding). All data files on multiuser systems are under the control of a database manager, with access limited to project staff on a "need-to-know" basis only.
- All data are secured on Lightspeed's database servers that reside only on private, backend servers that are behind layered firewall architecture. Data are never stored on a public network or outside the data tier. Relational database management systems (RDBMS) access is strictly controlled and limited to only a few authorized users whose access is limited to the minimum necessary to accomplish administrative tasks. Web and application servers communicate with the RDBMS only via a private network segment with a multilayer firewall architecture in place. Access control is provided to secure data directories. All client-specific data are stored in restricted-access data directories controlled by access control lists.

- All data transmission will be encrypted because the responses will be on a web site with an SSL certificate applied. Data will be passed through a firewall at RTI and then collected and stored on a protected network share on the RTI network. Only authorized RTI project staff members will have access to the data on the secure network.

11. Justification for Sensitive Questions

Most questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered of a sensitive nature in order to assess specific health behaviors, such as tobacco use and knowledge about the potential negative health consequences of tobacco products and tobacco smoke. Asking such questions is critical to the objectives to this information collection, namely to determine a format that promotes greater public understanding of HPHCs in tobacco products.

Assessing tobacco use is important to understand how presentations of HPHCs in tobacco products work among different populations of those for whom the information may be most relevant, namely, adult smokers, youth smokers, and youth who are susceptible to initiating smoking. Some questions about tobacco use are potentially sensitive because tobacco use among adolescents under age 18 is illegal in a few states, and sales to adolescents under age 18 are illegal in nearly every state (and under 21 in some jurisdictions). These questions are essential to the objectives of this information collection. Questions concerning lifestyle (e.g., smoking behavior, tobacco use) and demographic information, such as race and ethnicity, could be considered sensitive but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise respondents that these topics will be covered during the survey. This study includes several procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with a specific toll-free phone number for the RTI Office of Research Protection to contact in case they have a question or concern about the sensitive issue.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

Information will be collected through self-administered, online screeners and surveys of youth aged 13 to 17 and adults 18 or older. Approximately 5,200 respondents will complete a screener to determine eligibility for participation in the study, estimated to take approximately 3 minutes per response, for a total of 260 hours for screening activities. We estimate that 4,500 respondents will complete the survey at 20 minutes per response, for a total of 1,500 hours for completion of both adult and adolescent samples. This data collection will take place one time in

2020 Thus, the annualized response burden is estimated at 1,760 hours. Table 1 provides details about how this estimate was calculated.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Youth—Screener	1,800	1	1,800	0.05	90
Youth—Survey	1,500	1	1,500	0.33	500
Total Youth Hours					***590***
Adult—Screener	3,400	1	3,400	0.05	170
Adult—Survey	3,000	1	3,000	0.33	1,000
Total Adult Hours					***1,170***
Total Burden Hours					**1,760**

12b. ***Annualized Cost Burden Estimate***

The estimated value of respondents' time for participating in the information collection is $30,287. This value was calculated by multiplying the burden hours for adults (18+) and youth (13 to 17) by the 2015 mean hourly wage as reported by the U.S. Department of Labor, Bureau of Labor Statistics ($22.23) and the federal hourly minimum wage ($7.25), respectively. The annualized cost burden estimate is summarized in Table 2.

Table 2. Estimated Annualized Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Total Youth (13–17)	590	$7.25	$4,278
Total Adults (18+)	1,170	$22.23	$26,009
Total	**1,760**		**$30,287**

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for this study is $208,998 as shown in Table 3. Contractor costs attributable to this information collection are $134,412. This includes costs to program the survey, draw the sample, and collect the data. Other contractor activities outside data collection include coordination with FDA to develop the instrument and deliver the final data set and methodology report.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	15%	$103,435	$15,515
GS-13	15%	$100,203	$15,030
GS-14	25%	$133,689	$33,422
GS-15	5%	$134,789	$6,739
Total Salary Costs			$70,706
Contractor Costs			$155, 917.60
Total			**$226,623.60**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from this information collection will be used to estimate awareness of HPHCs in tobacco in order to assess the best way to present HPHC information in a manner that is understandable and not misleading to a layperson. The project schedule is shown in Table 4. Future development and research activities are dependent on the timely completion of the present study.

Table 4. Project Schedule

Activity	Date
Data Collection	Within 2 months following OMB approval
Receive draft methodology report	Within 4 months following OMB approval
Receive final methodology report and survey data	Within 5 months following OMB approval

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

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection. The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

1. Alexander J, Williams P, Blitstein *J. Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products: Findings from Phase 1 Individual Interviews*. 2017.