

Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

0910-NEW

Supporting Statement

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 (Attachment 1), 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 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. Section 393(d)(2)(D)). 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 and related FDA offices 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)) (Attachment 3). FDA is requesting approval of this new generic for collecting information through the use of quantitative methods (i.e., surveys, experimental studies) for studies about tobacco products. These studies will consist of self-administered surveys that may be used to collect information related to the formative pretesting of tobacco communication messages and other materials directed at consumers to help develop communication messages and campaigns. 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.

Quantitative research aligns with Agency objectives. One of the eight science priority areas for FDA is to “strengthen social and behavioral science to promote informed decision-making about FDA-regulated products.”¹ Quantitative research would play a large role in meeting this goal as it calls for identifying gaps in key areas of knowledge and in reaching diverse audiences, assessing knowledge and perceptions about tobacco-related topics with specific target audiences, evaluating the effectiveness of FDA’s risk communication, and integrating knowledge from research and evaluation into practice. Recently, FDA’s Commissioner and Deputy Commissioner asserted that “one of the greatest challenges facing any public health agency is that of risk communication.”² With tobacco as the most recent addition to the list of FDA-regulated products, the Agency fully intends to integrate formative pretesting into its risk communications on the use of tobacco products. Further, on September 22, 2006, the Institute of Medicine (IOM) released the report *The Future of Drug Safety: Promoting and Protecting the Health of the Public*. IOM’s report highlighted the importance of communication, referencing FDA’s mission of “helping the public get the accurate, science-based information they need...” to use FDA-regulated products to improve health.

FDA requests Office of Management and Budget (OMB) approval for a generic clearance to collect quantitative information related to the testing and development of tobacco communication messages and other materials directed at consumers collected via self-administered surveys. . 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 cover information collection activities ,to test and develop communication messages and other materials directed to consumers 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.³

FDA will submit individual collections under this generic clearance to OMB. Before submission to OMB, individual collections will undergo review by FDA’s Research Involving Human Subjects Committee (RIHSC), 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.

¹ Food and Drug Administration. About Science & Research at FDA. Silver Spring, MD: U.S. Department of Health and Human Services (HHS), July 2013. Accessed from <http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm342936.htm>.

² Hamburg, M.A., and Sharfstein, J.M. The FDA as a Public Health Agency. *New England Journal of Medicine*, 360 (24), 2493-2495, June 11, 2009.

³ 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.

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 messages. Data collected under this generic will inform the development of communications, such as 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.

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 consist of self-administered surveys;
- 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 necessary⁴ and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;⁵

- Information gathered are intended to inform pretesting of tobacco communication messages and other materials directed at consumers; and
- Information gathered are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

⁴ 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.

⁵ 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."

To obtain approval for a collection that meets the conditions of this generic clearance, full Supporting Statements Part A and Part B will be submitted to OMB along with supporting documentation (e.g., a copy of the study instrument, experimental stimuli, consent forms/language). Before submission to OMB, individual collections will undergo review by FDA's RIHSC, 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 on-line 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 97 percent of 18 to 29 year olds indicating in January of 2012 that they use the Internet,⁶ 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.

⁶ Internet User Demographics. Pew Internet & American Life Project, January 9-12, 2014 <http://www.pewinternet.org/data-trend/internet-use/latest-stats/>, accessed on July 18, 2014

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.

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 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 expend a large amount of resources on communications 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

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.

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 July 17, 2014 (79 FR 41696). FDA received four comments. However, only two comments were considered responsive to the PRA-related questions.

(Comment) One comment was supportive of the information collection stating "We support CTP's proposal to conduct formative pretests to ensure that health communication messages are received, understood and accepted by the intended audiences" and that they believe the proposed information collection is necessary and will have practical utility. The comment stated that

CTP's projection of the burden of the proposed collection effort seems reasonable. In addition the comment suggested that FDA consult with FDA's Risk Communication Advisory Committee on proposed information collections.

(Response) FDA agrees that the request in this collection of information is necessary and that the proposed burden is reasonable. Consultation with other HHS agencies, FDA advisory committees, and/or the public will occur when appropriate.

(Comment) One comment was supportive of the data collection stating that such "collections are, in fact, essential." That comment also made suggestions about what the specific goals of messages tested in information collections included under this generic collection should focus on, and suggested that those collections be made available for further public comments

(Response) FDA agrees that the request in this collection of information is essential to the mission of the FDA as a science-based agency in its implementation of the Tobacco Control Act. Although we appreciate suggestions for the content of future submissions submitted under this generic clearance, ultimately such decisions will be driven by needs determined by FDA in consultation with other HHS agencies and the public when appropriate.

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 research 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 self-administered surveys. Incentive amounts for information collections submitted under this generic will typically not exceed \$20 for online surveys and \$40 for in-person surveys involving populations that are difficult to recruit online. FDA will provide empirical evidence in the justification memo for any studies that propose to offer rates within and beyond this range.

10. Assurance of Confidentiality Provided to Respondents

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 or 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);⁷ and the fact that participation is

⁷ 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.

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.

Only personnel from a contractor conducting the information collection will have access to individual-level data. All project staff from a contractor conducting the information collection must take required measures to ensure the privacy and anonymity of data. 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 preserved. Reports will be used only for research purposes and for the development of communication messages.

Communications testing efforts are typically reviewed by FDA IRB and are determined exempt from the “Regulations for the Protection of Human Subjects” in accordance with 45 CFR 46.101(b)(3) (Attachment 5). 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 involved in the research 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 (whether the child's parents will be with him or her etc)), an explanation of any risks and pain associated with the study, an explanation of any anticipated change in the child's appearance, and an explanation of the benefits to the child or others.

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 (<http://www.whitehouse.gov/omb/fedreg/1997standards.html>).

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. FDA estimates submitting four data collections annually for approval under this generic clearance for a total of 12 collections over a 3 year period. Each data collection is estimated to account for 5,400 respondents (64,800 for 3 years) and 1,782 hours (21,384 for 3 years). Annually the FDA estimates 21,600 respondents and 7,128 burden hours for this generic clearance.

Table 1.--Estimated Annual Burden

Survey Type	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Self-Administered	21,600	1	21,600	.33 (20 minutes)	7,128

Surveys					
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12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The average salary for this group is \$22.33.⁸ The estimated annualized annual cost for the general public in this information collection for 14,400 hours of reporting time is \$321,552. 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

Survey Type	Total Burden Hours	Average Rate	Total Respondent Cost
Self-Administered Surveys	4,8000	\$22.33	\$107,184

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

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, \$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)).

⁸ U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, June 2010.

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

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 determined, 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 of 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 the quantitative research in these studies are intended to provide information to FDA for the testing and development of communication materials, 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 that information gathered are intended to inform pretesting of tobacco communication messages and are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

The specifics of quantitative research 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

<u>Activity</u>	<u>Time Schedule</u>
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.