United States Food and Drug Administration

Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces

OMB Control Number 0910-NEW

SUPPORTING STATEMENT – **Part 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 FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the 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.

The FD&C Act prohibits the dissemination of false or misleading information about medications in consumer-directed and professional prescription drug promotion. As part of its federal mandate, FDA regulates whether advertising of prescription drug products is truthful, balanced, and accurately communicated (see 21 U.S.C. 352(n)). FDA's regulatory policies are aligned with the principles of free speech and due process in the United States Constitution. To inform current and future policies, and to seek to enhance audience comprehension, the Office of Prescription Drug Promotion conducts research focusing on: (1) advertising features including content and format; (2) target populations; and (3) research quality. This proposed collection of information will investigate how physician perception of prescription drug information is influenced by variations in information context (presence of graphical elements and information delivery vehicle - medical journal abstract or sales aid), methodologic rigor of the underlying clinical study (high or low), and time pressure (present versus absent).

Ways in Which Information Context and Study Quality May Influence Perceptions

Physicians gain knowledge about medical product uses from a variety of information vehicles including peer-reviewed journal articles, compendia, continuing medical education (CME), and physician-directed promotion by or on behalf of manufacturers. Peer-reviewed scientific publications may report the results of a variety of studies, employing a wide range of methodologies with varying levels of rigor. As a result, information of varying quality is disseminated to the field. Physician detailing

sometimes includes information derived from peer-reviewed research which, in this context, serves a dual purpose: to both inform and market a particular product[1].

Prior research has examined some impacts of study quality and funding source on physician perception. For example, research by Kesselheim et al.[2] on study abstracts examined how methodologic rigor (high, medium, low) and information about the source of funding (industry, National Institutes of Health, none) affected physician perceptions of study quality, prescribing intentions, and interest in reading the full article. Results indicated physician participants were able to distinguish between levels of methodologic rigor. Physicians also used information about the funding source to distinguish materials: they reported less willingness to prescribe the drugs or read the full study from trials funded by industry, regardless of study rigor. Thus, funding source was a contextual factor that impacted physicians' perceptions of the information.

Research has also shown that physician prescribing behavior can be influenced by the context in which the information is delivered. Spurling et al.[3] examined the way in which information from a pharmaceutical company was delivered (using conventional promotional techniques such as sales rep visits, journal advertisements, or attendance at pharmaceutical-sponsored meetings versus not using conventional promotional techniques such as participation in company sponsored trials and representatives' visits for nonpromotional purposes) and prescribing outcome across 58 studies. They found conventional promotional techniques were associated with an increase in prescribing and a decrease in prescribing quality. We are proposing to test a different type of contextual factor in this study: whether the drug information appears in a medical journal abstract or a sales aid.

Ways in Which Graphics May Influence Perceptions

Promotional materials about prescription drugs that are directed toward physicians often include a variety of visual elements beyond simple text. In a study of professionally-directed prescription drug brochures left for physicians by pharmaceutical representatives, researchers found 95% contained a visual graphic (including bar charts, line graphs, pie charts, arrows) accompanying the presentation of data.[4] An analysis of professionally-directed prescription drug print advertisement in medical journals found 80% of the ads contained some type of image and 21% contained data-related graphics. A group of two physicians and one pharmacist judged these ads. This group found that of

[1] John, C. Yi, G. Anand Anandalingam, and Levi A. Sorrell. "An expert system to physician-detailing planning." *Expert Systems with Applications* 25.4 (2003): 533-544.

[2] Kesselheim, Aaron S., Christopher T. Robertson, Jessica A. Myers, et al. "A randomized study of how physicians interpret research funding disclosures." *New England Journal of Medicine* 367.12 (2012): 1119-1127.

[3] Spurling, Geoffrey K., Peter R. Mansfield, Brett D. Montgomery, Joel Lexchin, Jenny Doust, Noordin Othman, and Agnes I. Vitry. "Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review." *PLoS medicine* 7, no. 10 (2010): e1000352. https://doi.org/10.1371/journal.pmed.1000352

[4] Cardarelli, Roberto, John C. Licciardone, and Lockwood G. Taylor. "A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underlying studies: Is what they tell us important and true?" *BMC Family Practice* 7.1 (2006): 13.

those ads that contained images, 58% contained images that minimized the risks of the product and 24% of the images in the ads misled about product efficacy.[5]

Ways in Which Time Pressure May Influence Perceptions

We are also interested in how time pressure may impact physician perceptions. Time pressure can impact processing of information (e.g., accuracy and speed) as well as decision-making. Physicians are often under pressure to split their work time between myriad duties that may include clinical care, research, mentoring, teaching, and administrative duties.[6] Individuals under time pressure tend to rely on previously formed attitudes for decision-making and have less cognitive capacity to process information.[7],[8] This results in different decisions depending on the amount of time available.[9] Research suggests that in situations with high time pressure or increased ambiguity, experts use intuitive decision-making strategies rather than structured approaches.[10],[11] Physicians may therefore tend to rely on intuitive processes rather than evidence-based information under time pressure.

Research has also found that under time pressure, physician adherence to clinical practice guidelines concerning history taking and advice giving can be compromised.[12] One study that assessed the reading habits of physicians found that with limited time available for critical reading, practitioners relied heavily on abstracts and prescreening of articles by editors.[13] Thus, time pressure is an element of physicians' practice environment that can impact information-gathering and, consequently, decision-making and the quality of health care delivered.

2. Purpose and Use of the Information Collection

[5] Wilkes, Michael S., Bruce H. Doblin, and Martin F. Shapiro. "Pharmaceutical advertisements in leading medical journals: experts' assessments." *Annals of Internal Medicine* 116.11 (1992): 912-919.

[6] Fassiotto, Magali, Caroline Simard, Christy Sandborg, Hannah Valantine, and Jennifer Raymond. "An integrated career coaching and time-banking system promoting flexibility, wellness, and success: A pilot program at Stanford University School of Medicine." *Academic Medicine* 93.6 (2018): 881-887.

[7] Alison, Laurence, Bernadette Doran, Matthew L. Long, Nicola Power and Amy Humphrey. "The effects of subjective time pressure and individual differences on hypotheses generation and action prioritization in police investigations." *Journal of Experimental Psychology* 19.1 (2013): 83-93.

[8] Ratneshwar, Srinivasan, and Shelly Chaiken. "Comprehension's role in persuasion: The case of its moderating effect on the persuasive impact of source cues." *Journal of Consumer Research* 18.1 (1991): 52-62.

[9] Moore, Danny L., Douglas Hausknecht, and Kanchana Thamodaran. "Time compression, response opportunity, and persuasion." *Journal of Consumer Research* 13.1 (1986): 85-99.

[10] Dror, Itiel E., Beth Basola, and Jerome R. Busemeyer. "Decision making under time pressure: An independent test of sequential sampling models." *Memory & Cognition* 27.4 (1999): 713-725.

[11] Croskerry, Pat. "The cognitive imperative thinking about how we think." *Academic Emergency Medicine* 7.11 (2000): 1223-1231.

[12] Tsiga, Evangelia, Efharis Panagopoulou, Nick Sevdalis, Anthony Montgomery, and Alexios Benos. "The influence of time pressure on adherence to guidelines in primary care: an experimental study." *BMJ open* 3.4 (2013): e002700.

[13] Saint, Sanjay, Dimitri A. Christakis, Somnath Saha, Joann G. Elmore, Deborah E. Welsh, Paul Baker, and Thomas D. Koepsell. "Journal reading habits of internists." *Journal of General Internal Medicine* 15 (2000): 881-884.

The purpose of this study is to investigate how physician perception of professional prescription drug communications is influenced by variations in information context, methodologic rigor of the underlying clinical study, and time pressure. This study will provide FDA with empirical information of the effects of these variables on physician perceptions and inform FDA's regulatory approach to promotional materials of this type.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. One hundred percent (100%) of participants will self-administer the 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 participant, and by keeping the written parts of surveys to less than 20 minutes in both the pretests and main study.

4. Efforts to Identify Duplication and Use of Similar Information

This study is a partial replication and extension of a prior study on physician interpretation of funding disclosures (see Ref. 2). We have modified the design of the prior study to more precisely focus on variables relevant to FDA's regulation of prescription drug promotion.

5. Impact on Small Businesses or Other Small Entities

No small businesses will 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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the *FEDERAL REGISTER* of October 17, 2018 (83 FR 52490). FDA received three comments that were PRA-related. Within those submissions, FDA received multiple comments which the Agency has addressed.

(Comment) Two comments asked for clarity about the research objectives and hypotheses. One comment asked how FDA will use such knowledge to inform the regulation of prescription drug promotion in the future, particularly the variable of time. (Response) As described in the 60-day FRN, "We propose to investigate how physician perception of professional prescription drug communications is influenced by variations in information context, methodologic rigor of the underlying clinical study, and time pressure. We propose to test three different contextual presentations of drug information (medical journal abstract, sales aid without graphic design elements, sales aid with graphic design elements), and two types of study methodological rigor used by Kesselheim et al.[2] (classified as high or low). We have chosen to test a mock sales aid presentation and a medical journal abstract to examine the potential differences in perception that may arise by presenting the same information in different vehicles.

Mirroring the time constraints of practicing physicians, we will examine the role of time pressure by randomly assigning half of the study participants to a limited amount of available time to read the materials."

Our research questions are:

RQ 1: Does the information context in which the information appears affect processing of the information?
RQ 2: Does methodological rigor of the study affect processing of the information?
RQ2a: Do physicians correctly interpret the methodological rigor of the study?
RQ3: Does the time available to read the information affect processing of the information?
RQ4: What are the potential interactions between these factors?

Thus, the goal of our study is to understand the ways in which the presentation of information, methodological rigor, and time affect how physicians interpret information about drugs when it comes from different sources. Although we cannot speculate on any future action as a result of our research studies, the Agency is committed to examining and conducting research that will ensure that any changes are grounded in science and will have the greatest benefit to public health. For this reason, the FDA consistently conducts research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Results from studies we conduct are evaluated within the broader context of research and findings from other sources. The broader body of knowledge is used to inform both policy and regulatory approaches.

(Comment) Six comments focused on various aspects of the study design. Comments asked for: (1) clarity about the reasoning behind inclusion of the aspects of time pressure; (2) how time pressure reflects the reality of the HCP experience; (3) how time pressure will be operationalized; (4) justification for comparison of a sales aid to an abstract; (5) a suggestion to remove one of the sales aid conditions to simplify the design; and (6) more detail about how methodologic rigor will be defined and represented in a sales aid or an

abstract. One comment (7) asserted graphics in promotional materials are tested by pharmaceutical companies through market research to ensure correct interpretation and so the presence or absence of graphics cannot predict how HCPs will interpret information in promotional materials. This comment also asserted the 1992 supporting reference in the 60-day FRN was outdated.

(Response) (1-3) Prior research has found that many physicians have limited time to spend reading drug information.[6-11] To imitate physicians' real-world experiences in this study, half of the participants will be randomly assigned to a condition in which time pressure is present; the other half will experience no time pressure. Those in the time pressure present condition will receive instructions explaining they will have two minutes to review the study description, which will be reevaluated after pretesting. Those without time pressure will be told they have as much time as they need to review the study description.

(4-5) As described in the 60-day FRN, we have "…two primary comparisons for the information context independent variable: journal abstract vs. sales aid without graphics, and sales aid without graphics vs. sales aid with graphics. We will also do an exploratory comparison of journal abstract vs. sales aid with graphics." As further described in the 60-day FRN, we are examining "the potential differences in perception that may arise by presenting the same information in different vehicles." The same information will be presented in the context of an abstract and the context of a sales aid. Described another way, we are controlling the text of the information and varying its "wrapper" to explore whether the context in which the information appears has an effect on how the information is perceived. A comparison of abstract to sales aid without graphics, and sales aid without graphics to sales aid with graphics will enable us to examine perceptual differences that may arise from the context in which the information occurs. To control for extraneous effects, we are not presenting any other information in the sales aid.

(6) In addition to studying the presentation of information in different information vehicles (sales aid versus abstract), we will also examine two different levels of methodological rigor, either high or low quality.[2] Some key differences between the levels of rigor are: blinding, representative population, and drug safety reported.[2] For example, the high rigor study that half of the participants will view was a randomized double-blind study that had a representative patient population, and the drug was reported to be safe.[2] The low rigor study that the other half of the participants will view was open-label (no blinding), was not representative of the patient population, and there was no report of the safety of the drug.[2] We used the same criteria to develop our stimuli as did Kesselheim, et al.[2] For example, variables in the high rigor condition included double-blind, active comparator, and representative patient population. Variables in the low rigor condition included open-label, usual care comparator, and a non-representative patient population.

(7) It is possible that the presence of graphics affects the impressions of the product, which we are assessing in this study. To address the comment about the date of the referenced research, we conducted an additional search of the literature. In a study by

Othman et al.,[14] 28% of claims made in pharmaceutical advertisements were judged clear and not misleading. This suggests that 72% were misleading or unclear. We welcome the opportunity to review unpublished market research or other available data to inform this study.

(Comment) One comment questioned the sufficiency of the proposed analysis plan based on the information provided in the notice and asked for clarity about the main dependent variables.

(Response) Our primary dependent variables are likelihood to prescribe, confidence in study results, interpret data cautiously, would use data in prescribing, credibility of data, bias of data, and trust in promotion. We will conduct ANOVAs (for continuous variables) and logistic regressions (for dichotomous variables) with interaction terms and planned comparisons to test the research questions. We have outlined our research questions above.

(Comment) Three comments requested FDA disseminate the study stimuli, and one comment requested disseminating the questionnaire prior to requesting comments.

(Response) We have described the purpose of the study, the design, the population of interest, and the estimated burden. The 60-day notice published on October 17, 2018, provided an email address to obtain copies of the questionnaire (83 FR 52491, column 3) and we provided the questionnaire to individuals upon request. The content of the stimuli is taken from Kesselheim et al.[2] Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise the research.

(Comment) Two comments questioned limiting the sample to board-certified internists and not including specialists, particularly those who specialize in diabetes treatment and endocrinologists. Relatedly, one comment suggested a sample size of at least 200 physicians.

(Response) Our study is a partial replication of the Kesselheim et al. study.[2] In that study, internists were used as the target population and in keeping with the replication, we chose to evaluate internists as well. We encourage future research to expand to other physician specialties. The sample will provide us enough power to detect a medium-sized effect between the study variables.

(Comment) Two comments suggested changing the scale range of the questions so that all of the questions use a consistent scale range.

(Response) We are using several questions that have been validated in previous studies. Therefore, some of the scales have various lengths. We chose to maintain scale range to maintain validation rather than editing scales for consistency.

(Comment) Seven comments suggested changes to the questionnaire. These suggested changes included (1) adjusting the wording of the question that asks about the importance of the target study "to ensure more consistent interpretation by respondents, such as importance of study findings on respondent decision-making, etc."; (2) revising the question about perceptions of bias to avoid the respondent making the assumption that the data presentation is biased; (3) deletion of questions about perceptions of risk; (4) deletion of the question about places where information about unapproved drugs has been encountered because it appears unrelated to the study goals; (5) addition of a response choice to the question measuring decision to include colleagues as a source of information; (6) addition of screening questions about statistical training; and (7) addition of a question about how much time is typically spent reviewing materials such as this.

(Response) (1) The study importance question is taken from Kesselheim et al.[2] and we did not encounter any issues with this question during cognitive interviews. (2) Perceptions of the amount of potential bias is one of our primary dependent measures. We will change the wording of this question to read "How unbiased or biased is the study you saw?" [1 = very unbiased 5 = very biased]. (3) We acknowledge participants may have a difficult time answering questions about risk. We believe an overall risk-benefit assessment is possible based on the information provided. Thus, we have decided to retain these questions as variables of secondary interest. (4) The question about where participants may encounter information about unapproved drugs is taken from Healthcare Professional Survey of Professional Prescription Drug Promotion (Docket No. FDA-2018-N-0215). We have included it here so that we may compare results across the two populations in an exploratory manner. (5) We will add a question about seeking information in response to the data participants see in the study that includes a response choice that captures desire to discuss drug information with a colleague prior to prescribing. (6) We will add a question about statistical training to the demographic section of the questionnaire. (7) We will add a question about how long participants typically spend reading materials of this type.

(Comment) One comment suggested moving the non-terminating demographic screener questions to the end of the survey.

(Response) We appreciate this suggestion. We have moved these questions to the end of the survey.

(Comment) One comment asked that the results be broadly and systematically disseminated.

(Response) 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 at trade and academic conferences, publications, articles, and Internet posting.

<u>External Reviewers</u>

In addition to public comment, OPDP solicited peer-review comments from researchers in fields relevant to the communication of DTC prescription drug information. We received responses and incorporated the thoughts of the following individuals:

Aaron S. Kesselheim, M.D., J.D., M.P.H.
Associate Professor of Medicine at Harvard Medical School
Director, Program On Regulation, Therapeutics, And Law (PORTAL)
Division of Pharmacoepidemiology and Pharmacoeconomics
Brigham and Women's Hospital

Julie Donohue, Ph.D.
Professor, Health Policy Management
Vice Chair for Research, Co-Director of PhD Programs, Graduate School of Public Health
University of Pittsburgh

9. Explanation of Any Payment or Gift to Respondents

Historically, physicians are one of the most difficult populations to survey, partly because of the demands on their professional time. Consequently, incentives assume an even greater importance with this group. In a survey of physicians, Gunn and Rhodes (1981)[14] found the response rate to an initial survey with no incentive was 58 percent, with a $25 incentive, 69 percent, and with a $50 incentive, 77 percent, with the difference between the $50 and the $25 incentive rate being statistically significant. Several studies [15] have discussed the challenges of conducting HCP surveys and have concluded that offering substantial incentives is necessary to attain high response rates.

Each HCP will be offered an honorarium of $46 for completing the study. These incentives are informed by market rates that are offered to physicians and other HCPs for completing surveys. The incentive is an effective method of drawing attention to the study and gaining cooperation for completing the questionnaire. It is not intended as a payment for their time but rather a means for increasing response rates.

[14] Gunn, W.J., and Rhodes, I.N. (1981). Physician response rates to a telephone survey: Effects of monetary incentive level. *Public Opinion Quarterly*, 45(1), 109-115.

[15] Deehan, A., Templeton, L., Taylor, C., Drummond, C. and Strang, J. (1997). The effect of cash and other financial inducements on the response rate of general practitioners in a national postal study. *British Journal of General Practice*, 47, 87-90. Dykema, J., Stevenson, J., Day, B., Sellers, S.L., and Bonham, V.L. (2011). Effects of incentives and prenotification on response rates and costs in a national web survey of physicians. *Evaluation & the Health Professions*, 34(4), 434-447. Keating, N.L., Zaslavsky, A.M., Goldstein, J., West, D.W., and Ayanian, J.Z. (2008). Randomized trial of $20 versus $50 incentives to increase physician survey response rates. *Medical Care*, 46(8), 878-881. Tambor, E.S., Chase, G.A., Faden, R.R., Geller, G., Hofinan, K.J., and Holtzman, N.A. (1993). Improving response rates through incentive and follow-up: The effect on a survey of physicians' knowledge of genetics. *American Journal of Public Health*, 83(11), 1599-1603. Ziegenfuss, J.Y., Burmeister, K., James, K.M., Haas, L., Tilburt, J.C., and Beebe, T.J. (2012). Getting physicians to open the survey: Little evidence that an envelope teaser increases response rates. *BMC Medical Research Methodology*, 12(1), 41.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the participants' responses will remain private to the extent allowable by law. The consent form contains a statement emphasizing that no one will be able to link a participant's identity to his/her responses and that each participant will only be identified by a unique ID. Researchers will not tie respondents' personally identifiable information (PII) to their answers. All analyses will be done in the aggregate, and respondent information will not be appended to the data file used. Further, no identifying information will be included in the data files delivered by FMG to FDA.

The following procedures will be used to ensure participant confidentiality before, during, and after fielding: (1) data transfer between SERMO and FMG will be conducted via a secure password-protected File Transfer Protocol (FTP) site; (2) all screening-related information will not be tied to any PII but will be identified and matched by the assigned unique ID; (3) data sets and reports will not contain any PII; and (4) respondents will not be tied to their individual responses, and all analyses will be conducted in the aggregate (i.e., any data used in reporting will not be attributed to specific participants).

Any data sets and reports delivered to FDA will not include PII. All identifying information will be kept on a separate password-protected computer and/or in locked cabinets for a period of three years and will only be accessible by FMG. After three years, FMG will destroy the information by securely shredding documents or permanently deleting electronic information. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

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 Appendix B.

12. Estimates of Annualized Burden Hours and Costs

For both the pretests and main study, the questionnaire is expected to last no more than 20 minutes. This will be a one-time (rather than annual) collection of information. FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[2]
Pretest screener	197	1	197	.03 (2 minutes)	6
Main Study screener	700	1	700	.03 (2 minutes)	21
Completes, Pretest	158	1	158	.33 (20 minutes)	53
Completes, Main Study	566	1	566	.33 (20 minutes)	187
Total	1,621		1,621		267

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to next full hour

These estimates are based on FDA's and the contractor's experience with previous HCP studies.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is $179,670 ($59,890 per year for three years). This includes the costs paid to the contractors to manipulate the stimuli, program the study, draw the sample, collect the data, and create and analyze a database of the results. The contract was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not public information. The cost also includes FDA staff time to design and manage the study, to analyze the resultant data, and to draft a report ($97,000; 8 hours per week for three years).

15. Explanation for Program 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. See Part B for detailed information on the design, research questions, and analysis plan. 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 at trade and academic conferences, publications, articles, and Internet posting.

Table 2.--Project Time Schedule

Task	**Estimated Number of Weeks after OMB Approval**
Pretest completed	16 weeks
Main study data collected	40 weeks
Final methods report completed	42 weeks
Final results report completed	62 weeks
Manuscript submitted for internal review	68 weeks
Manuscript submitted for peer-review journal publication	76 weeks

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

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.