4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1794]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in Direct-To-Consumer Prescription Drug Ads

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in Direct-To-Consumer Prescription Drug Ads." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910-NEW

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.

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 (Ref. 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 (Ref. 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 reinforce the learning effects of the second exposure (Ref. 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 the effects of variation in ad exposure frequency on perception and mental processing of risk and benefit information in DTC prescription drug ads through empirical research.

The main study will be preceded by up to two pretests designed to delineate the procedures and measures used in the main study. Across pretests and the main study, participants will be individuals who have been diagnosed with seasonal allergies. All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Participants will be recruited in one of two geographic locations (Washington, D.C. and Raleigh, North Carolina) for in-person administration of protocols.

The experimental design is summarized below. Participants will be randomly assigned to view a prescription drug ad one, two, or four times as part of clutter reels embedded in 42 minutes of TV programming. They will then answer preprogrammed survey questions on laptops. Measures are designed to assess perception, memory, judgments about the ad, intentions to use the medication advertised, and possible moderators of effects, such as need for cognition and demographics. The questionnaire is available upon request.

Table 1.--Study Design

Experimental Arm No.	Episode #1			Episode #2		
	Clutter Reel 1	Clutter Reel 2	Clutter Reel 3	Clutter Reel 4	Clutter Reel 5	Clutter Reel 6
1 (views ad 1 time)						Mock DTC ad
2 (views ad 2 times)			Mock DTC ad			Mock DTC ad
3 (views ad 4 times)	Mock DTC ad		Mock DTC ad	Mock DTC ad		Mock DTC ad

In the Federal Register of November 12, 2014 (79 FR 67172), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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 Web page (Ref. 4) has recently been updated to reflect the current status of completed and ongoing research. As stated on our Web page, 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.

(Comment from Valeant Pharmaceuticals) Six exposures during the same 42-minute television program are 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 healthcare 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 taxpayer 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 1 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 (Refs. 5, 6, and 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.

(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. (Ref. 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 "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 (Ref. 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 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 (Ref. 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 (Ref. 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.

(Response) This item has been validated in the literature (Ref. 12) 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.

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described below, we will have sufficient power to detect small-to-medium sized effects in the main study.

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

Table 2.--Estimated Annual Reporting Burden[1]

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 (assumes 10% eligible)	6000	1	6000	.08 (5 min.)	480
Pretest 1 completes[2]	125	1	125	1.5	188
Pretest 2 completes[2]	125	1	125	1.5	188
Number of completes, main study[2]	620	1	620	1.5	930
Total	==	==	==	==	1,954

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

References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov. (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. Singh, S. N., D. Linville, and A. Sukhdial, "Enhancing the Efficacy of Split Thirty-Second Television Commercials: An Encoding Variability Application," Journal of Advertising, 24, pp. 13-23 (1995).

2. Haugtvedt, C. P., et al., "Advertising Repetition and Variation Strategies: Implications for Understanding Attitude Strength," Journal of Consumer Research, 21, pp. 176-189 (1994).

3. Naples, M. J., "Effective Frequency: Then and Now," Journal of Advertising Research, 37, pp. 7-12 (1997).

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

5. Janis, I. L. and S. Feshbach, "Effects of Fear-Arousing Communications," Journal of Abnormal and Social Psychology, 48, pp. 78-92 (1953).

6. Liberman, A. and S. Chaiken, "Defensive Processing of Personally Relevant Health Messages," Personality and Social Psychology Bulletin, 18, pp. 669-679 (1992).

7. Smith, S. M. and R. E. Petty, "Message Framing and Persuasion: A Message Processing Analysis," Personality and Social Psychology Bulletin, 22, pp. 257-268 (1996).

8. Krosnick, J. A., A. L. Holbrook, M. K. Berent, et al., "The Impact of 'No Opinion' Response Options on Data Quality: Non-Attitude Reduction or an Invitation to Satisfice?" Public Opinion Quarterly, 66, pp. 371-403 (2002).

9. Woloshin, S. and L. M. Schwartz, "Communicating Data About the Benefits and Harms of Treatment: A Randomized Trial," Annals of Internal Medicine, 155, pp. 87-96 (2011).

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

11. Chew, L. D., J. M. Griffin, M. R. Partin, et al., "Validation of Screening Questions for Limited Health Literacy in a Large VA Outpatient Population," Journal of General Internal Medicine, 23, pp. 561-566 (2008).

12. Horne, R., J. Weinman, and M. Hankins, "The Beliefs About Medicines Questionnaire: The Development and Evaluation of a New Method for Assessing the Cognitive Representation of Medication," Psychology & Health, 14, pp. 1-24 (1999).

Dated: June 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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