Supporting Statement for

Experimental Study: Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs

Submitted by

Center for Drug Evaluation and Research
Office of the Commissioner

Food and Drug Administration

June, 2009
Revised December 11, 2009

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act (FDAAA, Public Law 110-85). Title IX of FDAAA amends section 502(n) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 352) by requiring printed direct-to-consumer (DTC) advertisements for prescription drug products to include the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088." Title IX of FDAAA also requires the Secretary of Health and Human Services (Secretary), in consultation with the Advisory Committee on Risk Communication, to conduct a study not later than six months after the date of enactment of FDAAA to determine if this statement is appropriate for inclusion in DTC television advertisements for prescription drug products. As part of this study, the Secretary shall consider whether the information in the statement described above would detract from the presentation of risk information in a DTC television advertisement. If the Secretary determines that the inclusion of such a statement would be appropriate for television advertisements, FDAAA mandates the issuance of regulations implementing this requirement, and for the regulations to reflect a reasonable length of time for displaying the

statement in television advertisements. Finally, FDAAA requires the Secretary to report the study's findings and any subsequent plans to issue regulations to Congress.

In accordance with the requirements of FDAAA, FDA convened a meeting of the Risk Communication Advisory Committee on May 15-16, 2008. A draft design for studying this issue was proposed at that time and discussed by the Advisory Committee. Based on comments received at that meeting, changes were made to the proposed study design. The transcripts and materials from that meeting can be found online at http://www.fda.gov/ohrms/dockets/ac/oc08.html#RCAC.

Relevant Prior History and Research

Section 17 of the Best Pharmaceuticals for Children Act (the BPCA) (Public Law 107-109, January 4, 2002) required FDA to issue a final rule mandating the addition of a statement to the labeling of each drug product for which an application is approved under section 505 of the Act. Under the BPCA, the statements must include: (1) a toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs; and (2) a statement that the number is to be used only for reporting purposes, and it should not be used to seek or obtain medical advice (the side effects statement).

On April 22, 2004, FDA published a proposed rule with a proposed side effects statement for certain prescription drug product labeling and a proposed side effects statement for certain over-the-counter drug product labeling (69 FR 21778). In the proposed rule, FDA solicited comments on a proposed statement that FDA believed comported with the above mandate in the BPCA. The Agency received 12 comments suggesting changes to the specific wording proposed. The agency also received several comments suggesting that FDA engage in research to study the wording of the proposed side effects statement with consumers. Among the reasons

cited for testing the statement were: (1) to determine the best and most precise wording for the statement; (2) to evaluate consumer comprehension of the proposed statement; and (3) to address concerns that consumers who read the statement will mistakenly call FDA in search of medical advice rather than seeking appropriate medical treatment. In addition, during the clearance process for the proposed rule, both the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the Department of Health and Human Services suggested that FDA conduct focus groups or other consumer studies to inform the wording of the side effects statement.

During the spring of 2006, to assist in developing this study, FDA conducted two focus groups to gauge consumer understanding and preferences for a number of proposed side effects statements and to narrow the number of statements to be tested in subsequent experimental research. In addition to the information collected on which versions of the statements participants preferred, discussions showed that people varied in their understanding of when to call FDA or their practitioners and that some people would not call FDA even if they experienced a serious side effect. Several people in the focus groups suggested the addition of a website to report adverse side effects.

Based on the findings from the focus groups, nine statements were selected for quantitative testing. A labeling comprehension experiment was conducted with 1,674 men and women ranging in age from 21 to 95 with varying levels of education (OMB Control No. 0910-0497). The results from that quantitative test found that only one of the versions tested was rated as significantly less clear than the others, which were all rated as generally clear and understandable. The results also showed that participants reported they would not call FDA

seeking medical advice. Further, among those participants who said they would call the FDA, the majority indicated they would call their doctor for medical advice, rather than FDA, regardless of the severity of the side effect. Finally, participants indicated they could distinguish between serious and non-serious side effects, reporting that they would seek emergency medical care in the case of serious side effects. The report of the study is available in the docket for the final rule, Docket No. FDA-2003-N-0313. The final rule, *Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products* (73 FR 209, October 28, 2008), is available online at http://frwebgate6.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=378215277140+0+2+0&WAISaction=retrieve.

2. Purpose and Use of the Information Collection

The purpose of this study is to address the requirements of Congress as written in Title IX of FDAAA. Instead of automatically requiring the statement in television ads, Congress specified that research shall be conducted to address the issue of whether the inclusion of the toll-free statement will detract consumers from the risk information in the ads. This study, along with other considerations of public health issues and an analysis of MedWatch considerations, will determine whether the toll-free statement will be required. Specifically, if the research shows that the toll-free statement does not detract from the understanding of risk information at all, its inclusion in television ads is likely to be mandated. If, on the other hand, some detraction is demonstrated, then public health concerns and MedWatch considerations will play a larger role in determining whether the benefits of the inclusion of the statement outweigh the detraction from the risk information.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. The contracted research firm will collect data through Internet administration. The participant will self-administer the Internet survey via a computer, which will record responses and provide appropriate probes when needed. In addition to its use in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each respondent, and by keeping surveys to less than 20 minutes.

4. <u>Efforts to Identify Duplication and Use of Similar Information</u>

Although some previous studies have investigated various aspects of print DTC ads,[1] little published research has been conducted on television DTC ads. Published research has typically used content analysis and not rigorous experimental investigation.[2] Such research does not permit extrapolation to understanding consumers' perceptions or intended behavior.

As described in Section A1 (*Circumstances Making the Collection of Information Necessary*, p. 5) FDA completed a study examining the wording of a toll-free statement to be placed on prescription and non-prescription drug labels.[3] Aside from this usability study, which applied to printed material and not broadcast media, FDA is not aware of previous research on the role of a side effect-related statement in DTC ads.

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[1]See, for example:
Holmes, E.R. & Desselle, S.P. (2004). Evaluating the balance of persuasive and informative content within product-specific print direct-to-consumer ads. *Drug Information Journal, 38*, 83-98.
Munce, S.E., Robertson, E.K., Sansom, S.N., & Stewart, D.E. (2004). Who is portrayed in psychotropic drug advertisements? *The Journal of Nervous and Mental Disease, 192*, 284-288.

[2]See, for example:
Kaphingst, K.A., DeJong, W., Rudd, R.E., & Daltroy, L. (2004). A content analysis of direct-to-consumer television prescription drug advertisements. *Journal of Health Communications, 9*, 515-528.
Kaphingst, K.A., Rudd, R.E., DeJong, W., & Daltroy, L. (2005). Comprehension of the information in direct-to-consumer television prescription drug advertisements among adults with limited literacy skills. *Journal of Health Communications, 7*, 609-619.
Sumpradit, N., Ascione, F.J., & Bagozzi, R.P. (2004). A cross-media content analysis of motivational themes in direct-to-consumer prescription drug advertising. *Clinical Therapeutics, 26*, 135-154.

[3] The report of the study is available in the docket for the final rule, Docket No. FDA-2003-N-0313. The final rule, *Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products* (73 FR 209, October 28, 2008), is available online at http://frwebgate6.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=378215277140+0+2+0&WAISaction=retrieve.

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

No small businesses would be involved in this data collection.

6. **Consequences of Collecting the Information Less Frequently**

The proposed data collection is one-time only. There are no plans for successive data collections.

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

This collection of information fully complies with 5 CFR 1320.5. There are no special circumstances.

8. **Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

The 60-day public comment notice was published in the Federal Register on November 26, 2008, Volume 73, Number 229 (Docket No FDA-2008-N-0595). A copy of the 60-day Federal Register notice is included as Attachment 1.

FDA received six comments in response to our initial federal register notice, published on November 26, 2008. One of these comments, from an anonymous citizen, did not require specific responses, as it was outside the scope of the project (e.g., FDA approves too many drugs; harmful drugs are "being foisted on the population"), although it could be viewed as a statement of support for conducting the research.

In the following section, we outline the issues raised in the comments and provide our responses.

Angela Stanton, Ph.D.

Dr. Stanton does not recommend the placement of the toll-free statement in television ads because she feels they are better placed within written materials that accompany prescription

drugs. She recommends that some system for enforcing the legitimacy of calls is necessary, otherwise callers with an "agenda" or "the uninformed" could "doom medicines for no reason."

We thank Dr. Stanton for her comments. They mostly apply, however, to MedWatch procedures that are outside the scope of the proposed research. This study is addressing the understanding of information in the ad. We have notified the appropriate parties in the Agency of her comments.

American Society of Health-System Pharmacists (ASHP)

ASHP supports DTC advertising that is educational and "delayed until postmarketing surveillance data are collected and assessed," and believes that DTC television ads *should* include a toll-free statement. Overall, they support the proposed research, but have the following specific suggestions.

ASHP disagrees that the statement is best placed after the risk information. They suggest that it be placed during the presentation of non-life-threatening or minor side-effects. We agree that placement during non-life-threatening or minor side effects may be the best placement for the toll-free statement. Realistically, however, in a television ad, that information is presented in a very short amount of time, sometimes only seconds (and this varies depending on drug product). We have designed our study to allow the data to show for us what the best placement of the statement will be.

ASHP is concerned that neither of the proposed toll-free statements addresses whether consumers can distinguish between serious and non-serious side effects. They suggest a simulation study to assess this issue. We refer this commenter to previous research conducted by FDA on this topic, described in Section A1 (*Circumstances Making the Collection of Information Necessary,* p. 5). This study found that participants were easily able to distinguish

between serious and non-serious side effects and that they reported an ability to take the right action with regard to each one.

The remaining three comments were more detailed and raised several distinct points. For these comments, we will list the concern and our response to it individually.

Pharmaceutical Research and Manufacturers of America (PhRMA)

• Transparency and Validity of Protocol: PhRMA suggests that we post the proposed questionnaire, the primary endpoint(s) of the study with action standards, and provide the mock advertisement to interested parties for use in their research.

Response: The proposed questionnaire has been and continues to be available upon request. We agree that threshold levels and primary endpoints were not well explained in the 60-day notice and have worked to correct that in the 30-day notice. Please note the addition of specific hypotheses and the analysis plan. At the conclusion of our data collection, we will make the advertisement available to those who request it.

• Transparency and Accuracy of Stimuli Ads: PhRMA expressed concern that adequate provision issues will not be considered or addressed and that multiple telephone numbers or websites may confuse consumers. They also suggest alternate wording for the toll-free statement: "For information about PRODUCT X or to report side effects, see our ad in _____ magazine." Finally, they encourage the inclusion of payment assistance information, as this is often currently included in television ads.

Response: We have designed the stimuli ad to closely approximate an actual DTC ad—including adequate provision measures and other supers. DDMAC reviewers have examined the script and storyboard to ensure that the ad meets regulatory requirements. The contractor producing the ad has extensive experience with this type of production

and provided additional quality control measures. In directing us to complete this research, Congress was likely concerned about the same issues expressed by this commenter: i.e., that the toll-free statement may be confusing. That is one of the main research questions we will address. In terms of wording, Congress directed us to test specific language. In addition to this language, we propose to test another version that was found most acceptable in previous usability research conducted by the Agency. Finally, because payment assistance information is relatively new, not universal, and not required by regulation, we have not included this statement in our stimuli ads.

FDA has contracted with a professional multimedia company to create ad stimuli. In addition, FDA has instituted a procedure of extensive pretesting of the ad stimuli to be used. Our extensive experience with current and past DTC ads, pretesting, and collaboration with the contractor should ensure realistic ads that will enable us to successfully investigate our experimental variables.

• PhRMA recommended studying: multiple medical conditions including symptomatic and asymptomatic ones; diseases that affect different age groups; sufferers and non-sufferers; and consumers with varying about of knowledge.

Response: We do not have the resources to create mock ads to test multiple medical conditions. We see no a priori reason that the principles we study in this medical condition (e.g., placement, duration, wording, prominence) would be different applied to an ad for another medical condition. We welcome other parties to extend the current research by applying it to other conditions. We will ask respondents about their knowledge of their medical condition and will conduct analyses to see if this variable plays a role in their responses.

We have decided, however, to recruit for the study two distinct populations: those who have been diagnosed with high blood pressure and a general population sample. This approach will allow us to determine whether diagnosed individuals and other people who may be exposed to such television advertising will differ in their responses to the ad.

• PhRMA is concerned that using the condition where the toll-free statement is present during the whole ad to control for novelty will increase rather than decrease the attention to the statement.

Response: We agree that the condition in which the toll-free statement appears during the entire ad may increase notice of it. We think there is also a good possibility that it might cause a wash-out effect, in such a way that the statement might be more prominent in other conditions. To control for novelty, participants will see an unrelated DTC ad with the toll-free statement presented the same way as the test ad before they see the test ad. This may control for novelty in the test ad and may attenuate the belief that our test product has some unique quality that causes it to need a special toll-free statement.

• PhRMA is concerned that this protocol will take much longer than 15 minutes.

Response: We are also concerned that this protocol will take longer than 15 minutes, so we have revised our burden estimation to reflect a 20 minute protocol. Also, we have budgeted for two pretests of 675 individuals each to make sure that all test parameters are met, including timing of experiment.

sanofi-aventis

• The placement variable should be removed from study because regardless of placement, the statement may interrupt the flow of the most important information.

Response: This is an empirical question.

• The duration variable should be removed from the study because regardless of duration, the statement may interrupt the flow of the most important information.

Response: This is an empirical question. We will not know the answer to either of these questions until we collect data.

• sanofi-aventis recommends removing the audio-only condition because this eliminates hearing-impaired population. They also recommend including visually and hearing impaired to more accurately represent the population.

Response: Even in our audio-only condition as originally proposed, the website and phone numbers were placed on screen. That said, current requirements for the most important risk information, i.e., the major statement, are that it be placed in the audio portion of the ad. Thus, this is a reasonable condition to test. Upon further discussion, however, we agree that we do not need two distinct extra-prominent conditions, and will test only one. We do not plan to actively exclude people with audio or visual impairments from the study but we do not have the resources to actively recruit them.

• High blood pressure may not be the most representative condition for a general sample of consumers over the age of 18. The tested sample population should be representative of actual sufferers of the condition being advertised.

Response: Merck also mentioned this concern and we agree that this is an important consideration. Upon further discussion, we have decided to recruit for the study two distinct populations: those who have been diagnosed with high blood pressure and a general population sample. This approach will allow us to determine whether diagnosed individuals and other people who may be exposed to such television advertising will differ in their responses to the ad.

• sanofi-aventis does not believe the 4th commercial for an unrelated medical condition contributes to the study and may confound results and so suggests removal.

Response: Respondents will see four ads—the 2nd ad will be an unrelated DTC ad and 4th ad will be the test ad. We propose to include the other DTC ad with the matching toll-free statement parameters so that consumers do not think that our test ad reflects a special product that needs a special warning. It also may attenuate the effect of novelty.

• Since the toll-free statement may artificially increase impact of risk information, FDA should test information gleaned from the presence of the toll-free statement in print ads first.

Response: FDA has not collected any information on the presence of the statement in print ads, although we agree this would be valuable information. Moreover, Congress has instructed us specifically to test the toll-free statement in television ads.

• Including the manufacturer's toll-free number instead of the FDA contact number may help to mitigate the possibility that the toll-free statement artificially increases the impact of risk information.

Response: Sponsors already include the manufacturer's telephone number in all ads as a way to fulfill one part of the adequate provision requirement. The current study does not examine the replacement of that number with the toll-free statement, but instead the statement's inclusion above and beyond current requirements.

• Agency's expectation of yielding a sample of 2,000 people from a total of 2,400 is unrealistic based on a typical response rate of 5%.

Response: We do not expect to yield a sample of 2,000 people from a total of 2,400. As shown in the burden chart in Section A12 (p. 18), we have revised our sample numbers.

• sanofi-aventis expressed concern about how well an internet study can simulate a television environment.

Response: We agree that simulating an everyday television-watching environment would increase the realism of the study. Realistically, however, participation in an experiment in any context is unlikely to perfectly do so. We do not believe that a mall-intercept administration would increase the realism of the study and a phone-based survey is not feasible, given the modality of the advertisement in question. Moreover, an internet study may be as close to the television-watching environment as any other method, since participants will be in their own homes and some participants already watch streaming video on their computers.

• Will there be thresholds to identify the outcome of success for each question? Will it be the best response or will there be a level of positive responses that meet pre-specified criteria the Agency will deem acceptable in decision making?

Response: As mentioned in Section A2 (*Purpose and Use of the Information Collection*), if the study demonstrates that the inclusion of the toll-free statement does not interfere with the processing of the risk information, then Congress is likely to mandate its inclusion. If the data demonstrate *some* detraction from risk information, then the decision becomes more complicated. Certainly the more the statement interfered with the risk information, the less likely it is that it would be mandated. A tradeoff analysis will have to be conducted and this study will be only one part of the determination. That is, the amount of detraction will have to be weighed against the benefit of including the statement and this benefit will be determined in part by public health concerns and analysis of MedWatch data.

• sanofi-aventis is concerned that participants will see the test ad three times and that this may cause problems.

Response: Participants will see the test ad only once after seeing three other filler ads, one of which will be an unrelated DTC ad.

Merck

• Current proposed study is comprehensive and appropriate to address the primary research questions under consideration.

Response: Thank you.

• The toll-free statement in the unrelated DTC ad should be presented in the same way as in the test ad.

Response: We had planned to do so.

• The current sampling strategy will likely not include enough people who have high blood pressure and the content of the ad will not be salient to people who do not consider themselves at risk for the condition. Merck recommends screening for people who have or are at risk for high blood pressure.

Response: See above, (page 12 of this document), under response to similar comment from sanofi-aventis.

• The questionnaire does not specifically address the risk of non-treatment of the disease-condition.

Response: FDA acknowledges that this study does not address this risk. Nevertheless, this is outside the scope of the current investigation.

• Merck recommends asking if respondents suffer from diabetes, high cholesterol, obesity, or the condition treated in the unrelated DTC ad.

Response: FDA had planned to ask about the state of respondent's health. In considering this comment, we have added some additional questions to the questionnaire. Please see the revised questionnaire for details.

• Specific comments about questionnaire items.

Response: Thank you for your attention to the questionnaire. We have rearranged the questionnaire so that what was question 7 is now asked before any substantive questions. We do feel, however, that the wording of this question should remain vague. One purpose of the study is to determine whether people can recall the toll-free statement amidst adequate provision items, other supers, and other information. Thus, we do not want to specifically probe them for the statement by cueing them to the toll-free statement. We have made small wording changes to the question as well as other changes to the questionnaire to more closely reflect our goals. Please see the revised questionnaire for details.

• It is unclear how FDA plans to analyze results from this research, particularly what action consumers are expected to take after they have heard and understood the toll-free statement.

Response: The purpose of this research is not to determine what action consumers will take after seeing the ad. We addressed these issues in the previous study, referenced on page 5 of this document. The purpose of the current proposed study is to determine whether the risk information is adequately comprehended and whether the toll-free statement is noticeable and recalled.

• What are the thresholds for interference ("detraction") in this study? Specifically, will the statement be included only if it does not affect risk comprehension at all, or if it does not affect risk comprehension "much"—and if this is the case, what is too much?

Response: Please see the answer to a similar question by sanofi-aventis, located on page 14 of this document.

External Reviewers

As requested by Congress, the Agency consulted with the Risk Communications Advisory Committee in May of 2008. Please see section A1 (*Circumstances Making the Collection of Information Necessary*, p. 3) for more detail. This extensive and public vetting resulted in a stronger and sharper research endeavor.

9. Explanation of Any Payment or Gift to Respondents

Internet panel participants are enrolled into a points program that is analogous to a 'frequent flyer' card in that respondents are credited with points in proportion to their regular participation in surveys (for the households provided internet appliances and an internet connection, their incentive is the hardware and internet service). Panelists receive cash-equivalent checks approximately every four to six months in amounts reflecting their level of participation in the panel, which commonly results in distributions in the range of $4 to $6 per month. Because this survey will take a little extra time to complete, participants will receive a survey-specific incentive equivalent to $5. The incentive will be paid in points that can be converted into sweepstakes entries or cash.

10. Assurance of Confidentiality Provided to Respondents

All respondents will be provided with the assurance that their responses will be recorded in such a manner that they cannot be identified directly or through identifiers (45 CFR 46.101(b)(2)). This will be accomplished through the following measures:

- No personally identifiable information will be sent to FDA.

- All information that can identify individual respondents will be kept by the independent contractor in a form that is separate from the data provided to FDA.
- The information will be kept in a secured fashion that will not permit unauthorized access.

These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee, RIHSC) prior to collecting any information.

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' ADP Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The complete list of questions is available in Attachment 2.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 2,467 hours for this one-time collection (Table 1).

Table 1. Estimated Annual Reporting Burden[a]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener, pretesing	2,700	1	2,700	.03	81
Questionnaire, pretesting	1,350	1	1,350	.25	338
Screener, study	10,500	1	10,500	.03	315
Questionnaire,	5,250	1	5,250	.33	1,733

study					
Total					2,467

[a]There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with previous consumer studies.

13. Estimates of Other Total Annual Costs to Respondents and Record Keepers

There are no costs to respondents. There are no record keepers.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal Government for the collection of pretest and main study data is $850,000. This includes the costs paid to the contractors to create stimuli, to program the study, draw the sample, collect the data, and create a database of the results. The cost also includes FDA and DHHS staff time to design and manage the study, to analyze the resultant data, and to draft a report.

15. Explanation for Programs Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for experimental data, such as descriptive statistics, analysis of variance, and regression models, will be used to analyze the data. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations and articles at trade and academic conferences, publications, and Internet posting.

Project Timetable

Task	Estimated Completion Date

External Peer Review	May, 2008
RIHSC Review	June, 2009
30-day FR notice publication	August, 2009
OMB Review of PRA package	September-October, 2009
Pretesting	December, 2009
Data Collection	January-February, 2010
Receipt of Data and Methods Report from Contractor	March, 2010
Data Analysis	April, 2010
Draft Report	June, 2010
Internal Review of Draft Report	July, 2010
Revisions	August, 2010
Final Report	September, 2010

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

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.