

Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit
Information in Direct-To-Consumer Prescription Drug Ads

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance – None.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 1701(a)(4) of the Public Health Service Act (42 USC 300u(a)(4)) authorizes the Food and Drug Administration (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 USC 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.

In a typical promotional campaign, consumers may be exposed to a direct-to-consumer (DTC) prescription drug ad any number of times. Perceptual and cognitive effects of increased ad exposure frequency have been studied extensively using non-drug ads. For instance, one study demonstrated that a commercial message repeated twice generates better recall than a message broadcast only once.¹ Another study demonstrated that increased ad exposures improve product attitudes and recall for product attributes, particularly when the substance of the repeat messages is varied.² Generally, it has been argued that first exposure to an ad results in attention, second exposure affects learning of the advertised message, and third and subsequent exposures

1 Singh, S.N., Linville, D., & Sukhdial, A. (1995). Enhancing the efficacy of split thirty-second television commercials: An encoding variability application. *Journal of Advertising*, 24, 13-23.

2 Haugtvedt, C.P., Schumann, D.W., Schneier, W.L., & Warren, W.L. (1994). Advertising repetition and variation strategies: Implications for understanding attitude strength. *Journal of Consumer Research*, 21, 176-189.

reinforce the learning effects of the second exposure.³ To our knowledge, the literature concerning ad exposure frequency has not been extended to include specific attention to prescription drug ads. Prescription drug ads are unique in that they are required to provide both benefit and risk information whereas other ad types tend to include only benefit information. The Office of Prescription Drug Promotion (OPDP) plans to examine effects of variation in exposure frequency to DTC prescription drug television ads through empirical research.

2. Purpose and Use of the Information Collection

This research will examine effects of variation in exposure frequency to DTC prescription drug television ads. The long-term objective is to improve the communication of accurate and non-misleading information in DTC ads. Part of FDA's public health mission is to ensure the safe use of prescription drugs; therefore it is important to communicate the risks and benefits of prescription drugs to consumers as clearly and usefully as possible.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. Administration of study procedures will take place in person, but data will be collected using programmed surveys administered over the Internet, which will record responses and provide appropriate probes when needed. FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's request. 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.

4. Efforts to Identify Duplication and Use of Similar Information

³ Naples, M.J. (1997). Effective frequency: Then and now. *Journal of Advertising Research*, 37, 7-12.

We conducted a literature search to identify duplication and use of similar information. We conducted a systematic review of the scientific literature by locating relevant articles through keyword searches using four different databases, including PubMed and PsycInfo. We also identified relevant articles from the reference list of articles found through keyword searches. We did not find duplicative experimental work on the effects of variation in exposure frequency to DTC prescription drug television ads.

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 November 12, 2014 (Volume 79 FR 67172). FDA received five public submissions. In the following section, we outline the observations and suggestions raised in the comments and provide our responses. Comments that are not PRA-relevant (e.g., “Ban DTC”) or do not relate to the proposed study are not included below or addressed in our responses.

(Comment from Valeant Pharmaceuticals) Develop and publish a strategic plan for how FDA will collate and make use of data from all FDA-sponsored studies concerning consumer and physician perception and comprehension of prescription drug advertising and promotion.

(Response) The OPDP research webpage⁴ has recently been updated to reflect the current status of completed and ongoing research. As stated on our webpage, OPDP maintains an active research program designed to investigate applied and theoretical issues in the communication of risk and benefit information in DTC and professional promotional prescription drug materials. OPDP's research supports FDA's goal of science-based policy while maintaining its commitment to protect the public health. The research provides FDA management with evidence that can be considered along with other relevant research in future policy decisions.

(Comment from Valeant Pharmaceuticals) Provide data to confirm limiting the study recruitment to Washington, DC and Raleigh Durham, NC area is representative of the entire United States.

(Response) The research questions examined in this study (e.g., risk and benefit recall as a function of the number of target ad exposures) are believed to apply to human judgment and decision making and not to be contingent upon geographic residence. We acknowledge that collecting data across a greater number of geographic locations may provide value, but choose to allocate our limited funding in ways we believe more appropriately ensure the integrity of the research. For example, the requirement that participants view 60-minutes of programming led us to collect data in-person, which allows for us to supervise participant engagement with the survey and therefore ensure that stimuli are in fact viewed. Although the current research includes limited geographic diversity, note that other forms of diversity (e.g., gender, age, and race) will be sought during recruitment and accounted for in our analyses.

⁴ <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm>

(Comment from Valeant Pharmaceuticals) Six exposures during the same 42-minute television program is not reflective of how advertising is delivered and could inadvertently bias the results.

(Response) The study design has been revised such that the experimental groups will view the ad one, two, or four times over the course of the 60-minute viewing period. Additional details about this change are provided in later responses.

(Comment from Valeant Pharmaceuticals) Consumer comprehension of benefit and risk is not solely based on the viewing of the DTC TV ad in isolation. Consumer comprehension should take into account the role of the health care professional and other materials.

(Response) We appreciate that consumer judgment and decision making often results from multiple information sources. In many cases, DTC TV ads serve as the first source of information received, and therefore may influence whether or not additional information is sought, and ultimately whether or not a product is requested from a healthcare professional. Through broad research on DTC advertising, we seek to ensure that consumers are appropriately informed about the risks and benefits of prescription drugs across all information sources, when viewed in isolation or in combination with other sources.

(Comment from Valeant Pharmaceuticals) Because the study is limited to one DTC TV ad and one therapeutic area, the results should not be broadly applied to other forms of advertising or other therapeutic areas.

(Response) We agree that results should not be broadly applied to other forms of advertising. We do not agree that results necessarily need be restricted to the selected therapeutic area. Our primary research question for the study is whether increasing ad exposure frequency will result in different risk or benefit perceptions than less exposure to the ad. This question pertains to

human perception and judgment and is not thought to be unique to any particular therapeutic area. Nonetheless, we agree that replication of this research using other forms of advertising and different therapeutic areas would be valuable.

(Comment from Abbvie) It is not clear how the proposed collection is necessary for the proper performance of FDA's functions. It is difficult to ascertain how the Agency will utilize the results of this study within its statutory authority. For example, should the results of this study demonstrate that the frequency of ad exposure matters, how would the Agency modify the airing frequency of DTC TV ads or the frequency at which consumers are exposed to the advertisements in a real world setting? Rather than conduct this study, we suggest that FDA resources and tax payer dollars would be better directed to research that enhances the quality of how we communicate benefit and risk information to consumers regardless of the medium and the frequency of the exposure. Guidance is needed on the best practices for communicating benefit and risk information to consumers who are prescribed prescription drugs. This is particularly important as the quality of the communication has the power to result in a better informed consumer.

(Response) This research reflects the need to understand not only the message that consumers receive, but also the delivery of those messages, and how that delivery influences perception, judgment, and decision making. It may be that full comprehension of benefit information is achieved upon a single exposure, whereas full comprehension of risk information requires multiple exposures. Insight on this topic may allow FDA to make more informed judgments regarding consumer information processing of DTC television ads.

(Comment from Abbvie) Should the Agency proceed with this study, FDA could enhance the quality, utility, and clarity of the information to be collected by avoiding introducing bias into

the way the survey is conducted. For example, in the draft survey (version 10.22.14), FDA creates an artificial setting in which participants are instructed to watch the commercials that air during a 90 minute TV program during which the same ad airs three to six times. This is very different from the airing and viewing frequency of DTC ads that occur today. Hence, we question the applicability of the results of this study to a real world setting.

(Response) Please note that stimuli play for 60 minutes (not 90), and that the original design involved airing of the ad one, three, or six times (not three to six). We appreciate that six viewings would be unusual and so the study design has been revised such that the experimental groups will view the ad one, two, or four times over the course of the 60-minute viewing period. Additional details about this change are provided in later responses.

(Comment from Eli Lilly) The FDA sample does not currently include a 'General Population' control group, as all participants will be screened to qualify when identified as suffering from seasonal allergies, a condition that could be relieved by the drug described in advertisement. It may be helpful to the FDA's analysis plan to include a control group.

(Response) Researching each medical condition, or general population sample, requires significant resources. We are committed to conducting this research using our available resources while ensuring the integrity of the research by collecting data on a high prevalence condition for which participants might be thought of as sufficiently representative of the average consumer, thus allowing us to draw conclusions about broad perceptual and cognitive processing outcomes.

(Comment from Eli Lilly) In the proposed study design, respondents will watch a 42-minute television program with an embedded clutter reel of ads. Within this time period, respondents will be exposed to a drug ad 1, 3, or 6 times and then administered a survey instrument. While

we acknowledge that a consumer can be exposed to an ad 6 times or *more*, we do not believe 6 exposures in such a compressed time period represents a reasonable real-world experience and is likely to overstate consumer reaction, particularly given that such reactions will be tested immediately after viewing. We believe the current design imposes a risk of creating artificial differences between the study arms by skewing perception, judgment, retention of information, intent, *etc.*, ultimately leading to erroneous conclusions and unactionable expectations.

Specifically, research data on multiple ad exposures and "effective frequency" is long established. Based upon multiple studies, experience, and client preference across industries, a leading global media-buying firm with whom we work generally adheres to two {2} "units" per hour as its standard (i.e. a broadcast advertisement is delivered to the intended audience in a single program no more than twice each hour). While there may be occasions where some advertisers allow for increased frequency (such as holiday weeks or the like), the norm tends to gravitate to no more than two per hour. This implies that in the consumer packaged goods space, 6 exposures in a 42-minute television program exceeds standard practice. In the drug advertising category, that level of exposure would be well beyond reasonable expectations.

We recommend that FDA limit study arms to more realistic scenarios (e.g. 1, 2, and 3 exposures) *or*, alternatively, to spread out the higher frequency arm (e.g. 6) over a longer study period, preferably with a longitudinal design, to more closely represent how consumers receive and process information in a real-world environment.

(Response) We appreciate this insight. The study design has been revised such that the experimental groups will view the ad one, two, or four times over the course of the 60-minute viewing period. We consider the one and two exposure conditions to be realistic. The four exposure condition, while limited in its ecological validity, allows for experimental examination

of “excessive” exposures, which may be associated with outcomes such as consumer wearout; that is, deterioration or diminishment of effects of ad repetition on mental processing after a certain amount of exposure. Also, it is important to note that in studying advertising effects, it is necessary to create enough difference in the manipulations between experimental groups to allow for variation in outcomes to be detected. Given the laboratory setting, it is not possible to extend the viewing period longer than one hour without significantly increasing the burden on respondents.

(Comment from Eli Lilly) We were unable to determine if the study arms that will see multiple exposures will be exposed to the same version of the ad or variations of the ad. We recommend utilizing the same version of the ad for consistency between the study arms.

(Response) These participants will view the same ad across all exposures.

(Comment from Eli Lilly) In the pre-stimulus instructions/disclosure section, we recommend removing "on behalf of a public health agency." This language may trigger the respondent, who would see it before being exposed to the clutter reel, to be on the alert for health-related content and create bias that is not accurate in a real-world setting.

(Response) We agree with this concern. This language has been revised to “on behalf of a government agency.”

(Comment from Eli Lilly) In the post-stimulus/survey instrument instructions section, we recommend removing references to a) "a drug ad" and, b) specific product name. Introducing this language provides the name of the product they are asked to identify in the first survey instrument question. It may also create unnecessary bias by identifying for the respondent the subject of the survey instrument.

(Response) These references have been removed.

(Comment from Eli Lilly) We recommend combining Questions 6 and 7 (risks and benefits) and randomizing the order. We believe this will more accurately represent recall rather than grouping risks together and benefits together.

(Response) In natural settings, consumers may think about drug benefits and risks simultaneously or separately. We argue that there are empirical advantages to collecting data on these measures separately. There is literature to suggest personally relevant threatening information may be defensively processed^{5,6,7} and thus processed differently than benefit information. We prefer to compare responses to benefit and risk items to one another, and combining them into one question would hinder this analysis. Moreover, note that in related literature, these constructs are typically measured with independent scales, or at least independent scales within a single scale. This assessment is based on an ongoing literature review concerning item and scale measure development.

Additionally, splitting these measures reduces psychological burden on participants. It is believed to be easier for participants to respond to seven items concerning benefits in one matrix, followed by seven items concerning risks in another matrix, than for participants to respond to 14 items about both benefits and risks in a single matrix. Omitting items would reduce our ability to adequately measure either benefits or risks. Relatedly, collecting data on benefits and risks separately may increase the likelihood that participants take time to process each item and respond accurately.

5 Janis, I. L. & Feshbach, S. (1953). Effects of fear-arousing communications, *Journal of Abnormal and Social Psychology*, 48, 78-92.

6 Liberman, A. & Chaiken, S. (1992). Defensive processing of personally relevant health messages. *Personality and Social Psychology Bulletin*, 18, 669-679.

7 Smith, S. M., & Petty, R. E. (1996). Message framing and persuasion: A message processing analysis. *Personality and Social Psychology Bulletin*, 22, 257-268.

(Comment from Eli Lilly) We recommend adding a "Don't Know" answer choice for Questions 9, 10, and 13 as respondents may be unable to assess the likelihood or seriousness of side effects, or effectiveness of the product. The current range of answers may force inaccurate or speculative responses; a "Don't Know" answer would be a legitimate choice and informative for the study. Our standard practice is to provide a "Don't Know" option whenever it could be a valid answer.

(Response) We understand the value of providing such responses for items of a factual nature. The drawback to providing such response options to these questions, however, is that we may lose information by allowing respondents to choose an easy response instead of giving the item some thought. Research by Krosnick et al. (2002)⁸ demonstrated that providing “no opinion” options likely results in the loss of data without any corresponding increase in the quality of the data. Thus, we prefer not to add these options to the survey.

(Comment from Eli Lilly) We recommend randomizing the answers to Question 15 to avoid order bias. We note that the answer choices are in sequence of probable behavior after being informed by advertising.

(Response) Indeed, ordering of items was chosen to reflect sequence of probable behavior after being informed by advertising. We believe maintaining this continuum most appropriately reflects decision making on the part of the consumer. Moreover, we have conducted surveys both with and without randomizing these items, and no differences in responses were observed.

(Comment from Eli Lilly) For Question 16, we suggest explicitly stating "after being prescribed by a doctor" to the end of the question. The question currently does not provide this context, leaving respondents to interpret whether or not they are to consider how they feel about

8 Krosnick, J.A., Holbrook, A.L., Berent, M.K., Carson, R.T., Hanemann, W.M., Kopp, R.J...Conaway, M. (2002). The impact of “no opinion” response options on data quality: Non-attitude reduction or an invitation to satisfice? *Public Opinion Quarterly*, 66, 371-403.

"taking" Drug X without guidance from a learned intermediary. We believe this may render the data on this question ambiguous.

(Response) We have incorporated this suggestion into the revised questionnaire.

(Comment from Eli Lilly) For Questions 20 a and b, we suggest spelling out "FDA."

(Response) We have incorporated this suggestion into the revised questionnaire.

(Comment from Eli Lilly) For Questions 20 a and c, we recommend eliminating the adverb "extremely" as it may create ambiguity. It would be reasonable for some people to answer "false" to "extremely effective" while also believing simply "effective" was true, while other respondents may not see a distinction. This may skew the data artificially toward "false."

(Response) Indeed, participants may respond differently depending on whether or not the adverb "extremely" is included. The item is designed to assess perceptions of whether only extremely effective products are approved by the FDA (likewise, only "serious" risks are assessed in Q20b and Q20d.) We prefer to retain this item because it captures the intended outcome we wish to measure, whereas an item that excludes the adverb "extremely" would not. Also note that these items have been previously published elsewhere and we prefer to match the original language.⁹

(Comment from Eli Lilly) We recommend eliminating Question 20 g, which seems redundant with 20 f. If respondents were to answer False for 20 f but True for 20 g, it would provide no insight but could skew perceptions of the data. If the question is retained, we recommend eliminating the word "in" (i.e. "believe in"), which in this context may connote a broader judgment about the drug industry, for which there is ample existing data, than of the

9 Woloshin, S., Schwartz, L.M. (2011) Communicating data about the benefits and harms of treatment: A randomized trial. *Annals of Internal Medicine*, 155, 87–96.

regulatory oversight of drug advertisements. The language creates bias by implying that misleading information is embedded in drug ads, skewing the data toward "false."

(Response) We have deleted Q20g, and modified Q20f as follows: "All of the information in prescription drug commercials is approved by the US Food and Drug Administration." In addition, we have added the following items: "All of the benefit information in prescription drug commercials is approved by the US Food and Drug Administration," and "All of the risk information in prescription drug commercials is approved by the US Food and Drug Administration."

(Comment from Eli Lilly) For Question 20 h, we recommend changing the word "safest" to "safe," which may force respondents to make a subjective judgment about what constitutes "safest" (i.e. is there a set of safest, or simply the single-most safest drug?) even though they may believe that all advertised drugs have been deemed to be safe. This may strongly skew data toward "false."

(Response) We appreciate that asking about "safest" versus "safe" drugs will likely result in different responses. We prefer to retain the current language because it captures the intended outcome we wish to measure. Nonetheless, we will be careful to restrict our interpretation of findings pertaining to this question based on these potential differences in responding.

(Comment from Eli Lilly) Questions 21 a and b seem to be leading questions that may strongly bias respondents to presuppose that the ad is misleading and that the survey instrument is simply trying to understand the extent to which it is misleading. We acknowledge that the answer choices allow respondents to select "not at all misleading," but four-fifths of the answer options represent degrees of "misleading," which may create strong response bias. Although 21 c provides the alternative question, by the time the respondents reach this question they will

have been biased by the previous two questions that the ad is misleading, skewing the data toward "not truthful." We recommend this section be revised.

(Response) These three items were included in the survey for the purposes of cognitive testing. Results from cognitive testing suggest that participants have difficulty answering the question about "truthful" because they feel they do not know the truth. They generally provide the same answer to both questions that ask about how misleading the ad is. We therefore will omit questions 21a and 21c.

(Comment from Eli Lilly) For Questions 24 and 25, we recommend adding "or difficult" to the question to minimize biasing respondents that the product is "easy" to use and to make the question and answer choices consistent.

(Response) We have incorporated this suggestion into the revised questionnaire.

(Comment from Eli Lilly) We are concerned that Question 27 has potential to create bias and to confuse respondents. It contains language that may trigger respondents to believe they should be "concerned" to some extent. The question language combined with the inference of doctor's involvement is potentially confusing. We suggest revising this question, perhaps to something more simple like: "If you were considering taking [Drug X], how would you feel about the side effects mentioned in the ad?"

(Response) The suggested revised version of Q27 points out to participants that the ad notes side effects and so also "biases" participants but in a slightly different way. The core assumption that there are always side effects to be considered in some form seems sufficiently reflective of contemporary DTC prescription drugs and thus we prefer not to change the language.

(Comment from Eli Lilly) For Question 28, we recommend using "Neither Agree nor Disagree" as the midpoint of the scale, consistent with previous scale language in the survey instrument.

(Response) This measure of need for cognition has been published and validated in the literature.¹⁰ Thus, we prefer not to change the wording.

(Comment from Eli Lilly) Question 28 b is potentially unclear. We recommend revising the question.

(Response) This measure of need for cognition has been published and validated in the literature. Thus, we prefer not to change the wording.

(Comment from Eli Lilly) Question 29 seems to have an omitted word. We recommend revising to: "How confident are you about filling out medical forms by yourself?"

(Response) This is an item that has been used in the literature, and thus we prefer not to change the wording.¹¹

(Comment from Eli Lilly) We recommend revising Question 31 by deleting or amending the language "Below are statements other people have made about their medications." This language appears unnecessary and may bias respondents by implying that, because the statements are included in the survey instrument, they are truthful and may warrant the respondents to feel that way to some extent.

10 Cacioppo, J.T. & Petty, R.E. (1984). The Efficient Assessment of Need for Cognition, *Journal of Personality Assessment*, 48, 306-307.

11 Chew, L.D., Griffin, J.M., Partin, M.R, Noobaloochi, S., Grill, J.P., Snyder A., ... VanRyn M. (2008). Validation of screening questions for limited health literacy in a large VA outpatient population. *Journal of General Internal Medicine*, 23, 561-566.

(Response) This item has been validated in the literature¹² and thus we prefer not to change the language.

(Comment from Eli Lilly) Also for Question 31, we recommend using "Neither Agree nor Disagree" as the language midpoint of the scale, consistent with previous scale language in the survey instrument.

(Response) This item is from the Beliefs in Medicines Questionnaire. This item has been validated in the literature and thus we prefer not to change the language.

(Comment from Eli Lilly) In Questions 35 and 36, we believe there could be variability in consumers' definition of what constitutes "serious" side effect without additional definition. We recommend the survey design consider providing additional context for the consumer in the question wording.

(Response) We agree there is likely to be variability in how consumers define serious side effects. We examined these items in cognitive testing. Based on results from that cognitive testing, respondents generally define "serious" side effects as those that require medical attention or that are life threatening. It does not seem that respondents have trouble answering this question.

External Reviewers

Requests for peer review of the study design, methodology, and questionnaire were sent to eight experts. Feedback was provided by two experts:

- Prashant Malaviya, Ph.D., Associate Professor, Georgetown University.
- Andy Tan, Ph.D., Assistant Professor, Harvard School of Public Health

12 Horne, R., Weinman, J., & Hankins, M. (1999). The Beliefs about Medicines Questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. *Psychology & Health, 14*, 1–24.

9. Explanation of Any Payment or Gift to Respondents

Participants completing the pretest or main study research will receive \$100 cash incentive for completing a 90-minute interview. According to Karen Sollod of OMR Market Research and Focus Groups based in Washington, DC, \$75 had been the industry standard until a few years ago. At that time, facilities in Washington, DC, Philadelphia, Dallas, and Seattle began to offer a \$100 incentive for consumers. According to these facilities, with the current cost of gas and other travel expenses, \$100 is the new standard for ensuring participation in qualitative research. The two research facilities with which we will partner for this study have confirmed that \$100 would be the appropriate standard for the 90 minutes interviews. Given this information, we propose a \$100 incentive to ensure that we are able to attract a reasonable cross-section of consumers 18 and older with a diagnosis of seasonal allergies.

10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained 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. Confidentiality of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee, RIHSC) prior to collecting any information.

All respondents will be provided with an assurance of privacy to the extent allowable by law. The pretest and main study instructions and informed consent will include information explaining to respondents that their information will be kept confidential.

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.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this collection of information is 1,954 hours for this one-time collection.

FDA estimates the burden of this collection of information as follows:

Table 1: Estimated Annual Reporting Burden					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest 1 screener completes (assumes 10% eligible)	1,050	1	1,050	.08 (5 min.)	84
Pretest 2 screener completes (assumes 10% eligible)	1,050	1	1,050	.08 (5 min.)	84
Number of main study screener completes	6000	1	6000	.08	480

(assumes 10% eligible)				(5 min.)	
Pretest 1 completes	125	1	125	1.5 (90 min.)	188
Pretest 2 completes	125	1	125	1.5 (90 min.)	188
Number of completes, main study	620	1	620	1.5 (90 min.)	930
Total	==	==	==	==	1,954

Note: While target sample sizes for pretests are 105 and for main study is 600, we have accounted for some potential overage in the burden table. As data is being collected in two locations simultaneously, it may be possible that the target will be exceeded if alternates are included in order to try to achieve the target.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public	1,954	\$19.50 ^a	\$38,103

^a Based on the 2014 median weekly income of \$780 for both sexes, as reported by the Department of Labor, <http://www.bls.gov/news.release/pdf/wkyeng.pdf>.

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 total estimated cost to the Federal Government for the data collection is \$1,198,806 (\$399,602 per year for three years). This includes the costs paid to the contractor to perform a

literature review, design a study, create and test measures and experimental stimuli, recruit a consumer sample, collect and analyze data, write reports of work completed, and present findings. The task order 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.

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. See Part B for detailed information on the design, hypotheses, 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 posting on FDA’s website.

Table 2: Estimated Project Timetable

Task	Estimated Completion Date
60-day FRN publication	November, 2014
External peer review	January, 2015
RIHSC review	April, 2015
Cognitive testing	February-April, 2015

30-day FRN publication	June, 2015
OMB Review of PRA package	June, 2015
Pretesting	August, 2015
Main Study Data Collection	January, 2016
Data Analysis	June, 2016
Final Draft of Manuscript	October, 2016

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.