U.S. Food and Drug Administration
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

OMB Control No. 0910-0796

Supporting Statement Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

FDA's Center for Tobacco Products (CTP) oversees implementation of the Family Smoking Prevention and Tobacco Control Act, also known as the Tobacco Control Act, signed into law on June 22, 2009. Section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355) provides that FDA may take appropriate action to protect the public health when necessary. As part of this authorization, the Center for Tobacco Products also conducts studies to inform regulatory actions and communicates with the public on the health risks of tobacco use.

To ensure that regulatory actions and communications activities have the highest potential to be received, understood, and accepted by various audiences, CTP will conduct research studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C 241(a)). Since this collection was approved originally, FDA now has authority per the deeming rule over many newly regulated products. Therefore, FDA may need to gather more foundational and formative research on these newly deemed tobacco products to inform comprehensive and accessible communications that describe CTP regulatory actions to the public and other CTP stakeholders, aligned with CTP's Strategic Plan (Goal 1: Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance) as data gathered from information collections under this generic clearance will facilitate development of clear and accessible CTP public statements and communications. Aligned with CTP's Strategic Plan (Goal 4: Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use), this information will also aid CTP's strategy and development of communication messaging and educational initiatives related to public health (i.e., educating youth about the risks of tobacco product use; educating people who use tobacco products about the benefits of cessation; educating adults who smoke about the relative risks of tobacco products).

This information collections under this generic clearance will be used to inform the regulatory science and health communication knowledge base, as well as to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the agency. FDA is requesting approval of this extension for collecting information using qualitative methods (e.g., individual in-depth interviews (IDIs), focus group discussions, cognitive interviews, and asynchronous qualitative discussions, naturalistic observation, and ethnographic studies) for studies about tobacco products. Qualitative studies play an important role in exploring areas of research and gathering information because the studies allow for an in-depth understanding of individuals' attitudes, beliefs, motivations,

feelings, and behaviors. FDA will submit individual collections under this generic clearance to the Office of Management and Budget (OMB). Before submission to OMB, individual collections will undergo review by FDA's Institutional Review Board (FDA IRB) and/or defer to the contractor's Institutional Review Board (IRB), senior leadership in CTP, and Paperwork Reduction Act (PRA) specialists. FDA will prepare a report during the OMB collection renewal summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance.

2. Purpose and Use of the Information Collection

In conducting studies relating to the control and prevention of tobacco-related disease, FDA has employed qualitative research, such as individual in-depth interviews (IDIs), focus group discussions, and cognitive interviews both online and in person to better understand characteristics of various audiences (including their perceptions, knowledge, attitudes, beliefs, and behaviors) as well as to assess audience responses and reactions to messaging and other stimuli. The information collected through these studies has helped informed survey items and instruments, study stimuli, and communication messages directed at consumers.

Moving forward, we will continue to conduct qualitative research, such as IDIs, focus group discussions, and cognitive interviews to inform our messaging and materials. Additionally, we will be including additional methodologies such as asynchronous qualitative discussions (e.g., online journaling or web-based discussion boards), user experience study, usability testing, and naturalistic observation and ethnographic studies. These tools can help us further assess knowledge and perceptions about tobacco-related topics with specific audiences, employing both online and in-person data collection methods. A more expansive set of qualitative data collection methods will allow FDA to generate exploratory data on a given research topic or area of research, and to inform survey/research questions and study stimuli. FDA will collect, analyze, and interpret information gathered through this generic clearance in order to (1) better understand characteristics of various audiences, including their perceptions, knowledge, attitudes, beliefs, and behaviors—and use these in the development of appropriate survey/research questions, study stimuli, and materials directed to consumers; (2) more efficiently and effectively design survey/research questions and study stimuli; (3) more efficiently and effectively design experimental studies; and (4) gain an in-depth understanding of a pertinent research area and topic.

FDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low burden for respondents (based on considerations of total burden hours, total number of respondents, or burden hours per respondent) and are low cost for both the respondents and the Federal Government;
- The collections are noncontroversial;
- Personal identifiable information (PII) is collected only to the extent necessary[1] and is not retained or submitted by contractors to FDA;

[1] For example, collections that collect PII in order to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All privacy act requirements will be met.

- Information gathered will not be used for the purpose of substantially informing influential policy decisions or communications;[2]Information gathered will yield qualitative information. While study designs may additionally include collection of individual level quantitative or psychometric data (e.g., eye tracking data) to complement and enhance data from the interviews or discussions, the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

If these conditions are not met, FDA will submit an Information Collection Request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (e.g., a copy of the interview or moderator guide, screening questionnaire). Before submission to OMB, individual collections will undergo review by the IRB of record, senior leadership in CTP, and PRA specialists.

The types of collections that this generic clearance covers may include, but are not limited to:

- Focus groups or small group discussions, which may include 2 to 12 participants each
- Individual in-depth interviews (IDIs), including cognitive interviews
- Asynchronous discussion boards
- Usability and/or psychometric testing (including eye tracking)
- Moderated, un-moderated, in-person, and/or virtual (e.g., using webinar conferencing software or asynchronous qualitative research platforms)
- Naturalistic observation and ethnographic studies to observe participants or subjects in natural settings and environments (including digital environments)

3. Use of Improved Information Technology and Burden Reduction

Emphasis will be placed on collecting information electronically using online collaboration tools to reduce burden by allowing participants to participate in a location that is convenient to them and without the need for added travel/commuting. At this time, we expect at minimum, 80% of the information collections will be completed using online webinar, conferencing, and focus group software. Virtual interview and focus group participants will access an online platform such as Zoom, GoToWebinar, and other applications, which allow users to meet online and can be accessed using a computer, tablet, or mobile device. Asynchronous research participants would similarly access a web-based discussion board such as QualBoard to provide written or audio responses to open ended questions from the study moderator. Webinar platforms include several security protection features including, but not limited to, the ability to lock a meeting so no one else can join, restrict screen-sharing to the host only, enable a waiting room to restrict access to only those who should join, and remove a participant, if needed.

[2] As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

4. Efforts to Identify Duplication and Use of Similar Information

As each new research study is developed, FDA will review existing literature and databases, including pretesting reports on existing messages and materials. FDA will also consult with outside experts to evaluate available information on similar messages with comparable audiences. FDA will work with other HHS agencies responsible for communicating about tobacco use with the general public.

However, because communications to consumers, surveys, and studies on the use of tobacco will be diverse and vary by target audience, new data collection instruments generally will be prepared for each qualitative study.

Therefore, data collected by FDA is unique. Coordination with other agencies ensures that duplicative data is not being gathered. Further, no similar data are gathered or maintained by FDA or are available from other sources known to FDA.

5. Impact on Small Businesses or Other Small Entities

Small businesses, or other small entities, may be involved in efforts related to collections of information approved under this clearance. However, FDA will minimize the effect and burden on them by sampling appropriately.

6. Consequences of Collecting the Information Less Frequently

Often, this qualitative collection of information is used as a first step to explore concepts of interest and assist in the development of quantitative study proposals. The collection of timely data will be important to the development and conduct of ongoing and future research efforts at the agency. Without these types of feedback about consumer knowledge and perceptions, FDA will not have timely information to adjust its survey/research questions, study stimuli, and draft communication messages.

This information may also be used to help develop materials directed at the public and tobacco consumers for use prevention and education. FDA is using a variety of messages and materials to inform and educate the public about the risks of tobacco use. Communicating effectively about the risks of using tobacco products involves conveying complex concepts, and without detailed data from qualitative research, FDA cannot fully understand priority audiences and ensure that tobacco messages and materials directed at these audiences are serving their intended purpose. As a result, FDA could spend a large amount of money on communications, surveys, or other studies that are ineffective in achieving the intended purpose of reducing tobacco-associated costs to people’s lives and to the government.

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

There are no special circumstances for this collection of information. The information collected will be voluntary.

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 on the proposed collection of information in the FEDERAL REGISTER of January 9, 2024 (89 FR 1097). FDA received two (2) PRA related comments.

(Comment) The comment expressed that the Paperwork Reduction Act (PRA) was written to reduce burden on the public, but the overuse of surveys is encouraged generically, making it even easier to collect information with no need based. The comment stated further that “This seems to be counterintuitive to the purpose of the PRA and exactly what the Act was supposed to be protecting us from, another survey we do not have time or resources to complete buy you would like to give us with no specific goal. Overuse.”

(Response) FDA disagrees with the comment suggesting that the generic information collection process enables the overuse of surveys and undermines the PRA. In response to this comment, FDA has updated Supporting Statement Part A to clarify the necessity of the information collected under this generic clearance for the proper performance of FDA CTP’s function and the practical utility of collecting such information. The information collected will support FDA CTP’s function by advancing CTP’s Strategic Plan and its specific goals: "Goal 1: Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance" and "Goal 4: Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use." The practical utility of the collected data is evidenced by its role in facilitating the development of clear and accessible CTP public statements and communications, such as web content, press releases, fact sheets, and retailer resources. Furthermore, the utility is demonstrated by CTP achieving the following objectives with specific audiences:

- Educating youth about the risks of tobacco product use.
- Educating people who use tobacco products about the benefits of cessation.
- Educating adults who smoke about the relative risks of tobacco products.

This foundational research has helped FDA to understand audiences and inform message development and the testing of messages in communicating the risks of tobacco use, how to quit using tobacco products, and FDA’s role in regulating tobacco. Obtaining this information has allowed FDA to improve messages, materials and implementation strategies while revisions are still affordable and possible.

(Comment) The comment expressed the lack of specificity regarding FDA’s public education goals. Specifically, the comment notes that FDA vaguely states it will collect qualitative data to "explore concepts of interest and assist in the development of quantitative research proposals" and "help identify and develop communication messages, which may be used in education

campaigns." The comment stated further that they encourage “FDA to prioritize educating adults, particularly adult smokers and physicians and medical staff who advise adult smokers about tobacco harm reduction. […], FDA’s public education campaigns should aim to improve understanding among adult smokers where there currently exists significant uncertainty and confusion about materially important issues that are detrimental to public-health efforts. These important issues include “educating the adult public, particularly adult smokers, about the continuum of risk, and where alternatives to combustible cigarettes fall on that continuum,” and ‘correcting misunderstandings about the absence of any direct causal link between nicotine and tobacco-related diseases.’”

(Response) FDA disagrees with the comment suggesting that an overarching purpose or plan for communications, information goals, or target audiences was not provided. In response to this comment, FDA has updated Supporting Statement Part A to clarify that the information collected under this generic clearance is necessary for the proper performance of FDA CTP's function and will be of practical utility in advancing CTP's Strategic Plan and its specific goals. The information collected under this generic clearance will advance CTP’s objectives to educate people who use tobacco products about the benefits of cessation and to educate adults who smoke about the relative risks of tobacco products. The following generic information collections were recently approved under 0910-0796. FDA has summarized how they address specific objectives such as educating adults about tobacco products' relative risks:

- “Consumer Perceptions of Cessation and Harm”: Focus group study with established cigarette smokers ages 25 and up. The objective is to learn about consumer perceptions (and misconceptions) regarding nicotine and tobacco products.

- “Consumer Perceptions of Modified and Reduced Risk (MoRR)”: Focus group study with current and established cigarette smokers ages 21 and older. The objective is to gain information to inform health communication materials dedicated to modified risk products and/or the continuum of risk. This may help reduce misperceptions and lack of awareness.

- “Menthol User Audience Research”: In-depth interviews conducted with adult menthol smokers ages 21 and older. The objective is to examine demographic, sociocultural, psychographic, and behavioral characteristics of adult menthol cigarette users; to identify segments that are most likely to adopt less harmful behaviors in response to targeted messaging; and to identify communication strategies to support menthol smokers in adopting less harmful behaviors.

- “Qualitative Study of Product Category Comparison Statements (MRTPs and HPHCs)”: Focus group study with adult current and former cigarette smokers ages 18 and older. The objective is to understand participants’ knowledge, attitudes, beliefs, and perceptions about different tobacco products. This includes a stimulus-driven discussion of harmful and potentially harmful constituents (HPHC) information and modified risk tobacco product (MRTP) claims.

9. Explanation of Any Payment or Gift to Respondents

To align with standard practice in commercial market research, participants in interviews and focus groups may receive some form of renumeration as a token of appreciation for the time they spend engaged in an information collection activity. Instances for offering a small token of appreciation will be determined on a case-by-case basis (depending on the information collection design).

For adult participants recruited from the general population for qualitative research (e.g., focus groups or interviews), the following token of appreciation values will be offered: $50 (45-60 minutes) and $75 (90 minutes).

For youth participants recruited from the general population for qualitative research (e.g., focus groups or interviews) the following token of appreciation values will be offered: $30 (45-60 minutes) and $50 (90 minutes). FDA qualitative research for message testing may recruit youth considered at risk for tobacco product use (e.g., youth who are susceptible to tobacco product use), which poses challenges for recruitment due to lower representation of youth groups in research panels.

For information collections that recruit adults from geographically isolated or rural hard-to-reach populations (e.g., American Indian and Alaskan Native or AI/AN groups), the following tokens of appreciation values will be offered: $115 (45-60 minutes) and $145 (90 minutes). For information collections that recruit youth from geographically isolated or rural hard-to-reach populations (e.g., American Indian and Alaskan Native or AI/AN groups), the following tokens of appreciation values will be offered: $50 (45-60 minutes) and $75 (90 minutes). While FDA has capabilities to conduct virtual research, studies involving geographically isolated or rural hard-to-reach populations such as AI/AN groups benefit from in-person data collection methods. A technological divide, particularly pronounced in rural areas and tribal lands, poses challenges for virtual research participation for some populations.[3] This digital disparity disproportionately affects rural and tribal communities which are among the most underserved populations in terms of broadband internet access.[4] In 2019, a substantial percentage of residents in rural areas (22%) and tribal lands (28%) lacked broadband internet coverage, compared to 1.5% of residents of US urban areas. Many residents of rural and/or tribal areas also lack reliable cell phone coverage.[3] Access to high-quality broadband internet and reliable high-quality cell phone coverage are essential to utilizing the video conferencing software needed to participate in virtual and online

[3] Federal Communications Commission (2020). 2020 Broadband deployment report. Retrieved from https://docs.fcc.gov/public/attachments/FCC-20-50A1.pdf

[4] Sanders, C. K., & Scanlon, E. (2021). The digital divide is a human rights issue: Advancing social inclusion through social work advocacy. Journal of Human Rights and Social Work, 6, 130-143. https://doi.org/10.1007/s41134-020-00147-9

research. For those without access to broadband internet, participation may result in significant data usage on their internet plans, resulting in additional utility fees. Moreover, participation could impose financial or logistical barriers, especially if participants need to rent equipment or travel to access reliable internet connectivity.

Community partners and subject-matter-experts from geographically isolated and rural hard-to-reach populations have indicated that sufficient levels of token of appreciation amounts are needed for successful study recruitment for these populations. These amounts are justified by considering the distance to and the needed travel time to qualitative research sites or a place that has connectivity and/or equipment to enable participation in virtual focus groups or interviews. Based on input from FDA's community partners and SMEs for geographically isolated or rural hard-to-reach populations (such as AI/AN groups), distances to the nearest community center for broadband access or to qualitative research sites are variable but may require traveling at minimum 50 miles one way. To calculate cost of travel, we use the U.S. General Services Administration reimbursement of $0.67 per mile when taking a trip in a personally owned vehicle.[5] This equates to $67 for round trip travel costs. Adding these travel costs to the token of appreciation values for the general populations leads to sufficient and equitable values for participants from geographically isolated or rural hard-to-reach populations such as AI/AN groups.

For information collections that recruit adults that are healthcare professionals or providers (such as primary care physicians, NP, or PAs) for focus groups or interviews, incentive amounts will be based on healthcare specialty. For a 60-minute focus group or interview, specialty physicians will be offered an incentive of $225, primary care physicians (MD or DO) will be offered $200 and other healthcare professionals will be offered $125. If we struggle to schedule enough participants from this difficult to recruit population, an additional $50 may be offered. A similar tiered strategy was approved by OMB for FDA's CFSAN Adverse Event Reporting System (CAERS) Healthcare Provider (HCP) In-Depth Interviews (OMB Control No. 0910-0891).

FDA will provide justification for any studies that propose to offer incentives. FDA may propose incentives at a higher rate if evidence is provided that larger incentives are necessary for successful recruitment.

10. Assurance of Confidentiality Provided to Respondents

CTP consulted the agency Privacy Officer to identify potential risks to the privacy of participants and other individuals whose information may be handled by or on behalf of FDA in the performance of this generic clearance. FDA will design studies, underneath this generic clearance, 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

[5] U.S. General Services Administration. (2024). Privately owned vehicle (POV) mileage reimbursement rates. https://www.gsa.gov/travel/plan-book/transportation-airfare-rates-pov-rates-etc/privately-owned-vehicle-pov-mileage-reimbursement

(NIST), Special Publication 800-53, Security and Privacy Controls for Federal Information Systems and Organizations. CTP has identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. FDA received approval of a Privacy Impact assessment for studies under this generic clearance by the Department of Health and Human Services.

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.

PII Collection

For respondent enrollment, PII will be collected on an as needed basis to assess study eligibility during the enrollment/screening process and will not be maintained or linked to other study information. Mailing address and/or e-mail addresses may be collected for contacting the respondent regarding enrollment details (e.g., directions, schedule. Contractors and subcontractors that collect data on behalf of FDA never transfer any PII to the agency or stored on FDA network servers. For studies involving virtual data collection, the webinar or discussion board platform collects information that a participant gives them to access the platform (e.g., name, email address and/or phone number, etc.). Webinar or discussion board platforms also collect additional data once the platform is accessed such as IP address, MAC address, and device type. FDA staff and contractors will not have access to any data that participants provide to use the webinar platform or any data that the webinar platform collects while the platform is in use. Furthermore, FDA staff and contractors will not have the ability to link data obtained from the webinar platform to any participant.

For data quality management, PII in the form of audio recordings (biometric identifiers) or screen recordings may be used as a means of quality control and/or data assurance. Permission (active consent) for this type of PII is obtained from all respondents. Respondents must agree to have study activities audio recorded. Audio files are used to produce a transcript for the purpose of developing a report and then destroyed. Audio recordings, including any transcripts made from the audio recordings, will not be linked to any other PII or transmitted to FDA.

For study implementation, PII in the form of e-mail and IP addresses and/or zip codes may be collected on an as needed basis for study implementation. This type of PII may be checked against respondent data to avoid duplicates and reduce fraudulent activity. If multiple e-mails have the same IP address, researchers will review the data, retain the first recorded response, and remove duplicates from the final analytical dataset. Researchers may also contact respondents to convey follow-up information about the study or if there is an issue with token of appreciation delivery. PII collected as part of the study implementation will not be included in the dataset used for analysis or maintained. There will be no secondary uses, PII will only be used to for primary study purposes.

FDA has minimized the risk of unnecessary access, disclosure, use, or proliferation of PII about respondents. FDA and other parties involved in the study collect and maintain study records containing PII only as long as required. For many studies the information is not retained once the study is completed (e.g., email addresses needed to re-contact participants for the follow-up session of a study). PII is always removed before any data is sent to FDA. PII may be linked to data by a code, only when necessary, or more commonly fully disassociated from the data.

Notice and Transparency

Neither FDA nor direct contractors, including third parties, share PII gathered via this collection with any other individuals or entities.

All participants are provided notice regarding the collection and use of the information they submit. A panel provider may collect IP addresses when participants register for the panel, but FDA does not receive IP addresses. FDA and its contractors will notify participants if IP addresses are recorded. In some cases, FDA sponsorship of the study will not be made known to respondents prior to data collection out of concern for the potential introduction of bias to study results. In such cases, FDA sponsorship will be made known after the data are collected.

Individual Participation and Control

While anonymity of respondents generally cannot be assured unless there is a statutory requirement associated with the information collection, information provided by respondents will be kept private and anonymous, to the extent allowable by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups, telephone interviews, and consent forms. Respondents also will be advised of the following: the nature of the activity; the purpose and use of the data collected; FDA sponsorship (when appropriate); and the fact that participation is always voluntary. Because responses are voluntary, respondents will be assured there will be no penalties if they decide not to respond to the information collection as a whole or to any questions.

Data Security

Contractors are required to maintain appropriate administrative, technical, and physical safeguards to ensure the security and confidentiality of collected data. User roles and responsibilities will determine the type and content of data access necessary for job function (both PII and non-PII). Role-based access will determine who will have access to PII on an as needed basis. Access to the system is restricted on the business need to ensure minimum extent necessary.

Only personnel from a contractor conducting the information collection will have access to focus group or interview data. All project staff from a contractor conducting the information collection must take required measures to ensure the privacy and anonymity of data. PII will be limited to information that may be required in the process of respondent enrollment. PII will be accessible to contractors on an as needed basis and will not be linked to interview data. All PII will be

destroyed following data collection at the completion of the study. Neither FDA employees nor any Federal employee of another agency will have access to this information. Transcripts and recordings will be de-identified prior to submission to the government.

All electronic and hard copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers and hard copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of communication messages.

Before data are collected, FDA researchers will obtain either an exemption or a full approval for all research from FDA's Institutional Review Board (FDA IRB).

Minors (or children) are persons who have not attained the legal age for consent to treatments or procedures described in the study are covered under the applicable law of the jurisdiction in which the research will be conducted. Where FDA's IRB determines that minors are capable of giving assent, the IRB will determine whether adequate provisions are made for soliciting assent. Generally, assent to the research requires securing the signature of a minor in a separate assent form, in addition to the consent form the parent or legal guardian signs. An assent document should contain an explanation of the study, a description of what is required of the subject (e.g., what the child will experience (in what setting the interview or focus group will take place, whether the child's parents will be with him or her, etc.)), an explanation of any risks or mental anguish associated with the study topic, and an explanation of the benefits to the child or others.

Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls.

11. Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of the audience that FDA is trying to reach. Efforts to match characteristics may require asking questions that may be considered sensitive, such as about race and ethnicity, income, education, sexual orientation, gender identity, and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that FDA speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information is voluntary and will be treated as private and anonymous. All information on race/ethnicity will comply fully with the standards of revised OMB Statistical Policy Directive No. 15,(https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and).

Because FDA research activities may be concerned with the prevention of premature mortality or morbidity or other risks from tobacco use, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. This information is needed to gain a better understanding of various audiences so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature, while not as personal as those about sexual behavior or religious beliefs, still require some sensitivity in how they are worded and approached. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

FDA tobacco research and communications may also be concerned with discouraging tobacco use by adolescents before they start. FDA acknowledges the sensitivity of questions about the purchase and use of tobacco, which is now illegal for anyone under the age of 21, as well as use of tobacco-adjacent products such as marijuana and other nicotine products. Because questions may be asked of teenagers, interviews will be conducted by moderators specifically trained for interaction with adolescents.

Raw data from data collections that may include sensitive information (for example, screening questionnaires and audio tapes) are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

12. Estimates of Annualized Burden Hours and Costs

A variety of instruments and platforms will be used to collect information from respondents. The annual respondent burden hours requested (399,192) are based on the number of collections we expect to conduct over the requested time frame for this clearance (Table 1).

12a. Annualized Hour Burden Estimate

Table 1.-- Estimated Annual Reporting Burden

Type of Interview	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
In-Person Individual In-depth Interviews	4,500	1	4,500	1 (60 minutes)	4,500
In-depth Interview (IDI) Screener	22,500	1	22,500	0.083 (5 minutes)	1,868
Focus Group Screener	56,000	1	56,000	0.25 (15 minutes)	14,000
Focus Group Discussion	252,000	1	252,000	1.5 (90 minutes)	378,000
Discussion Board Screener	8,000	1	8,000	0.083 (5 minutes)	664
Discussion Board Participation	100	1	100	1.5 (90 minutes)	150
Total	343,100		343,100		399,182

The number of respondents to be included in each new pretest may vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during the 3-year period. Time to read, view, or listen to the message being tested is built into the ‘‘Hours per Response’’ figures.

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The mean hourly compensation for this group as of January 2024 is $34.55 (BLS). The estimated annualized annual cost for the general public in this information collection for 399,192 hours of reporting time is $27,583,476.20. We double this to account for benefits and overhead, yielding an hourly wage rate of $69.10. The number of respondents and length of response was determined on the basis of FDA’s prior experience with communications testing and an estimate of the communication needs of CTP. The actual numbers will vary depending upon the topic of interest.

Type of Interview	**Total Burden Hours**	**Average Rate**	**Total Respondent Cost**
In Person Individual In-depth Interviews	4,500	$69.10	$310,950
In-depth Interview Screener	1,868	$69.10	$129,078.80
Focus Group Screener	14,000	$69.10	$967,400
Focus Group Discussion	378,000	$69.10	$26,119,800
Discussion Board Screener	664	$69.10	$45,882.40
Discussion Board Participation	150	$69.10	$10,365.00
TOTAL			00

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

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

14. Annualized Cost to Federal Government

FDA incurs costs to set up IDIs and focus groups, including potentially hiring a contractor to provide a facilitator/moderator, support online video conference platforms or rent meeting space and travel to conduct the groups (when applicable), and provide respondents with minimum payment cost in the form of a token of appreciation.

Costs will include contractor expenses for designing and conducting information collection activities, including recruiting participants, training interviewers, collecting, and analyzing information, and reporting findings. Contractor expenses may vary from $20,000-$250,000 depending on the size of the study. Therefore, it is anticipated that approximately $1 million in contractor expenses will be expended to fund at least two large scale studies and eight smaller scale studies.

In addition, government staff costs may be incurred for monitoring by the government Project Officer and Senior Analyst, projected to be about 25 percent of an FTE's time per year (522 hours). Given an FDA average personnel cost of $56.52 per hour, $29,504.63 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is $1,029,504.63 (which is equal to the total of contractor expenses ($1 million) plus FDA government staff salary cost ($29,504.63)).

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 384,248 hours and a corresponding increase of 314,926 responses. We attribute this adjustment to the number of study responses used during the current approval and now estimated for the next three years. A greater number of qualitative studies will be conducted over the next three years due to the need to develop new creative messages and content. Recent years have seen a dramatic change in media. With the shift to digital media, FDA must adapt to communicate effectively in a digital environment. As digital tobacco use prevention/interventions are still in their infancy, we must better understand the types of digital channels available. To impact public health outcomes, we need to understand how to reach our intended audience. New foundational studies are needed (including those on digital metrics, measurement, and implementation). Additionally, we have also updated the cost burden estimate based on current Bureau of Labor and Statistics salary figures.

16. Plans for Tabulation and Publication and Project Time Schedule

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. Findings will be used to inform experimental research, public education, disseminations (including peer-reviewed publications) or communication activities.

FDA will disseminate the findings when appropriate, strictly following FDA's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public,"[6] and will include specific discussion of the limitation of the qualitative results discussed above.

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

We are not requesting an exemption to this requirement. The OMB expiration date will be displayed.18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities comply with the requirements in 5 CFR 1320.9 and involve no exception to the Certification for Paperwork Reduction Act Submissions.

[6]HHS ASPE "HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public" at https://aspe.hhs.gov/hhs-guidelines-ensuring-maximizing-disseminated-information.