Testing Communications on Medical Devices and Radiation-Emitting Products

0910-0678

ABSTRACT FOR USE IN ICRAS

This generic ICR collects information through a variety of research methods for developing and testing communications involving medical devices and radiation-emitting products that are regulated by FDA. The information will be used to assess the need for communications on specific topics and to assist in the development and modification of communication messages to promote public health and compliance with regulations.

FDA creates and uses a variety of media, including print, broadcast, and electronic formats to communicate with the public and health professionals about the risks and benefits of regulated products. 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 will conduct research and studies relating to the control and prevention of disease. This type of research involves (1) assessing audience knowledge, attitudes, behaviors and other characteristics for the planning/development of health messages, communication strategies, and public information programs; (2) testing these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions; and (3) evaluating the final communication products to determine the effectiveness of the messages and distribution methods.

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SUPPORTING STATEMENT

Terms of Clearance: OMB approves this umbrella generic ICR, with the understanding that FDA will submit each individual IC into ROCIS for approval. Justification must be provided for the collection of any personally identifiable information.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is seeking approval from the Office of Management and Budget (OMB) for the generic clearance, Testing Communications on Medical Devices and Radiation-emitting Products. FDA is the regulatory agency responsible for the safety and effectiveness of medical products including biologics, drugs, foods, cosmetics, medical products, radiological products, and animal drugs. The purpose of the information collection is to provide tools to assess the need for communications on specific topics and to assist in the development and modification of communication messages to promote public health and compliance with regulations. FDA is requesting approval for collecting information through a variety of research methods for developing and testing communications involving medical devices and radiation-emitting products that are regulated by FDA.

Section 505 of the Federal Food, Drug, and Cosmetic Act (the 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 act. Further, the act also authorizes FDA to conduct educational and public information programs (21 U.S.C. Section 393(d)(2)(D). Finally, FDA is authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of regulated products.

The Food and Drug Administration (FDA) is requesting approval for collecting information through a variety of research methods for developing and testing communications involving medical devices and radiation-emitting products that are regulated by FDA. This information will be used to assess the need for communications on specific topics and to assist in the development and modification of communication messages.

FDA creates and uses 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 communicate with the public and health professionals about the risks and benefits of regulated products.

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 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). This type of research involves 1) assessing audience knowledge, attitudes, behaviors and other characteristics for the planning/development of health messages, communication strategies, and public information programs; 2) testing these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions; and 3) evaluating the final communication products to determine the effectiveness of the messages and distribution methods.

Testing messages 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 early testing is to improve materials and strategies while revisions are still affordable and possible. Testing 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 communication messages need to be modified should be greatly reduced.

FDA must conduct testing to maximize the usefulness of its risk communications. Message testing 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] Testing also aligns with FDA's 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 knowledge gained through research/evaluation into practice, FDA will help ensure that the public has the information they need about FDA-regulated products.

FDA requests OMB approval for a generic clearance to collect information related to the testing of communication messages on the safety of medical devices and radiation-emitting products. To coordinate efforts, FDA proposes that this generic clearance cover all information collection activities for medical devices and radiation-emitting products communications conducted by the

[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.

[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.

Center for Devices and Radiological Health 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 up to 23 tests of communication messages using methods described in section B with respondents from target audiences. The total number of respondent burden hours will not exceed 2,076 annually. FDA will submit individual requests for approval under this generic clearance into OMB's ROCIS tracking system. Before being submitted to OMB, individual collections will undergo rigorous review by FDA's Research Involving Human Subjects Committee (RIHSC), senior leadership within the Center from which the proposal arose, 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 with other generic clearances

A.2. Purpose and Use of the Information

FDA plans to use the data collected under this generic clearance to inform its medical device communications campaigns. FDA expects the data to guide the formulation of its communication objectives on medical devices and radiation-emitting products. 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 using medical devices to formulate the basic objectives of its risk communication campaigns. To effectively inform consumers about the risks and benefits of use of medical devices, FDA must understand critical influences on people's decision-making process when choosing to use, not use, or stop using medical devices and radiation-emitting products. Qualitative information on decision-making processes will also give FDA a better understanding of the needs of its different target audiences.

FDA must also understand the general beliefs of physicians and healthcare adjuncts. Prescribers and technicians, including nurses, play a key role in the use of medical devices. FDA must determine their informational needs and the most effective communication channels and formats for reaching and educating them about new warnings and guidelines. This information will allow FDA to engage healthcare professionals as partners in safe and effective use of medical devices and radiation-emitting products.

[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.

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. Testing 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. Initial testing may provide information on any of the following factors.

- *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 (for example, maintain radioactive technology according to specifications) 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 use of medical devices 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 communications testing has been widely adopted by health education program planners as an integral step in the development and targeted dissemination of messages and materials. Through communications testing 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.

The targeted population to respond to the particular questions, and the specific questions, will change depending on the particular topic in question.

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 telephone or in-person 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 test 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 testing 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

[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

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.

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 testing 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 DHHS, AHRQ, CMS, as well as other government agencies that are responsible for communicating about use of medical devices with population segments or the general public.

However, because risk communications on the use of medical devices and radiological products will be diverse and vary by target audience, new data collection instruments generally will be prepared for each project. The areas in which testing of effective communication messages will be needed (as described in A.2. above - attention, comprehension, etc.) are generally similar from project to project. 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 will focus primarily on subjects in their roles as individuals during their own time. In some instances we might want to question hospital or other healthcare facilities staff. In most cases, we believe that such facilities are very unlikely to include small businesses, and we will strive to avoid including small businesses unless they are a targeted audience. If we believe that employees of small businesses should be examined, we will ensure understanding that the information collection is completely voluntary. We anticipate the burden on small businesses or other small entities as no more than one-half hour per respondent.

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. Sound research and evaluation are needed as integral parts of communication design rather than as afterthoughts. Unless the public understands communications about regulated products sufficiently well to make appropriate choices, FDA will not be serving the public as mandated.

Without testing, FDA could be expending considerable funds on communications that will not achieve the intended purpose of improving public health – and could in fact be creating

unintended harmful results. FDA intends to test as frequently as is appropriate to ensure that communications, especially highly impactful ones, are appropriately designed. Testing on an ad hoc basis will be needed to assess initial and continuing relevance of 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 communications testing 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 communications testing 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 July 13, 2010 (75 FR 39952). There were no comments on the information collection.

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 personal interview activity. Instances for offering a small incentive will be determined on a case-by-case basis (depending on the particular information collection design). Small amounts of money (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 beyond 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 may participate at their own expense 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 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. Personally identifiable data shall be limited to information that may be required in the process of respondent enrollment. Personally identifiable information will be accessible to only those contractors who need them and will not be linked to interview data. All personally identifiable data will be destroyed following interview data collection. Neither FDA employees nor any federal employee of any other Agency will have access to this information.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of communication messages.

Communications testing 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.

[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.

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 communications may be concerned with the prevention of premature mortality, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. The probability of sensitive questions occurring depends upon the topic of the communication. 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.

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 is never a part of a system of records containing permanent identifiers that can be used for retrieval.

A.12. Estimates of Annualized Burden Hours and Costs

Table 1 is based on the maximum number of data collections expected on an annual basis. It is highly unlikely that respondents will be contacted more than once per year due to the variable nature of the medical product issues and the need to address different respondent groups. 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	0.75	270

General Public Focus Group Interviews	144	1	1.50	216
Intercept Interviews: Central Location	200	1	0.25	50
Intercept Interviews: Telephone	4,000	1	0.08	320
Self-Administered Surveys	2,400	1	0.25	600
Gatekeeper Reviews	400	1	0.50	200
Omnibus Surveys	1,200	1	0.17	204
TOTAL (General Public)	8,704			1,860
Physician Focus Group Interviews	144	1	1.50	216
TOTAL (Physician)	144			216
TOTAL (Overall)	8,848			2076

The general public will complete the majority of data collections. The average salary for this group is $30.02.[7] The estimated annualized annual cost for the general public in this information collection for 1,860 hours of reporting time is $55,837. Other labor groups include primary care physicians and medical specialists, whose average salary, respectively, is estimated as $119.15 and $124.22. The estimated annualized annual cost for physicians in this information collection for 144 hours of reporting time is $26,284. The estimated annualized annual cost for 2,076 hours of reporting time is $82,121.

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 Devices and Radiological Health. The actual numbers will vary depending upon the topic of interest.

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 on 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 $150,000 for an in-depth interview study. The maximum estimated annualized expense for contractor expenses in this data collection is $1,645,000.

In addition, government staff costs may be incurred for monitoring by the government Project Officer, projected to be about 25% of an FTE's time per year (522 hours). Given an FDA personnel cost of $57.13 per hour, $29,708 would be spent annually on government staff salaries.

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

The total estimated annual cost to the government for this collection of information is $1,674,708. This is equal to the total of contractor expenses ($1,645,000) plus FDA government staff salary cost ($29,708).

A.15. Explanation for Program Changes or Adjustments

FDA is requesting extension of the information collection approval. There are no program changes or adjustments.

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

The process for developing the analytical plan for communications testing is similar to that used in any formal evaluation. The staff will review the material to be tested, discuss the objectives with the individuals responsible for developing the materials, determine the analytic questions to be addressed, and then prepare the procedures, instruments, and data analysis plan. The analyses conducted for each project will be determined by the communication objectives, the messages being tested, and the audience for the messages. Specifics of the analyses cannot be determined until the messages to be tested 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 this data collection is to provide information to the developers of the messages for the purpose of improving them, FDA makes 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 and Drug Information Association. Some results may be published in professional journals such as the Journal of Public Policy and Marketing. 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 the results.

The specific messages to be tested and the timing of these messages are not known at this time. However, as indicated in section A.1., approximately 23 studies are planned. While the period varies somewhat depending on the complexity of the testing and number of respondents required, the typical communications testing project will require approximately 12 weeks once OMB clearance is obtained. A schedule for a typical project 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 results	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.