SUPPORTING STATEMENT

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

FDA's newly established Center for Tobacco Products will oversee 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. In addition to regulating the manufacture, distribution, and promotion of tobacco products, FDA's Center for Tobacco Products also intends to take the lead in communicating with the public on the health risks of tobacco use.

FDA's Center for Tobacco Products will 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. Section 393(d)(2)(D)) (Attachment 2). The Center for Tobacco Products will create and use a variety of media, including print (e.g., brochures, posters, fact sheets, information kits), broadcast (e.g., Public Service Announcements, video news releases), and electronic formats (e.g., Internet, listservs, CD-roms) to inform and educate the public, tobacco retailers, and health professionals about the risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco. Production of these materials will be the major way that FDA relays messages to its audiences.

To ensure that such health communication messages 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). In conducting such research, FDA will employ formative pretests. Formative pretests are conducted on a small scale. The focus is on developing and assessing the likely effectiveness of communications with specific target audiences. 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; and 2) pretesting these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions.

Formative pretesting is a staple of best practices in communications research. Obtaining feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program.[1] 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.

[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.

FDA must conduct formative pretesting to maximize the usefulness of its risk communications. Formative pretesting aligns with the major objective set forth by the Department of Health and Human Services (DHHS) to increase the proportion of health communication activities that include research and evaluation.[2] Formative pretesting also aligns with agency objectives. 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. More recently, FDA's Commissioner and Deputy Commissioner asserted that "one of the greatest challenges facing any public health agency is that of risk communication."[3] To that end, FDA has developed a strategic plan for risk communication. A major initiative of the strategic plan is the goal of strengthening the science that supports effective risk communication. By identifying gaps in key areas of public health knowledge, evaluating the effectiveness of communication messages, and integrating information gained through research/evaluation into practice, FDA will help ensure that the public has the information they need about FDA-regulated products. With tobacco as one of the most recent additions 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.

FDA requests OMB approval for a generic clearance to collect information related to the formative pretesting of tobacco communication messages. To coordinate efforts, FDA proposes that this generic clearance cover all information collection activities for tobacco risk communications conducted by either the Center for Tobacco Products or other FDA offices. FDA intends to utilize best practices for effective health communication research set forth by other DHHS agencies such as the National Cancer Institute.[4]

Approval is requested for 30 studies using methods described in section B with respondents from target audiences. The total number of respondent burden hours will not exceed 2,860 annually. FDA will submit individual collections under this generic clearance to OMB. Before being submitted to OMB, individual collections will undergo rigorous review by FDA's Research Involving Human Subjects Committee (RIHSC), senior leadership in the Center for Tobacco Products, and Paperwork Reduction Act Specialists. OMB will, in turn, provide feedback on the individual collections within ten working days, whenever possible, as is currently the case. FDA will send OMB an annual report at the end of each year summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance.

[2] U.S. Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000.
[3] Hamburg, M.A., & Sharfstein, J.M. The FDA as a Public Health Agency. New England Journal of Medicine, 360 (24), 2493-2495, June 11, 2009.
[4] 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.

A.2. Purpose and Use of the Information

FDA plans to use the data collected under this generic clearance to inform its tobacco communications campaigns. FDA expects the data to guide the formulation of its tobacco communication objectives. FDA also plans to use the data to help tailor print, broadcast, and electronic media communications in order for them to have powerful and desired impacts on target audiences. The data will not be used for the purposes of making policy or regulatory decisions.

The information collected will serve two major purposes. First, formative research will provide qualitative information about target audiences – their needs, decision-making processes, and misperceptions – that is critical to initial communications planning and development. Different formative research will have different foci, depending on the audience addressed and the questions needing to be answered to develop effective communications. For example, FDA must explore consumers' beliefs and perceptions about tobacco use to formulate the basic objectives of its risk communication campaigns. To effectively inform consumers about the risks of tobacco use, FDA must understand critical influences on people's decision-making process when choosing to use, not use, or quit using tobacco products. Qualitative information on decision-making processes will also give FDA a better understanding of the needs of its different target audiences. For example, it is critical that FDA understand the decision-making processes of both adults and adolescents (ages 13 to 17). For the former, communication will likely focus on quitting, whereas for the latter, communications will likely aim to discourage tobacco use before it starts.

FDA must also understand the general beliefs of retailers in the tobacco product supply chain. Retailers play a key role in the success of tobacco control as they are directly impacted by many of the regulations FDA will issue under the Tobacco Control Act. FDA must determine retailers' informational needs and the most effective communication channels and formats for reaching and educating them about new regulations. This information will allow FDA to engage retailers as partners in tobacco control by better equipping them with the tools needed to comply with these regulations.

Finally, FDA must understand general beliefs about the consequences of the Tobacco Control Act and FDA's role in tobacco control. The legislation was very clear in Section 1, paragraph 46 that one potential consequence of the law could be that inspection or approval by the FDA might be misconstrued to suggest that tobacco products are safe or endorsed by the FDA. Formative research can provide information about the prevalence of Tobacco Control Act misperceptions.

Second, initial testing will give FDA some information about the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Pretesting messages with a sample of the target audience will allow FDA to refine messages while they are still in the developmental stage. Respondents may be asked to give their reaction to the messages in individual or group settings.

- *Attention* - The extent to which factors such as language, placement, typography, and graphic images attract and hold the audience's attention.
- *Comprehension* – The extent to which communication messages clearly convey risks, both in terms of the needs of low-literacy audiences and with respect to plain language principles and design.
- *Personal Relevance and Self-efficacy* – Perceptions that communication messages apply to target audience members personally, that the information is considered important, and that target audience members feel they are capable of acting on the message.
- *Credibility* – Perceptions that communication messages are credible and are being issued by a trustworthy and knowledgeable source.
- *Acceptability* – Detection of negative reactions and the extent to which target audience members find communication messages to be offensive, unacceptable, or culturally insensitive.
- *Behavioral Intent* – The extent to which respondents think they will take action (i.e., stop or not start using tobacco products) as a result of seeing the communication messages.

Respondents' input and reactions to each of these areas provide insight into how target audiences may react and how the messages should be formulated or revised to communicate most effectively. Other information gathered on respondents' gender, age, socioeconomic level, race/ethnicity, and personal/family tobacco use provides a basis for evaluating whether the messages may be perceived differently by various segments of the audience. For example, selected age groups may find a particular message or graphic image more compelling than other age groups.

Systematic formative pretesting has been widely adopted by health education program planners as an integral step in the development and targeted dissemination of messages and materials. Through pretesting FDA is able to:

- Better understand characteristics of the target audience–its attitudes, beliefs, and behaviors–and use these in the development of effective risk communications;
- Design messages and select formats that have increased potential to influence the target audience's attitudes and behavior in a favorable way;
- Help determine promotion and distribution channels to reach the target audience with appropriate messages; and
- Expend limited program resource dollars wisely and effectively.

Data collected under this generic clearance will also help inform the FDA's newly established Risk Communication Advisory Committee and would constitute a further effort to respond to the Institute of Medicine's recommendation in its September 2006 report *The Future of Drug Safety* that FDA improve its communications with the public.

A.3. Use of Information Technology and Burden Reduction

The information will be collected through one-on-one interviews, focus groups, or self-administered surveys, depending upon the target audience being questioned, expectations about whether the information will be evaluated in an individual or group context, and the need to present visual stimuli (e.g., graphic displays of negative health outcomes). As computer technology has continued to improve and become more widespread, opportunities to pretest messages on the Internet using either Web-based surveys or on-line focus groups have increased. 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 in-person or group interviews. Wherever possible, FDA will make use of Web-based data collection methods.

Improved technology in the collection and processing of data will be used to reduce respondent burden and make processing maximally efficient. Possible information technologies for formative pretesting include the following:

Computer-Assisted Telephone Interviewing (CATI)

Surveys conducted by telephone are well suited to the use of computer-assisted telephone interviewing technology. CATI's technological capabilities include automated dialing, scheduling unanswered calls or interrupted interviews for efficient callbacks, random selection of respondents, automated skip patterns, instantaneous out-of-range checks, insertion of information from one question to guide a subsequent question, and the automated generation of databases for subsequent analysis. When telephone interviews are used, CATI will be employed whenever possible.

Computer-Assisted Personal Interviewing (CAPI)

CAPI technology allows interviewers to ask questions of a respondent using a computer to enter data. Some primary advantages of CAPI include:

- The elimination of routing and looping problems within a paper-and-pencil questionnaire.
- Respondents and interviewers cannot accidentally skip questions.
- Interview questions are customized to account for personal information provided by the respondent (e.g., respondent's age, information from previous questions).
- CAPI software can automatically perform mathematical calculations and tabulations.
- CAPI software checks for inadmissible or inconsistent responses.
- CAPI allows interviewers to administer surveys to geographically isolated groups, respondents without telephones or Internet access, or other difficult-to-reach populations.
- CAPI eliminates errors that arise from separate data entry.

Audio and Computer-Assisted Self-Interviewing (ACASI)

ACASI software technology offers many advantages of CAPI technology, but removes the need to have a person administer an interview; instead, survey questions are pre-recorded and played back through the sound system of a computer, which the respondent can listen to privately by using headphones. Respondents select an answer by pressing a key that corresponds to one choice shown on the screen, after which answers are fed directly into a computer database. ACASI surveys can also be administered over a telephone by entering the response on the telephone keypad. ACASI technology is particularly useful in administering surveys to low-literacy populations or when addressing sensitive topics that respondents may not feel comfortable discussing in the presence of someone else.

Web-based Surveys

Web-based surveys, 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 92% of 18 to 29 year olds indicating in April of 2009 that they use the Internet, [5] 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.

Videoconferencing

Videoconferencing uses video and satellite technology to allow a group of focus group participants located in multiple geographic locations to interact with one another both visually and aurally. A facilitator and a technical team located in a hub site maintain the video and audio connections among participating sites.

Internet conferencing

Internet conferencing is especially useful for discussions with specific individuals or international participants. This format functions as a sort of "chat room" in which a moderator intercepts and distributes e-mail transmissions from participants who have logged onto a specially designated Web site.

Teleconferencing

Teleconferencing uses telephone technology to facilitate an exchange among participants located in multiple geographic locations. Participants dial into a specially designated phone number or "bridge line" that is moderated by a focus group facilitator.

[5] Usage Over Time. Pew Internet & American Life Project, July 15, 2009, http://www.pewinternet.org/Trend-Data/Usage-Over-Time.aspx, accessed on October 6, 2009

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

As each new communication message or strategy is developed, FDA reviews existing literature and databases, including pretesting reports on existing messages and materials. FDA also consults with outside experts to evaluate available information on similar messages with comparable audiences. In addition, FDA will be working with both CDC and NCI, the two other key government agencies responsible for communicating about tobacco use with the general public.

However, because risk communications on the use of tobacco will be diverse and vary by target audience, new data collection instruments generally will be prepared for each pretest. The areas in which pretesting of effective tobacco communication messages will be needed (as described in A.2. above - attention, comprehension, etc.) are generally similar from pretest to pretest. However, the specific questions that are asked of respondents will differ with the message content, target audiences, and medium of the message.

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

These proposed data collection activities are likely to focus primarily on people in their roles as individuals during their own time. However, FDA expects that required regulations will have significant impact on retail sellers of tobacco products, many of which are small businesses. Consequently, it is especially important that FDA communicate effectively with this group about the meaning, and legal and other ramifications, of the regulations. Since any message testing with individuals who are employed by or own small businesses would be completely voluntary, FDA believes that the likely impact on such businesses would be minimal. FDA also believes that the minimal time spent responding to questions would be balanced by the value of their receiving information that is more likely to be responsive to their needs.

A.6. Consequence of Collecting the Information Less Frequently

FDA plans to use a variety of media messages and materials to inform and educate the public about the risks of tobacco use. During these first few pivotal years of tobacco regulation, it is critical that FDA invest the time and resources into strategic risk communication. Sound research and evaluation are needed as integral parts of initial program design rather than as afterthoughts to program implementation. Unless the public is able to effectively use FDA communications to make appropriate choices, FDA will not be serving the public as mandated.

Communicating effectively about the risks of using tobacco products involves conveying complex concepts. Without pretesting, FDA cannot fully ensure that tobacco messages are serving their intended purpose. As a result, FDA could be spending millions of dollars on communications that are ineffective in achieving the intended purpose of reducing tobacco-associated costs to people's lives and to the government. FDA recognizes that risk communication requires more than ensuring the accuracy of product labeling. FDA must effectively assess whether tobacco communication messages are appropriately reaching targeted audiences in an understandable fashion and being incorporated into their belief structures and

their behaviors. Continued pretesting 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.

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

Because FDA's formative pretesting activities will be primarily qualitative in nature, the results are not generalizable to the population at large or the particular target audience under study. However, the nature of pretesting is such that generalizability is not a critical feature; the emphasis is on obtaining timely, useful information that can be fed back into the development of new messages or materials or the revision of existing ones. There are no other special circumstances.

A.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 in the FEDERAL REGISTER of March 1, 2010 (75 FR 9225; Docket No. FDA-2010-N-0084). FDA received comments from four public entities, including two corporations, one nonprofit organization, and one city health department. Comments supported FDA taking a science-based approach to its communication activities. None of the comments objected to the estimated annual reporting burden or questioned the practical utility of the information to be collected.

FDA acknowledges one request for additional details on the information to be collected and the planned research methodology, but notes that its notice asked for comment on FDA's request for a generic clearance to collect information related to the formative pretesting of tobacco communication messages. Under this generic clearance, details of individual studies will be tailored to specific formative communications-related questions. For each study FDA would request under this clearance, FDA will provide OMB with details on the information collection, including the specific research question(s) and methodology(ies) involved. The communication development process will inform the purpose of the data collection and hence its methodology. For very early message development, purely qualitative research such as focus groups or in-depth interviews will be appropriate. At later communications development stages, more quantifiable methodologies, such as structured web-based surveys or experiments might be more informative.

One comment noted that FDA separately requested comment on a specific study of the efficacy of graphic cigarette warning labels (Docket No. FDA-2010-N-0079). In response to this comment, and to avoid apparent duplication of effort, FDA agrees that it will not conduct any pretesting of tobacco warning labels under this proposed generic clearance. Further, FDA will not use studies conducted under this generic clearance to make regulatory policy or enforcement decisions. However, FDA may conduct research concerning the development of informational campaigns related to warning labels.

After careful consideration, FDA determined that limiting pretesting to adults to minimize the burden of information collections on the public, as suggested by one comment, would reduce the utility of study results. This suggestion goes against commonly accepted communication practice, and the advice of FDA's Risk Communication Advisory Committee, to target intended audiences with messages tailored to their specific needs. Segmenting pretesting by audience will produce results that will better inform FDA's development of messages relevant to intended audiences' specific needs, beliefs, and attitudes. A major objective of FDA tobacco communications will be to discourage tobacco use by adolescents before they start. Therefore, it is critical that FDA understand the decision-making processes among 13 to 17 year olds. Also, the suggestion to eliminate the pretesting of messages delivered across multiple platforms (e.g., television, print, radio) ignores a fundamental research goal of matching appropriate messages with effective distribution channels. Limiting pretesting in this way would leave FDA to base its communication activities on assumptions rather than science-based research.

A.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 pretest 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 (where appropriate, $20 or less) may be offered as an incentive for participation in in-person interviews.

As standard practice in commercial market research, and as has been approved by OMB in the past, focus group participants may be offered an incentive at a regionally appropriate market rate (usually $50 to $75) as remuneration. FDA will provide a rationale in the justification memo for any studies that propose to offer rates out of this range. For example, incentives for Web-based or telephone focus groups may be offered at a lower rate. Incentives for difficult-to-recruit populations may be offered at a higher rate, with the upper bound at $300 for certain medical specialists.

Circumstances, however, do not always require that remuneration be given; many audiences including the public, patients, survivors, and some health professionals often participate *gratis* because of their interest or involvement in the topic, or as a professional courtesy.

A.10. Assurance of Confidentiality Provided to Respondents

Information provided by respondents will be kept private and anonymous, except as otherwise required 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[6]); and the fact that participation is voluntary at all times. Because responses are

[6] 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, 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 survey, interview, or focus group 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; 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.

Pretesting efforts described in this proposal are typically considered exempt from the "Regulations for the Protection of Human Subjects" in accordance with paragraph (b)(3) of 45 CFR Sec. 46.101 (Attachment 5). Before data are collected, FDA researchers must obtain either an exemption or a full approval for all research from FDA's 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 shall determine whether adequate provisions are made for soliciting assent. Generally, assent requires securing the signature of a minor to the research 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 they will experience (whether they will be in the hospital, 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.

A.11. Justification for Sensitive Questions

As mentioned in sections A.2. and A.10., some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. This 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 FDA tobacco communications 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. In the event that questions are asked of teenagers (ages 13 to 17), interviews will be conducted by moderators specifically trained for interaction with adolescents.

Raw data from data collections that 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.

A.12. Estimates of Annualized Burden Hours and Costs

The number of respondents to be included in each new pretest will vary, depending on the nature of the material or message being tested and the target audience. However, for illustrative purposes, Table 1 provides examples of the types of studies that may be administered and estimated burden levels that may be incurred during each year of the three-year period. Time to read, view, or listen to the message being tested is built into the "Hours Per Response" figures. Proposed data collection methodologies are described in more detail in Section B.

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

	Number of Respondents	Frequency of Response	Hours Per Response	Total Hours
Individual In-Depth Interviews	360	1	.75	270
General Public Focus Group Interviews	144	1	1.5	216
Intercept Interviews: Central Location	600	1	.25	150
Intercept Interviews: Telephone	10,000*	1	.08	800
Self-Administered Surveys	2,400	1	.25	600
Gatekeeper Reviews	400	1	.50	200
Omnibus Surveys	2,400	1	.17	408
TOTAL (General Public)	16,304			2,644
Physician Focus Group Interviews	144	1	1.5	216
TOTAL (Physician)	144			216
TOTAL (Overall)	16,448			2,860

* Brief interviews with callers to test message concepts and strategies following their call-in request to the FDA Center for Tobacco Products 1-800 number.

Unlike surveys of establishments, which can require detailed record keeping to provide responses to very specific survey questions, the aim of formative pretesting research is to collect attitude and opinion data from individuals. There is no annual cost to respondents to collect the information.

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

No capital or start-up costs will be incurred as a result of these information collection activities.

A.14. Annualized Cost to the Federal Government

Costs will include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, training interviewers, collecting and analyzing information, and reporting and disseminating findings. Because this request for generic clearance includes various procedures for the collection of information, contractor expenses may vary from an estimated $20,000 for a small focus group study to an estimated $125,000 for a telephone or Web-based survey. Therefore, in a given year, it is anticipated that approximately $200,000 in contractor expenses will be expended to fund at least 1 large scale study and 3 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% 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 $225,238.70 (which is equal to the total of contractor expenses [$200,000] plus FDA government staff salary cost [$25,238.70]).

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The process for developing the analytical plan for the pretest is similar to that used in any formal evaluation. Staff review the material to be pretested, discuss the objectives with the individuals responsible for developing the materials, determine the analytic questions to be addressed in the pretest, and then prepare the pretest procedures, instruments, and data analysis plan. The analyses conducted for each pretest will be determined by the objectives of the pretest, the messages being pretested, and the audience for the messages. Specifics of the analyses cannot be determined until the messages to be pretested are prepared.

Techniques include primarily qualitative analyses (for example, content analysis for in-depth interviews), although some results, including those from central location intercept interviews or Web-based surveys, are summarized quantitatively using descriptive statistics. In cases where quantitative data is collected, 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.). Statistical analyses may 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; non-parametric 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 a pretest is to provide information to the developers of the messages for the purpose of improving them, FDA makes pretest 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 pretest work at professional association meetings, including those of the American Public Health Association and Drug Information Association. Some pretesting 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 nonrepresentative nature of its pretests.

The specific messages to be pretested and the timing of these messages are not known at this time. However, as indicated in section A.1., approximately 30 pretest studies are planned. While the pretesting period varies somewhat depending on the complexity of the testing and number of respondents required, the typical pretest will require approximately 12 weeks from initial design to preparation of the report of pretest findings. A schedule for a typical pretest 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 on pretest	12 weeks after OMB approval

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

The OMB expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

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