

**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 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. Also, 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. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Further, the FD&C Act also authorizes FDA to conduct educational and public information programs (21 U.S.C. 393(d)(2)(D)). The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product as subject to FDA regulatory authority (deeming) (section 901(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to other newly regulated products (81 FR 28973). In addition to regulating the manufacture, distribution, and promotion of tobacco products, 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 those for whom they are intended, FDA's Center for Tobacco Products will conduct research and 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 formative research on these newly deemed tobacco products. FDA is requesting approval of this extension for collecting information through the use of qualitative methods (i.e., individual in-depth interviews (IDIs), small group discussions, and focus groups) 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, and feelings. This information will be used to inform the regulatory science 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. This information may also be used to help develop communication messages and educational campaigns related to public health.

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 Research Involving Human Subjects Committee (RIHSC) and/or a defer to the contractor'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 Collection

In conducting studies relating to the control and prevention of tobacco-related disease, FDA will need to employ qualitative research, including individual in-depth interviews (IDIs), small group discussions, and focus groups to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve two major purposes. First, it will provide critical knowledge about target audiences. FDA must first understand people's knowledge and perceptions about tobacco-related topics prior to developing survey/research questions, stimuli for experimental studies, and draft communication messages directed at consumers. Second, initial testing will allow FDA to assess consumer understanding of survey/research questions and draft messages. These 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 while they are still in the developmental stage. FDA will collect, analyze, and interpret information gathered through this generic clearance in order to (1) better understand characteristics of the target audience—its 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;
- Personally identifiable information (PII) is collected only to the extent necessary¹ and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;² and
- Information gathered will yield qualitative information; 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.

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.

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."

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 FDA's RIHSC, senior leadership in the Center for Tobacco Products, and PRA specialists.

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

- Focus groups or small group discussions, which may include 2 to 12 participants
- Individual in-depth interviews (IDIs)
- Moderated, un-moderated, in-person, and/or remote.-

3. Use of Improved Information Technology and Burden Reduction

Consideration will be given to collecting information electronically or using online collaboration tools to reduce burden. However, the applicability of such tools to in-person interviews and/or discussions is at present relatively unlikely, since the quality and level of detail in qualitative data collection would be difficult to obtain via virtual data collection methods. A recent [study³](#) found that virtual focus groups may be better to reach less healthy populations, but did not reduce costs or result in faster recruitment than in-person groups. Therefore, due to the nature of qualitative research, approximately 5 percent of these information collections will be completed 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, 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.

³ Rupert, D. J., Poehlman, J. A., Hayes, J. J., Ray, S. E., & Moultrie, R. R. (2017). Virtual versus in-person focus groups: Comparison of costs, recruitment, and participant logistics. *Journal of Medical Internet Research*, 19(3), [e80]. DOI: 10.2196/jmir.6980

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 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 consumers. 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 testing, FDA cannot fully ensure that tobacco messages and materials directed at consumers 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 and will not be used for statistical purposes.

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 November 17, 2017 (82FR 54351). FDA received one comment by a private citizen that was PRA-related. The commenter stated that FDA should use the data we have collected in the past instead of collecting new information. The comment does not go in detail or provide any alternatives.

(Response) This collection is a valuable tool for conducting research. The studies FDA has conducted through this collection of information have been essential in assisting FDA meet its mission as a science-based agency and in its implementation of the Tobacco Control Act. Future submissions submitted under this generic clearance will continue to assist FDA in its mission to promote and protect public health.

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 particular information collection design). Small amounts of money may be offered as an incentive for participation in in-person interviews. Incentives for in-person activities, including cognitive interviews, and focus groups, will not be more than \$40 for 60 minutes or more than \$75 for in person focus groups of 90 -120 min. FDA will provide empirical evidence will be presented to justify proposed incentives beyond these standards. Lower incentives for Web-based or telephone focus groups will be offered. In certain instances of difficult-to-recruit populations, FDA may propose incentives at a higher rate if evidence is provided.

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. CTP submitted a privacy impact assessment which is under review with the FDA privacy office.

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 never pass along any PII, and at the most we receive ID numbers. For these collections, we don't have any systems where we maintain or retrieve PII. In most if not all our contracts we even specify that contractors cannot send FDA any PII.

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 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.

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 it's 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 as a whole 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 a full approval for all research from FDA’s Investigational Review Board (IRB), the Research Involving Human Subjects Committee.

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.gpo.gov/fdsys/pkg/FR-1997-10-30/pdf/97-28653.pdf>).

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 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.

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 illegal for minors in some states. Because questions are being 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 (9,293) are based on the number of collections we expect to conduct over the requested time frame for this clearance.

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden, by Anticipated Data Collection Methods

<u>Type of Interview</u>	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
In-Person Individual In-Depth Interviews	1,092	1	1,092	1.0	1,092
Indepth Interview Screener	1,800	1	1,800	0.083	150
Focus Group Interviews	4,701	1	4,701	1.5	7,052

Focus Group Screening	3,996	1	3,996	.25	999
Total					0

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The average hourly compensation for this group as of January 2018 is \$22.34 (BLS). The estimated annualized annual cost for the general public in this information collection for 9,293 hours of reporting time is \$207,605.62. The number of respondents and length of response was determined on the basis of 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

<u>Type of Interview</u>	Total Burden Hours	Average Rate	Total Respondent Cost
In Person Individual In-depth Interviews	1,092	\$22.34	\$24,395.28
Indepth Interview Screener	150	\$22.34	\$3,351
Focus Group Screener	999	\$22.34	\$22,317.66
Focus Group Interviews	7,052	\$22.34	\$157,541.68
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, rent meeting space, travel to conduct the groups, and provide respondents with minimum payment cost in the form of a token stipend.

Costs will 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 \$1 million 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 average personnel cost of \$50.69 per hour, \$26,460.18 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is \$1,026,460.18 (which is equal to the total of contractor expenses (\$1 million) plus FDA government staff salary cost (\$26,460.18)).

15. Explanation for Program Changes or Adjustments

FDA has updated the existing burden from 6,184 to an estimated 9,293 hours. This is based on our experience the last three years and forecasting the generics to be submitted during the next approval. Additionally, we have also updated the cost burden estimate and the cost to the Federal government based on current salary figures.

FDA is also noting that the burden figures in ROCIS (24,050 responses and 29,059 hours) are incorrect. An error was made after approval and the updated burden was not entered into ROCIS. The burden should have been updated to 14,800 responses and 6,184 hours.

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, or communication activities.

FDA will disseminate the findings when appropriate, strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public," 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.