

# TESTING COMMUNICATIONS ON NUTRITION AND FOOD PRODUCT SAFETY

## SUPPORTING STATEMENT

### A. JUSTIFICATION

#### 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 nutrition and food 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 foods.

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)) (Attachment 1) to conduct educational and public information programs relating to the safety of foods and nutritional safety.

The Food and Drug Administration (FDA) is requesting approval for collecting information through a variety of research methods for developing and testing communications involving food products and nutrition. 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 consuming food 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 2). 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.<sup>1</sup> 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.<sup>2</sup> 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."<sup>3</sup> 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 pertaining to the testing of communication messages on the safety of food products and nutrition safety. To coordinate efforts, FDA proposes that this generic clearance cover all information collection activities for communications about foods and nutrition conducted by the Center for Food Safety and Applied Nutrition 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.<sup>4</sup>

Approval is requested for 30 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 2,860 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.

## **2. Purpose and Use of the Information**

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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 plans to use the data collected under this generic clearance to inform its foods communications campaigns. FDA expects that the data collected will help to tailor print, broadcast, and electronic media communications in order that they achieve the 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, it will provide the critical knowledge needed about target audiences' preferences. FDA must explore audiences' beliefs, perceptions, and decision-making processes about nutrition and food consumption in order to hone its risk communication campaigns. Such knowledge will provide the needed target audience understanding to design effective communication strategies, messages, and product labels. These communications will aim to improve public understanding of the risks and benefits of consuming certain food products by providing users with a better context in which to place risk information more completely.

FDA must also understand the general beliefs of physicians and healthcare adjuncts. Prescribers and pharmacists play a key role in the provision of nutritional information and the appropriate consumption of foods. 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 foods.

Further, food distributors and grocery chains provide a key link to FDA's mission to educate the public on foods, nutrition, and food safety. FDA needs to determine the informational needs and the most effective communication channels and formats to insure the support of food distributors in FDA food safety and nutritional campaigns.

Second, as initial testing, it 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 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 messages.
- *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 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 and product labels 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 specific foods or

diets 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 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 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.

### **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. 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 may include the following:

#### Web-based Surveys

Web-based surveys represent an especially convenient option for eliciting feedback on visual stimuli. With Web-based surveys, respondents complete an on-line questionnaire 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,<sup>5</sup> Web-based surveys offer an especially useful way to solicit responses from young adults and adolescents. In addition, newer software may make interactive surveys on the Web more feasible. This may be accomplished through chat boxes, in which survey personnel interact with the respondent via a box on the screen, the purpose of which is to ask questions in order to probe more deeply on respondent’s answers.

#### 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

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<sup>5</sup> 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

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.

### **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 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 may work with CDC, NIH, AHRQ and other agencies that are responsible for communicating about foods and nutritional safety with the general public.

However, because risk communications on the safety of food products or on nutritional safety 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 Section 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.

### **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 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 burdens on small businesses or other small entities as no more than one-half hour per respondent.

## **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.

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

Because FDA's 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 communication 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.

## **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 December 29, 2010 (Volume 75, No. 249) (Attachment 3). FDA received one comment. It complimented the data collection tools that FDA proposed to use within this clearance and suggested use of newer technologies to improve data collection. It also noted that automated survey data collection (ACASI, for example), does not reduce respondent burden, which the FDA acknowledges. The other parts of the comment were beyond the scope of the questions asked in the 60-day Federal Register Notice.

## **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 test 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 an upper bound of \$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<sup>6</sup>); 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 contracted project staff 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 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 preserved. Reports will be used only for research purposes and for the development of communication messages.

Communications for 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 4). 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 under the applicable law of the jurisdiction in which the research will be conducted. Where the 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: what they will experience, whether the child's parents will be with him or her, an explanation of the study risks, and an explanation of the benefits to the child or others.

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<sup>6</sup> In some cases, FDA sponsorship will not be made known to respondents prior to data collection to reduce the potential for bias to study results. In such cases, FDA sponsorship will be made known after the data is collected.

## 11. Justification for Sensitive Questions

As mentioned in Sections 2 and 10, some studies require the inclusion of people who match selected characteristics of the target audience(s) 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 or quality at the end of life, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. Fears of specific diseases and experiences may also be covered. 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 never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

## 12. Estimates of Annualized Burden Hours and Costs

Table 1 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 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***

	<u>Number of Respondents</u>	<u>Frequency of Response</u>	<u>Hours Per Response</u>	<u>Total Hours</u>
Individual In-Depth Interviews	360	1	.75	270
Focus Group Interviews	144	1	1.5	216
Self-Administered Surveys	2,400	1	.20	480
Telephone or Web Surveys	2,800	1	.25	700
TOTAL (General Public)	5,704			1,666694
Physician Focus Group Interviews	144	1	1.5	216
TOTAL (Physician)	144			216
TOTAL (Overall)	5,848		0.3233	1,882910

The general public will complete the majority of data collections. The average salary for this group is \$30.02.<sup>7</sup> The estimated annualized annual cost for the general public in this information collection for 5,7041,694 hours of reporting time is \$50,013.854. 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 216 hours of reporting time is \$26,284. The estimated annualized annual cost for 1,882910 hours of reporting time is \$76,29777,138.

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 Food Safety and Applied Nutrition. The actual numbers will vary depending upon the topic of interest.

### **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.

### **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 \$1,340,000.

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 \$57.13 per hour, \$29,708 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is \$1,369,708. This is equal to the total of contractor expenses (\$1,340,000) plus FDA government staff salary cost (\$29,708).

### **15. Explanation for Program Changes or Adjustments**

This is a new collection of information.

### **16. Plans for Tabulation and Publication and Project Time Schedule**

The process for 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.

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<sup>7</sup> U.S. Bureau of Labor Statistics, [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm), June 2010.

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 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 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. 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 1., approximately 30 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***

<u>Activity</u>	<u>Time Schedule</u>
Finalize materials	1 week after OMB approval
Finalize design	3 weeks after OMB approval
Collect data	5 weeks after OMB approval
Analyze data	10 weeks after OMB approval
Report on analysis	15 weeks after OMB approval

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

The OMB expiration date will be displayed.

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

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