**U.S Food and Drug Administration**
**Quantitative Study of Tobacco Facts Designed to Inform Youth Tobacco Prevention Messaging**

**OMB Control No. 0910-0810**

**Supporting Statement: Summary**

- The goal of this project is to measure youth's perceptions of various tobacco-related facts and the effectiveness of these facts among three target audiences: (1) multicultural youth aged 13–17 at risk for using or experimenting with cigarettes or have ever used cigars/cigarillos/little cigars, or hookah, who represent the target audience for CTP's *Fresh Empire* youth tobacco prevention campaign, (2) White males aged 13–17, living in rural areas and at risk for using or experimenting with smokeless tobacco, who represent the target audience for CTP's *The Real Cost Smokeless* campaign, and (3) AI/AN youth aged 13-17 at risk for using cigarettes or e-cigarettes, who represent the target audience for CTP's *American Indian/Alaska Native* tobacco prevention campaign.

- The study will be conducted using web-based surveys that are self-administered on personal computers and mobile devices. The study will use an online survey to target approximately 800 multicultural youth who are at risk for using or experimenting with cigarettes, or have ever used cigars/cigarillos/little cigars, or hookah, approximately 400 White male youth living in rural areas who are at risk for using smokeless tobacco or have experimented with smokeless tobacco, and approximately 400 AI/AN youth who are at risk for using cigarettes or e-cigarettes or have experimented with these products. The study will take approximately 20 minutes to complete per participant.

- Results of the survey will help CTP better understand youth receptivity to the tobacco-related facts and help refine tobacco messaging for existing tobacco prevention campaigns.

- **REQUESTED APPROVAL DATE: April 29, 2019**

**Study Materials (attached):**
***Fresh Empire***
C1: *Fresh Empire* Youth Assent Form (Survey)
C2: *Fresh Empire* Parent/Guardian Notification/Opt-Out Form (Survey)
C3: *Fresh Empire* Screener (Survey)
C4: *Fresh Empire* Recruitment Ads (Survey)
A5: *Fresh Empire* Survey Instrument
A6: Cigarette, Cigar, Hookah, and E-cigarette Facts

***The Real Cost: Smokeless***
D1: *The Real Cost: Smokeless* Youth Assent Form (Survey)
D2: *The Real Cost*: *Smokeless* Parent/Guardian Notification/Opt-Out Form (Survey)
D3: *The Real Cost*: *Smokeless* Screener (Survey)
D4: *The Real Cost: Smokeless* Recruitment Ads (Survey)
B5: *The Real Cost: Smokeless* Survey Instrument

B6: Smokeless Tobacco Facts
***AI/AN***
**Social Media Recruit**
E1: *AI/AN* Youth Assent Form (Social Media)
E2: *AI/AN* Parent/Guardian Notification/Opt-Out Form (Social Media)
E3: *AI/AN* Screener (Social Media)
E4: *AI/AN* Recruitment Ads (Social Media)
E5: *AI/AN* Survey
E6: *AI/AN* Cigarette and E-cigarette Facts

**Online Panel Recruit**
F1: *AI/AN* Email Invitation and Parental Permission Form (Online Panel)
F2: *AI/AN* Youth Assent Form (Online Panel)
F3: *AI/AN* Screener (Online Panel)
E5: *AI/AN* Survey
E6: *AI/AN* Cigarette and E-cigarette Facts

**Quantitative Study of Tobacco Facts Designed to Inform Youth Tobacco Prevention Messaging**
**0910-0810**
**Supporting Statement: Part A**

## A. JUSTIFICATION

### 1. Circumstances Making the Collection of Information Necessary

In support of FDA's efforts to refresh campaign messaging, the Center for Tobacco Products (CTP) will conduct a quantitative research study to inform the development of appropriate messaging for FDA's American Indian/Alaska Native (AI/AN), Fresh Empire, and The Real Cost (TRC) Smokeless campaigns. The goal of this project is to measure youth's perceptions of various tobacco-related facts and the effectiveness of these facts among three target audiences: (1) AI/AN youth aged 13-17 at risk for using or experimenting with cigarettes or e-cigarettes, (2) multicultural youth aged 13–17 who are influenced by the Hip Hop peer crowd and are at risk for using or experimenting with cigarettes, or have ever used cigars/cigarillos/little cigars, or hookah, and (3) White, Non-Hispanic males aged 13–17, living in rural areas and at risk for using or experimenting with smokeless tobacco. Multicultural includes races and ethnicities such as Hispanic/Latino, African American, Asian/Pacific Islander, or a mix of various races and ethnicities. Rurality is defined according to the U.S. Department of Agriculture's Rural–Urban Continuum (RUC) codes 5–9. RUC codes 5–9 are defined below:

- RUC 5: Nonmetro - Urban population of 20,000 or more, not adjacent to a metro area
- RUC 6: Nonmetro - Urban population of 2,500 to 19,999, adjacent to a metro area
- RUC 7: Nonmetro - Urban population of 2,500 to 19,999, not adjacent to a metro area
- RUC 8: Nonmetro - Completely rural or less than 2,500 urban population, adjacent to a metro area
- RUC 9: Nonmetro - Completely rural or less than 2,500 urban population, not adjacent to a metro area

The study will be conducted using web-based surveys that are self-administered on personal computers and mobile devices. The study will use an online survey to target up to 400 AI/AN youth who are at risk for using or experimenting with cigarettes or e-cigarettes, up to 800 multicultural youth who are at risk for using or experimenting with cigarettes, or have ever used cigars/cigarillos/little cigars, or hookah, and up to 400 White male youth living in rural areas who are at risk for using smokeless tobacco or have experimented with smokeless tobacco. The study will take approximately 20 minutes to complete per participant. This survey will ask participants to provide feedback on approximately 15 randomly selected facts and then answer questions about their knowledge, attitudes, and beliefs about these facts.

Under the 2009 Family Smoking Prevention and Tobacco Control Act, CTP is responsible for regulating the manufacturing, marketing, and distribution of tobacco products. CTP oversees several public health education campaigns aimed at preventing tobacco use among groups of youth and young people who have reported disproportionately high rates of tobacco use:

- The Real Cost: FDA's first national public education campaign targeting youth at-risk for tobacco use which has expanded to include reducing smokeless tobacco use among rural male youth and reducing e-cigarette use among youth;

- Fresh Empire: FDA's campaign that is targeted toward multicultural youth; and

- This Free Life: The campaign's target audience is lesbian, gay, bisexual, and transgender (LGBT) young adults.

Tobacco use is the leading cause of preventable disease and disability in the United States, responsible for at least 480,000 deaths per year (USDHHS, 2014). Each day, more than 3,200 youth smoke their first cigarette and each day, an estimated 2,100 youth and young adults who have experimented with cigarettes become daily cigarette smokers (USDHHS, 2014). Current use of e-cigarettes and hookah has increased among middle and high school students from 2011 to 2016, with approximately 11.3% of high school students reporting that they used electronic cigarettes in the past 30 days, and almost 5% of high school students reported that they used hookah within the past 30 days (CDC 2013, 2017a). A recent study indicates that among multicultural youth, approximately 23.4% are either experimenting with or at risk for cigarette use (Walker et al., 2018).

Additionally, smokeless tobacco use is two to three times higher in rural areas of the United States compared to metropolitan areas, with 4.6% of rural youth 12–17 years old reporting smokeless tobacco use (compared to 1.6% of urban youth 12–17 years old). Furthermore, smokeless tobacco regular use among rural Non-Hispanic White males in 12th grade (16.5%) is more than double the average for all rural youth (6.8%), indicating the high level of risk for this particular demographic segment (Johnston, 2012). According to the most recent data from the FDA's Population Assessment of Tobacco and Health (PATH) study, 31.8% of rural, white males 12–17 years of age are either experimenting with or are at-risk for using smokeless tobacco – this amounts to approximately 629,000 male youth nationwide (NIH, 2016; US Census Bureau, 2015).

Despite comprising a relatively small proportion of the U.S. population, American Indian/Alaska Native (AI/AN) adults and youth have significantly higher smoking rates than any other racial or ethnic group in the country, leading to major disparities in health outcomes (CDC, 2017; Odani, Armour, Graffunder, Garrett, & Agaku, 2017). AI/AN youth tend to initiate cigarette smoking earlier than non-AI/AN youth and are more likely to currently use tobacco compared to the general population, including cigarettes, cigars, smokeless tobacco, and electronic cigarettes (CDC, 2015; RTI International, 2013; Schinke, Schilling, Gilchrist, Ashby, & Kitajima, 1989). These trends may be, in part explained by the fact that tobacco has a long-ingrained influence in many of these communities, some of which are unique to AI and AN culture (RTI International, 2013; Hodge, 2001).

The disproportional ways in which tobacco use affects the AI/AN population demands our prompt attention and will be addressed through a culturally tailored and targeted public health education campaign. However, AI/AN youth receptivity to tobacco messaging approaches is an area that has not been explicitly explored in the existing literature. In order to develop the appropriate messaging to inform the public, it is important for the FDA to conduct research to

gain insight into youth perceptions of tobacco prevention messaging. Information obtained through this study will inform CTP's effort to target AI/AN youth with tobacco education messaging that will effectively influence teens at risk of tobacco use.

Participants will be recruited through social media, namely Facebook and Instagram, and we will develop messages and targeted advertising to encourage social media users to take the survey (see Attachments C4: *Fresh Empire*, D4: *TRC Smokeless*, and E4: *AI/AN* for messages and images that will be used to create the advertisements). After youth click the ad, they will be directed to complete the screener (see attachments C3 for *Fresh Empire*, D3 for *TRC Smokeless*, and E3 for *AI/AN* ), provide an email address if they qualify to take the survey based on their screener responses, and provide the email address for their parent/guardian to receive the notification/opt-out form (see attachments C2 for *Fresh Empire*, D2 for *TRC Smokeless*, and E2 for *AI/AN*). Should the parent/guardian choose to opt out, youth will <u>not</u> receive a link to the survey. If the 24-hour period passes without the parent/guardian opting out, youth will be emailed a link to complete the assent form (see attachments C1 for *Fresh Empire*, D1 for *TRC Smokeless*, and E1 for *AI/AN*) then begin the survey (see attachments A5 for *Fresh Empire*, B5 for *TRC Smokeless*, and E5 for *AI/AN*).

In addition to recruiting participants through social media, approximately 200 of the 400 *AI/AN* participants will be recruited through Lucid, an existing online panel of adults with children ages 13-17 who have been prescreened for their willingness to have their child to participate in online surveys. Adult panelists will receive an initial email invitation from Lucid that indicates their child has been invited to participate in a new survey (see Attachment F1). If the parent determines that they would like their child to participate in this particular survey, they will be asked to provide parental permission and an email address for the child. An introductory email will then be sent to the youth inviting them to participate in the study and requesting their assent (Attachment F2). If the youth gives their assent, they will be redirected to the online screener portion of the survey (Attachment F3). If they qualify to participate in the study, they will begin the survey (Attachment E5).

We anticipate that data collection will take approximately five months. Results of the survey will help CTP better understand youth receptivity to the tobacco-related facts and help refine tobacco messaging for existing tobacco prevention campaigns.

## 2. <u>Purpose and Use of the Information</u>

The information obtained from the proposed data collection activities is collected from youth ages 13–17 in American households, and will be used to inform FDA, prevention practitioners, and researchers about youth's receptivity to tobacco-related facts. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed data collection:

- Understand what type of tobacco-related facts youth perceive as most effective to prevent tobacco use;
- Inform FDA, policy makers, and other stakeholders on the impact of potential campaign messages; and
- Inform future programs that may be designed for similar purposes.

To achieve these goals, data collection will consist of a survey disseminated to approximately 800 multicultural youth who are at risk for using or experimenting with cigarettes, or have ever used cigars/cigarillos/little cigars, or hookah, approximately 400 White male youth living in rural areas who are at risk for using smokeless tobacco or have experimented with smokeless tobacco, and approximately 400 AI/AN youth who are at risk for using or have experimented with cigarettes or e-cigarettes. The survey dissemination will occur over a five-month period. Youth will not be re-contacted in this study.

All surveys will be conducted by Fors Marsh Group (FMG) using convenience sampling to reach the desired target audiences.

**3. Use of Information Technology and Burden Reduction**

This study will rely on web-based survey data collection on receptivity to tobacco-related facts among youth ages 13–17 who have either experimented with tobacco products or are at risk for initiating use of tobacco products. Using an online confidential survey allows the respondent to be more candid with their responses. This allows for more accurate data because respondents provide more honest responses than when other types of data collection methods are employed, especially when it is clear that the answers will remain private. In addition, using a survey will allow for more participants to respond in a cost-effective and timely manner. The self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. An added benefit is also increased data protection by limiting the amount of personally identifiable information (PII) collected from participants, reducing the risk of data security issues. Finally, as noted above, this technology permits respondents to complete the survey in privacy. The use of a more private data collection method makes reporting potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) less threatening and enhances response validity and response rates.

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

FDA's youth tobacco prevention campaign efforts are relatively new, and therefore it is important to develop messages which will have the largest impact on reducing tobacco use among at-risk youth. To date, there has been one study conducted by RTI International that tested youth reactions to different types of tobacco facts, although those were specific to cigarettes and e-cigarettes, and were tested with a broader range of youth, rather than the specific target audiences that this study seeks to survey.

**5. Impact on Small Businesses or Other Small Entities**

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

**6. Consequence of Collecting the Information Less Frequently**

Respondents to this data collection will answer only once to ensure the participant burden is as low as possible. Without the data collection requested for this study, it would be difficult to determine the most effective messages to use in upcoming tobacco prevention campaigns. Failure to collect these data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for youth in the United States.

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

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

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

FDA collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the Centers for Disease Control and Prevention, Office on Smoking and Health (CDC/OSH), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health National Cancer Institute (NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of proposed messages for advertisements;
- Review of questionnaires for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

FDA will share the findings from this collection of information with these agencies. CDC and FDA are developing complementary but distinct communication campaigns to educate the public about the harmful effects of tobacco products. FDA's Health Communication and Education unit works closely with OSH's Health Communications Branch. Regularly scheduled conference calls are held to review plans, discuss campaign coordination and share research findings of mutual interest. Staff members in FDA's Health Communication and Education unit are thus working closely with staff in OSH's Health Communications Branch, ASPA, ASPE, and other HHS OPDIVS as appropriate. It was determined that message testing proposed in this GenIC does not duplicate CDC/OSH efforts.

Points of contact for this coordination are:

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

CDC: Deesha Patel, Health Communication Specialist, Health Communication Branch, Phone: (770) 488-8503, Email: wnm2@cdc.gov

NCI: Erik Augustson, Program Director, Tobacco Control Research Branch, Phone: (240) 276-6774, Email: augustse@mail.nih.gov

NCI: Yvonne Hunt, Program Director, Tobacco Control Research Branch, Phone: (240) 276–6975, Email: huntym@mail.nih.gov

**9. Explanation of Any Payment or Gift to Respondents**

As a token of appreciation, participants recruited through social media who complete and submit the survey will receive a $10 electronic gift card. AI/AN participants recruited through the online panel will receive non-monetary 'points' through the parent's Lucid account. Points can later be redeemed by the parent on behalf of their child. These points can be redeemed by the parent through Lucid's system for goods or gift cards. The approximate value of the points is $10 per survey. We estimate that the survey will take about 20 minutes to complete. In this study, we are using the $10 gift card and 'points' equivalent to $10 as a token of appreciation to equalize the burden placed on participants with respect to their time, and to reduce overall burden by increasing questionnaire completion rates among youth who qualify on the screener. As participants often have competing demands for their time, a token of appreciation for participation in research is warranted. The use of a token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort participants expend to participate. Numerous empirical studies have also shown that a token of appreciation can significantly increase response rates in cross-sectional studies and reduce attrition in longitudinal studies (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Shettle & Mooney, 1999; Singer, 2002). Additionally, evidence indicates that at-risk and multicultural populations may be particularly difficult to recruit and retain in health research (Hooven, Walsh, Willgerodt, & Salazar, 2011; Zand et al., 2006; Post, Gilljam, Bremberg, & Galanti, 2012; Patel, Doku, & Tennakoon, 2003; Siddiqui, Flay, & Hu, 1996; Giuliano et al., 2000; Murthy, Krumholz, & Gross, 2004), but that the use of a token of appreciation can be an effective means of recruiting and retaining participants from these populations (Martinson et al., 2000; Booker, Harding, & Benzeval, 2011; Caldwell, Hamilton, Tan, & Craig, 2010; Walter, Burke, & Davis, 2013).

**10. Assurance of Confidentiality Provided to Respondents**

FDA's Research Involving Human Subjects Committee (RIHSC) has reviewed and approved the protocol and consent forms for the study (RIHSC study #18-049CTP). RIHSC's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

Overview of Data Collection System

All information will be collected electronically through a self-administered survey instrument hosted in a secure, online, web-based data collection system. Approximately 1,400 participants will be recruited via social media and approximately 200 participants will be recruited through an online panel (Lucid). All participants will be screened for eligibility prior to administration of the survey instrument. All respondents will meet inclusion criteria for one of the following groups: (1) multicultural youth (e.g., African-American/Black, Hispanic/Latino, Asian-Pacific Islander) aged 13–17 at risk for using or experimenting with cigarettes or who have ever used cigars/cigarillos/little cigars, or hookah, (2) White males aged 13–17, living in rural areas and at risk for using or experimenting with smokeless tobacco, and (3) AI/AN youth aged 13-17 who are at risk for using or experimenting with cigarettes or e-cigarettes. Eligible youth recruited through social media will be asked to provide an email address for their parent/guardian to receive a parental notification/opt-out form. Should the parent/guardian choose to opt out, youth will not receive a link to the survey. If the 24-hour period passes without the parent/guardian opting out, the youth will receive a link to the survey. Parents/guardians youth recruited through the online panel will need to provide parental permission for the youth to complete the survey. Each participant will give feedback on approximately 15 tobacco-related facts, followed by a series of questions about their knowledge, attitudes, and behaviors in regard to specific tobacco products, and complete the survey by answering basic demographic information. The participant will complete the survey at the time of his or her choosing. There is no website content directed at children younger than 13 years of age.

Overview of How Information will be Shared and for What Purposes

Information will be collected by Fors Marsh Group (FMG). FMG will conduct data cleaning screening and the majority of the analyses. Data will be kept in an aggregated dataset. These datasets will be shared with FDA using a secure transfer file protocol.

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

The following procedures will be used to ensure participant privacy before, during, and after fielding: (1) PII in the form of participants' email addresses will be stored separately from screening-related data and survey data, and email addresses will be deleted after survey completion; (2) datasets and reports will not contain any PII; and (3) respondents' information will not be tied to their individual responses and all analyses will be conducted in the aggregate (i.e., any data used in reporting will not be attributed to individual participants). All datasets and reports delivered to FDA will not include PII. All identifying information will be kept on a separate password-protected computer for a period of three years and will only be accessible by FMG.

PII will be collected in the form of email addresses for the purposes of contacting the parent/guardian to receive permission for youth participation, and to provide the survey link to qualifying participants. No additional personal identifiers (e.g., full name, phone number, social security number) will be collected aside from basic demographic information (e.g.,

gender, age, and race). PII will be stored separately from any survey responses and destroyed by secure deletion once surveys are completed.

Overview of Voluntary Participation

Potential participants will be advised of the nature of the survey, the length of time it will require, and that participation is voluntary. The parental permission and notification/opt-out forms as well as the youth assent form will inform the participant that their participation is voluntary. Participants will be assured that they will incur no penalties if they wish not to respond to the data collection as a whole or to any specific questions. Participants will have the option to decline to respond to any item in the survey for any reason and may drop out of the survey at any time. These procedures conform to ethical practices for collecting data from human participants.

Overview of Data Security

Participants will use a link to enter the survey, FMG's survey software will assign them a unique ID, and the responses will be anonymous. No PII will be linked to the survey data. All those who handle or analyze data will be required to adhere to the standard data security policies of FMG, which include limited access to project materials, a locked storage facility, encrypted files (including data files), and secure network storage. All data will be reported in the aggregate only. During data collection, all data will be stored on password-protected computers to which only FMG employees working on this project will have access.

## 11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors, such as tobacco product use. These questions are essential to the objectives of this data collection. Although we do not anticipate any risks from these health questions, some participants may perceive them to be sensitive. Questions about messages concerning lifestyle (e.g., current tobacco product use) and some demographic information, such as race and ethnicity could also be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. The informed consent protocol will notify participants that these topics will be covered in the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer;
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses; and
- Participants will be provided with a phone number and email address for the FMG Principal Investigator and an email address for FDA RIHSC should they have any questions or concerns about the study or their rights as a study participant.

## 12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection will be approximately 1,371 hours (Table 1). This includes the time burden associated with the screener. To obtain a final sample of approximately 1,600 youth (approximately 800 multicultural youth ages 13–17 who have experimented with or are at risk for using cigarettes or have ever used cigars, or hookah; approximately 400 White, Non-Hispanic rural males ages 13–17 who have experimented with or are at risk for using smokeless tobacco; and approximately 400 AI/AN youth ages 13-17 who have experimented with or are at risk for using cigarettes or e-cigarettes) we will need to screen approximately 5,860 potential participants. Based on FDA experience with previous surveys, we anticipate about one-third of participants contacted will be eligible for the study.

**Table 1. Estimated Annual Reporting Burden[1]**

| Type of Respondent | Activity | Number of Respondents | Number of Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Hours[1] |
|---|---|---|---|---|---|---|
| **Screening and Informed Consent** | | | | | | |
| Parents/Guardians | Parental Permission (Online panel recruit) | 1,200 | 1 | 1,200 | 0.08 (5 minutes) | **100** |
| | Parental Notification/Opt-out (Social media recruit) | 1,400 | 1 | 1,400 | 0.08 (5 minutes) | **117** |
| Youth aged 13–17 | Youth Recruiting and Screening | 5,860 | 1 | 5,860 | 0.08 (5 minutes) | **488** |
| Youth aged 13–17 | Youth Assent | 1,600 | 1 | 1,600 | 0.08 (5 minutes) | **133** |
| **Survey** | | | | | | |
| Youth aged 13–17 | Multicultural youth who have experimented with or are at risk for using cigarettes or have ever used cigars or hookah | 800 | 1 | 800 | 0.33 (20 minutes) | **267** |
| | White, Non-Hispanic males living in rural areas who have experimented with or are at risk for using smokeless tobacco | 400 | 1 | 400 | 0.33 (20 minutes) | **133** |
| | AI/AN youth who have experimented with or are at risk for using cigarettes or e-cigarettes | 400 | 1 | 400 | 0.33 (20 minutes) | **133** |
| **Total Annualized Hours** | | | | | | **1,371** |

[1] The total number of respondents is 5,860 for this study 1,600 represent the total number of participants.

12b. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. FMG has

conducted many smoking-related surveys of similar length among youth. We have examined diagnostic data from prior surveys and estimate that data collection for this study will take approximately 20 minutes per participant. We have also allocated time for parents to give their permission for their child to participate and for youth to give their assent to participate.

To calculate this cost, the mean hourly wage of $7.25 was used for youth and $24.98 was used for parents. The youth price represents the minimum wage, and the parental costs represent the mean hourly wage for all occupations from the Department of Labor's Occupational Employment Statistics survey (May 2018 data). There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of $7.25 and $24.98 (youth and parent), the estimated one-year annualized cost to participants will be $13,786. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

**Table 2. Estimated Annual Cost**

| Type of Respondent | Activity | Annual Burden Hours | Hourly Wage Rate | Total Cost[1] |
|---|---|---|---|---|
| Parents/Guardians | Parental Permission | 100 | $ 24.98 | $2,498 |
| | Parental Notification/Opt-out | 117 | $ 24.98 | $2,922 |
| Youth Participants (ages 13–17) | Youth Recruiting and Screening | 488 | $ 7.25 | $3,538 |
| | Youth Assent | 133 | $7.25 | $964 |
| | Youth Survey | 533 | $ 7.25 | $3,864 |
| Total | | 1,371 | | $13,786 |

[1] Cost was rounded up to the next dollar.

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

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

## 14. Annualized Cost to the Federal Government

**Table 3. Itemized Cost to the Federal Government**

| Government Personnel | Time Commitment | Average Annual Salary | Total[1] |
|---|---|---|---|
| GS-12 | 5% | $86,894 | $4,345 |
| GS-13 | 10% | $106,668 | $10,667 |
| GS-13 | 10% | $106,668 | $10,667 |
| | | **Total Salary Costs** | $25,679 |
| | | **Contract Cost** | $313,565 |
| | | **Total** | **$339,244** |

[1] Cost was rounded up to the next dollar.

## 14. Explanation for Program Changes or Adjustments

This is a new individual generic data collection.

## 15. Plans for Reporting and Project Time Schedule

The analysis will examine overall ratings of tobacco-related facts that were tested. Each outcome will be analyzed for each tobacco fact. Comparisons between fact outcomes will be made. Findings from these analyses will be used to inform FDA CTP health communication strategy and messaging.

Reporting

Reporting will consist of a draft report and a final report containing background information on the project objectives, scope and methodology, and key findings and conclusions. The approximate dates for completing project tasks are listed in Table 3.

**Table 3. Approximate Project Schedule**

| Project Activity | Date |
|---|---|
| Survey | May 2019 to September 2019 (Approximate) |
| Data Analysis | October 2019 to November 2019 (Approximate) |
| Report Writing | November 2019 to December 2019 (Approximate) |

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

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

## 17. Exceptions to Certification for Paperwork Reduction Act Submissions

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

**References**


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