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

OMB Control No. 0910-0810

Supporting Statement Part A: Justification

1. Circumstances Making the Collection of Information Necessary

In order to conduct educational and public information programs relating to tobacco use as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA's Center for Tobacco Products will conduct research and use a variety of media to inform and educate the public, tobacco retailers, and health professionals about the health risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco.

To ensure that these educational and public information programs have the highest potential to be received, understood, and accepted by those for whom they are intended, the Center for Tobacco Products will conduct research and develop health messages relating to the control and prevention of disease. In conducting such research, FDA will use quantitative methods (i.e., surveys, experimental studies) for studies about tobacco products. These studies may be used to collect information related to foundational research informing message development or the formative pretesting of tobacco communication messages and other materials directed at consumers. This type of research involves: (1) assessing audience knowledge, attitudes, behaviors, and other characteristics for the purpose of determining the need for and developing health messages, communication strategies, and public information programs; (2) pretesting these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions; and (3) adding to the regulatory science knowledge base. Quantitative studies play an important role in exploring areas of research and gathering information because they can be used to summarize a population of interest on key variables or reveal systematic relationships between variables.

Foundational research to inform message development and the formative pretesting of messages are a staple of best practices in communications research. Obtaining voluntary feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program. The purpose of obtaining information from formative pretesting is that it allows FDA to improve materials and strategies while revisions are still affordable and possible. Formative pretesting can also avoid potentially expensive and dangerous unintended outcomes caused by audiences' interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which tobacco communication messages need to be modified should be greatly reduced.

The voluntary information collected will serve the primary purpose of providing FDA information about various measures of ad performance including message comprehension, perceived effectiveness, emotional responses and knowledge, attitudes, and behaviors change to assess the ability of messages, advertisements, and materials to reach and successfully communicate with their intended audiences. Quantitative testing messages and other materials with a sample of the target audience will allow FDA to refine messages, advertisements, and materials directed at consumers while the materials are still in the developmental stage. In addition, quantitative information is needed by FDA to track changes in response to policy and regulatory actions and to expand the tobacco regulatory science base by providing information on changing behaviors, knowledge and attitudes about tobacco products, including post-marketing surveillance of tobacco products.

FDA requests Office of Management and Budget (OMB) approval for an extension of this generic clearance to collect quantitative information related to the testing and development of tobacco communication messages and other materials directed at consumers and to assess knowledge and perceptions about tobacco-related topics with specific target audiences. FDA conducts research relating to tobacco products under its statutory authority in section 1103(d)(2)(C) of the FD&C Act, to conduct research "relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out the act." To coordinate efforts, FDA proposes that this generic clearance continue to cover all information collection activities aimed to better understand knowledge and perceptions about tobacco-related topics, to add to the regulatory science base, and to test and develop communication messages by the Center for Tobacco Products. FDA intends to utilize best practices for effective health communication research set forth by other DHHS agencies such as the National Cancer Institute.[1]

FDA will submit individual collections under this generic clearance to OMB. Before submission to OMB, individual collections will undergo review by FDA's Institutional Review Board (IRB) senior leadership in the Center for Tobacco Products, 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

FDA plans to use the data collected under this generic clearance to better understand consumers' responses to tobacco related topics and concepts. Data may also be collected to better understand consumers' behavior, knowledge and attitudes about tobacco products, including testing of tobacco communication and post-marketing surveillance of tobacco products. Data collected under this generic will inform the regulatory science base and the development of FDA's public education campaigns and other materials directed at consumers. The data will not be directly used for the purposes of making policy or regulatory decisions.

[1] National Cancer Institute (NCI). Making Health Communications Work: A planner's guide, Pink Book. Pub. No. T068. Washington, DC: U.S. Department of Health and Human Services (HHS), August 2004.

Screening for inclusion in any specific collection will ensure that participants included represent the group needed for the specific collection. Screening may focus on age, tobacco use status, or other demographic and/or behavioral factors of individuals to ensure that the intended study population is included in the collection. For example, if testing public education materials targeted towards youth age 13-17 who are current cigarette smokers, then screening would ensure that youth age 13-17 who are current cigarette smokers are included in the collection, but a 24-year-old never smoker (for whom the public education materials are not intended) would not be included.

The information collected will add to the regulatory science knowledge base and may help FDA understand gaps in knowledge and attitudes about tobacco products, as well as behaviors and behavioral intentions for tobacco use. This information can help to inform communication directed at consumers. Further, quantitative research can give FDA information about the perceived effectiveness and reactions to messages, advertisements, and materials in reaching and successfully communicating with consumers.

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[2] and is not retained; and
- Information gathered will not be used for substantially informing influential policy decisions.[3]

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 study instrument, experimental stimuli). Before submission to

[2] 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.
[3] 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."

OMB, individual collections will undergo review by FDA's IRB, senior leadership in the Center for Tobacco Products, and PRA specialists.

3. Use of Information Technology and Burden Reduction

As computer technology has continued to improve and become more widespread, opportunities to implement web-based data collection via the internet have increased. Thus, wherever possible, FDA will make use of web-based data collection methods when collecting quantitative data. Using computer-assisted information technology to transmit data collection instruments and/or collect responses will continue to reduce the burden on respondents. For example, respondents can access and respond to data collection requests at a time and place that is convenient to them, eliminating the need to travel for survey administration.

Web-based data collections, including those using experimental designs, are an especially convenient option for eliciting feedback on visual stimuli. With web-based surveys, respondents complete an online survey and then submit the data electronically over the internet. Closed-ended questions (e.g., multiple-choice items, Likert scales) will be employed whenever possible. With 99 percent of 18-to-29-year old's indicating in of 2021 that they use the internet, [4] web-based surveys offer an especially useful way to solicit responses from young adults and adolescents and to assess the relative efficacy of alternative message presentations. Approximately 90 percent of respondents will respond to this collection of information electronically.

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 on the use of tobacco will be diverse and vary by target audience, new data collection instruments generally will be prepared for each quantitative study.

Therefore, each set of 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.

[4] Internet/Broadband Fact Sheet. Pew Research Center, April 7, 2021 https://www.pewresearch.org/internet/fact-sheet/internet-broadband/, accessed on July 22, 2021

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. Consequence of Collecting the Information Less Frequently

FDA is using a variety of media 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. Continued quantitative research is also needed to assess the continued relevance of such messages given dynamic social and environmental factors and the changing education and information needs of the public. Without quantitative testing and data collections, FDA cannot fully ensure that tobacco messages and materials directed at consumers are serving their intended purpose. As a result, the FDA could spend a large amount of money on communications that are ineffective in achieving the intended purpose of reducing tobacco-associated costs to people's lives and to the government. Further, quantitative research is often necessary to track changes in response to policy and regulatory actions.

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

Generally, studies under this collection rely on quantitative methods and use convenience samples rather than probability samples. As a result, the results are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters. However, some studies submitted under this generic may use panels that may yield nationally representative results. When probability samples are employed (such as through an online panel), representative estimates to the national population will not be made.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside 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 March 5, 2021 (86 FR 12952). FDA received one comment that was PRA-related.

Comment: The comment suggested specific types of messages that FDA should test and the implement in public health campaigns.

Response: FDA appreciates the comment. The content and focus on studies submitted through this generic clearance will depend on agency priorities and needs, which are not yet determined at this time.

9. Explanation of Any Payment or Gift to Respondents

It is standard practice in commercial market research to offer recruited respondents some form of remuneration for the time they spend engaged in a personal interview activity. Instances for offering a small incentive will be determined on a case-by-case basis (depending on the information collection design). Small amounts of money may be offered as an incentive for participation in in-person interviews. FDA will provide a rationale in the justification memo for any studies that propose to offer incentives for participation.

10. Assurance of Confidentiality Provided to Respondents

In developing this study, 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 study. FDA designed the study to minimize privacy risks in keeping with the Fair Information Practice Principles (FIPPs) and applying controls selected from the National Institute of Standards and Technology (NIST), Special Publication 800-53, Security and Privacy Controls for Federal Information Systems and Organizations. CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. FDA submitted a Privacy Impact Assessment to the privacy office that has been approved by the Department of Health and Human Services (PIA Unique Identifier: P-9008729-198376).

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 during the enrollment/screening process. Mailing address and/or e-mail addresses may be collected for contacting the respondent regarding enrollment details (e.g. directions, schedule). PII will be collected during the screening process to assess study eligibility. PII collected as part of the respondent enrollment will not be maintained or linked to other study information. Contractors and subcontractors that collect data on behalf of CTP are contractually prohibited from passing along any PII, and at the most FDA receive ID numbers. For these collections, FDA does not have any systems to maintain or retrieve PII.

For data quality management, PII in the form of audio recordings (biometric identifiers) 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 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.

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 incentive 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 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 that 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. That PII may be is 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 3rd parties share PII gathered via this collection with any other individuals or entities.

All PII subjects 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. FDA sponsorship when appropriate (in some cases, FDA sponsorship 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.); and that participation is voluntary at all times.

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 voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection or to any particular questions.

Data Security
Contractors are required to maintain appropriate administrative, technical and physical safeguards to ensure the security and confidentiality of records. User roles and responsibilities

will determine the type and content data and information necessary for job function (both PII and non-PII). Role-based access will determine and control who will 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 any other agency will have access to this information.

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. Interviews are typically considered exempt from the "Regulations for the Protection of Human Subjects" in accordance with 45 CFR 46.101(b)(3).

Before data are collected, FDA researchers will obtain either an exemption or approval for the research from FDA's Institutional Review Board (IRB) or an external accredited 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 an 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. Other appropriate controls have been selected from the National Institute of Standards

and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

11. Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. Efforts to match characteristics may require asking a question about race/ethnicity, income, education 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 OMB Statistical Policy Directive No. 15, October 1997 (https://www.whitehouse.gov/wp-content/uploads/2017/11/Revisions-to-the-Standards-for-the-Classification-of-Federal-Data-on-Race-and-Ethnicity-October30-1997.pdf).

Because these data collections may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. Fears of heart disease and cancer and experiences with both may also be covered. Graphic displays of negative health outcomes (e.g., cancerous lung tissue, gum disease and tooth loss) may also be presented as stimuli to assess the ability of such displays to encourage current tobacco users to quit or prevent non-tobacco users from initiating use. This information is needed to gain a better understanding of the target audience 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. As noted in section A.10., 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 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 illegal for minors in some states.

Raw data from data collections that may include sensitive information (for example, screening questionnaires) 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

Table 1 provides an estimate of anticipated burden levels that may be incurred during a 3-year period.

Table 1. -- Estimated Annual Reporting Burden

Survey Type	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Screener	485,580	1	485,580	0.083 (5 minutes)	40,465
Self-Administered Surveys	133,728	1	133,728	0.33 (20 minutes)	44,576
Total					85,041

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The mean average hourly compensation for this group is $27.07.[5] The estimated annualized annual cost for the general public in this information collection for 85,041 hours of reporting time is $2,302,059.87. The number of respondents and length of response was determined based on FDA prior experience with communications testing and an estimate of the communication needs of the Center for Tobacco Products. The actual numbers will vary depending upon the topic of interest.

	Total Burden Hours	Average Rate	Total Respondent Cost
Screener	40,465	$27.07	$1,095,387.55
Self-Administered Surveys	44,576	$27.07	$1,206,672.32
Total			$2,302,059.87

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 information collection.

14. Annualized Cost to the Federal Government

[5] U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, May 2020.

Costs will also include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, 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, in a given year, it is anticipated that approximately $500,000 in contractor expenses will be expended to fund at least two large scale study 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 personnel cost of $48.35 per hour, an estimated $25,238.70 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is $525,238.70 (which is equal to the total of contractor expenses ($500,000) plus FDA government staff salary cost ($25,238.70)).

15. Explanation for Program Changes or Adjustments

The burden for this information collection is proposed to increase by 60,000 hours from the current inventory. The burden increase is result of an increase in the number of new quantitative studies that are anticipated underneath this information collection during the next three years.

16. Plans for Tabulation and Publication and Project Time Schedule

The process for conducting quantitative research includes the following steps: first, the objectives are discussed, next the analytic questions to be addressed are determine, then the procedures, instruments and data analysis plan are developed. The analyses conducted for each quantitative research study will be determined by the objectives, the data being collected, and the characteristics of the participants. Specifics of the analyses cannot be determined until the survey instrument is developed.

Techniques include primarily quantitative analyses using descriptive statistics. Descriptive statistics — including percentages, cross tabulations, and averages — will be calculated and presented, along with demographic descriptions of study respondents. Information collected from study participants will be subjected to subgroup analyses to uncover potential differences among key groups (defined by gender, age, race/ethnicity, etc.). Inferential statistical analyses may also be conducted using cross-tabulation procedures with categorical variables (e.g., chi-square) and between-group procedures with continuous variables (e.g., ANOVA and t-tests). Parametric statistical tests will be used in the case of sufficient sample sizes, normal distributions, and continuous or interval data; nonparametric procedures will be used otherwise. All the analyses will be done in the context of understanding the limitations of the data with respect to their not representing population parameters.

While the primary purpose of quantitative research is to provide information to FDA, FDA may make the results available to a variety of health program planners at Government agencies, voluntary organizations, health professional organizations, and medical institutions. In addition, FDA may present the findings of its work at professional association meetings, including those of the American Public Health Association. Some results may be published in professional journals such as the *Journal of Public Policy and Marketing* and *Tobacco Control*. In any findings presented at professional association meetings or in professional journals, FDA will state the limitations of the data by recognizing the qualitative and non-representative nature of its pretests.

Specific timelines associated with the individual quantitative research projects are not known at this time. While data collection period varies somewhat depending on the complexity of the design and number of respondents required, the typical study will require approximately 12 weeks from initial design to preparation of the report of findings. A schedule for a typical data collection is shown below:

Project Time Schedule

Activity	Time Schedule
Finalize materials	1 week after OMB approval
Finalize design	3 weeks after OMB approval
Collection of data	5 weeks after OMB approval
Analysis of data	10 weeks after OMB approval
Report	12 weeks after OMB approval

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 involve no exception to the Certification for Paperwork Reduction Act Submissions.