PRETESTING OF TOBACCO COMMUNICATIONS

0910-0674
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Abstract

In order to conduct educational and public information programs relating to tobacco use, as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(D)), and to develop stronger health warnings on tobacco packaging as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), it is beneficial for the Food and Drug Administration (FDA) to 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)). In this generic collection of information, FDA will use formative pretests to assess the likely effectiveness of tobacco communications with specific target audiences. The information collected will serve two major purposes: (1) It will provide the critical knowledge needed about target audiences and the decisionmaking process when choosing to use, not use, or quit using tobacco products, including adolescents (ages 13 to 17) where communications will aim to discourage tobacco use before it starts. (2) It will allow FDA to assess 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.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

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: provide information about target audiences and provide information about potential effective of communications with the intended audiences.

First, formative research will provide qualitative information about target audiences — their needs, decisionmaking 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 decisionmaking process when choosing to use, not use, or quit using tobacco products. Qualitative information on decisionmaking 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 decisionmaking processes of both adults and adolescents (ages 13 to 17). For adults, communication will likely focus on quitting; for adolescents, communications will likely aim to discourage tobacco use before it starts.

FDA must 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 affected 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.

FDA must also understand general beliefs about the consequences of the Tobacco Control Act and FDA's role in tobacco control. 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 misperceptions about the Tobacco Control Act.

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. 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 the Office of Management and Budget (OMB) for approval. 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 10 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.

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 FDA 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.

Failure to collect this information may result in communications from FDA being less effective to target audiences.

The respondents are individual adults or households, adolescents (ages 13 to 17) where communications will aim to discourage tobacco use before it starts, and retail establishments in the private sector.

3. Use of Improved 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). 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 may include computer-assisted personal interviewing, audio and computer-assisted self-interviewing, Web-based surveys, video conferencing, Internet conferencing, and teleconferencing. FDA estimates that 98 percent of the respondents will use electronic means to fulfill the Agency's requirement or request.

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 the Centers for Disease Control and Prevention and the National Cancer Institute, 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 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.

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 requirements of the 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.

6. Consequences 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. For 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. Thus, FDA could be spending millions of dollars on communications that are ineffective in achieving the intended purpose of reducing tobacco-associated costs for the public and 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. Given the dynamics of social and environmental factors and the changing education and information needs of the public, continued pretesting is needed to assess the continued relevance of such messages.

Surveys and interviews of the targeted audience will generally be a one-time collection.

There are no legal obstacles to reduce the burden.

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 used in the development of new messages or materials or the revision of existing ones. There are no other special circumstances.

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 in the FEDERAL REGISTER of August 17, 2012 (77 FR 49819). Three comments were received, which included one comment that was not PRA-related and beyond the scope of this document and one comment that was in full support of pretesting tobacco communications. The third commenter indicated that the authorizing statute was incorrectly identified. The correct authorizing statute is section 1003(d)(2)(D) of the FD&C Act. The commenter also indicated that there was not enough information provided about the design and methodology of the pretests and the studies to effectively comment on the collection of information. In response, the information collection is for a broad spectrum of pretests and studies using a variety of methodologies and is dependent on the material being tested and the target audience. In addition, OMB will review each collections design and methodology prior to approval for use.

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.

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[1]); 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.

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 45 CFR 46.101(b)(3) (Attachment 5). Before data are collected, FDA researchers must obtain either an exemption or a full approval for all research from FDA's institutional 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 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 the child will experience (whether the child 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.

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

[1] 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.

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 nontobacco 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 participants 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.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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 Part B. 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. FDA estimates the burden of this collection of information as follows:

Table 1

Estimated Annual Reporting Burden

	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[1]	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

[1] 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.

12b. Annualized Cost Burden Estimate

There are no annual costs to respondents to collect the information.

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 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 one large scale study and three 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 $225,238.70 (which is equal to the total of contractor expenses $200,000 plus FDA government staff salary cost $25,238.70).

15. Explanation for Program Changes or Adjustments

This is a request for an extension without change. The burden has not changed from the burden in the current inventory.

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 members 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; 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 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, 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

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

The Agency is not seeking approval to not display the expiration date of OMB approval for these information collections.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.