



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1819]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Spousal Influence on Consumer Understanding of and Response to Direct-to-Consumer Prescription Drug Advertisements

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Spousal Influence on Consumer Understanding of and Response to Direct-to-Consumer (DTC) Prescription Drug Advertisements". 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, PRASStaff@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.

Spousal Influence on Consumer Understanding of and Response to Direct-to-Consumer Prescription Drug Advertisements--(OMB Control Number 0910-NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes 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(d)(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.

Consumers are often thought of as individual targets for prescription drug advertisements (ads), as if they are always exposed to DTC ads individually and subsequently make judgments about advertised products on their own. However, judgments about prescription drugs portrayed in DTC television ads are likely made in social contexts much of the time. For example, a potential consumer and his or her spouse (e.g., marital or domestic partner) may view an ad together and discuss drug benefits, side effects, and risks. These social interactions may result in unique reactions relative to consumers who view DTC prescription drug television ads alone. For example, spouses may influence their partner by expressing concern about risks and side effects that might occur, or pressuring their partner to consider the drug despite its risks and side effects. These outcomes have important public health implications. The Office of Prescription

Drug Promotion plans to examine differences between consumers viewing prescription drug ads with a spouse versus alone through empirical research.

The main study will be preceded by pretesting designed to delineate the procedures and measures used in the main study. Pretest and main study participants will be couples who are married or in a marital-like living arrangement in which one member (consumer) has asthma and the other does not (spouse). All participants will be 18 years of age or older and married or cohabiting for 6 months or longer. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Data collection will take place in person.

Participants will be randomly assigned to one of four experimental conditions in a 2 X 2 design, as depicted in Table 1. We will compare one version of an ad that depicts a low benefit and low risk drug with a second version that depicts a high benefit and high risk drug.

Participants will be randomly assigned to view the ad alone or together with their spouse.

Participants in both viewing conditions will individually complete a prequestionnaire. In the “together” condition, participants will view the ad with their spouse and then engage in a brief discussion together about the ad. In the “alone” condition, participants will view the ad without their spouse, take a short break, and then respond to a postquestionnaire consisting of questions about information in the ad. The short break in the “alone” condition will facilitate reflection about the ad to mirror discussion engaged in by those in the “together” condition. The consumer in the “together” condition will complete the same postquestionnaire administered to those in the “alone” condition, and the spouse will complete a slightly different questionnaire that assesses key measures that relate to consumer reactions. These procedures are depicted in Table 2.

Participation is estimated to take approximately 60 minutes.

Measures are designed to assess memory and understanding of risk and benefit information as well as other ad content, intention to seek more information about the product, and variables pertaining to the consumer-spouse relationship such as relationship closeness and communication style. The questionnaire is available upon request.

Table 1.--Experimental Study Design

Viewing Condition	Risk/Benefit Condition	
	Low Risk/ Low Benefit	High Risk/ High Benefit
Alone	Condition A	Condition B
Together	Condition C	Condition D

Table 2.--Overview of Data Collection Process for Alone and Together Conditions

Steps	Viewing Condition	
	Alone	Together
1	Consumer completes prequestionnaire	Consumer and spouse complete prequestionnaire separately (spouse completes selected measures).
2	Consumer views advertising stimuli alone	Consumer and spouse view advertising stimuli together.
3	5 minute break	Couples engage in a 5 minute semi-structured conversation related to the advertising stimuli.
4	Consumer completes postquestionnaire	Consumer and spouse complete postquestionnaire separately (spouse completes selected measures).

In the Federal Register of November 14, 2014 (79 FR 68278), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from two organizations in response to our Federal Register notice. In the following section, we outline the observations and suggestions raised in the comments and provide our responses.

(Comment from Abbvie) It is difficult to ascertain how the Agency will utilize the results of this study should it demonstrate that the perception of ads differs when viewed alone or with

someone else. Regulating companion versus solitary viewing practices would present insurmountable legal and practical hurdles. 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 setting in which the ad is viewed.

(Response) Much research in the social sciences demonstrates the strong influence of environmental and social conditions under which humans think and act. In regard to prescription drug advertising, it may be that when a risk is perceived as particularly negative, viewing with a partner reinforces this perception. Conversely, it may be that partners downplay risks or emphasize benefits, leading to alternate perceptions and intentions. These potential outcomes have implications for public health. Thus, it is important to generate insight about not only the message portrayed in DTC TV ads but also the conditions under which these messages are received and processed. Pending findings from this research, organizations involved in developing DTC drug communications may be encouraged to remain aware of the social context in which DTC ads are often viewed and the influence of this context on consumer perceptions, judgments, and decisions. Consideration of this broader context may facilitate the development of better DTC drug communications that remain accurate and balanced regardless of setting.

(Comment from Eli Lilly) Compelling a discussion between the consumer and spouse about the advertisement is likely to generate data that may or may not be applicable in a real-world setting. Consider removing the prescribed interaction and allow a discussion to occur if the couple so chooses.

(Response) Allowing a discussion to occur if the couple chooses could confound the research design and undermine our ability to make conclusive statements. Implementing the

procedures systematically across the sample is a stronger study design (Ref. 1). There is a long tradition in the social and behavioral sciences of studying marital communication as proposed (Ref. 2). This research tradition continues because this method is more objective than participant self-reports (Ref. 3). Also, measures taken from these spousal communications are linked with important real world outcomes including health behavior and well-being (Ref. 4, Ref. 5), divorce, and marital satisfaction (Ref. 6, Ref. 2). This research method compels a discussion between partners as a way to understand the content and style of their communication. Thus, our proposed study is in keeping with the methods in this research area.

(Comment from Eli Lilly) We are challenged to understand how this research yields any useful, actionable information when it is impractical to influence who is watching TV advertisements at any given time.

(Response) As stated in response to a previous comment, it is important to generate insight about not only the message portrayed in DTC TV ads but also the conditions under which these messages are received and processed. Such insight may facilitate the development of better DTC drug communications regardless of setting.

(Comment from Eli Lilly) Include a “General Population” control group.

(Response) Researching each medical condition, or general population sample, requires significant resources. We are interested in response to the ads among consumers for whom the ad is personally relevant (i.e., they or their partner have been diagnosed with asthma). 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) Q12 invites speculation from respondents who may be unable to evaluate what is or is not a “serious” side effect. Consider eliminating this question or re-phrasing to: “Please rate the seriousness of the side effects for [Drug X] that you remember from the ad.”

(Response) We have conducted cognitive interviews to refine and improve the survey questions. Through this process, we found that a number of participants had difficulty reading and/or answering Q12 in its original form. We also tested an alternative version of this question that conforms to the reviewer’s re-phrasing, “In your opinion, how serious are the side effects of [Drug X]?” Many cognitive interview participants preferred this alternative version, and we will adopt it for the final questionnaire.

(Comment from Eli Lilly) Response options in Q16 may be interpreted qualitatively (i.e., on the whole, the risks outweigh the benefits) or literally (i.e., how many more risks were stated than benefits). Rephrasing to reflect true intent is recommended.

(Response) We appreciate this comment. This item was tested in a rigorous cognitive interview protocol and there was no indication that participants had difficulty interpreting the response options. However, we will also be conducting pretesting which will provide an additional opportunity to identify and remove questions that do not function as intended, further refining the questionnaire prior to the main study.

(Comment from Eli Lilly) Q19b is ambiguous and unclear. Rephrasing or deletion is recommended.

(Response) We tested this item as part of our cognitive interview protocol. The majority of participants understood this question, and their answers suggest that the question did a good job of distinguishing between those who focused on the arguments and facts presented in the ad

versus those who paid more attention to peripheral cues, such as the visual narrative. Because the item functioned as intended, we intend to retain Q19b.

(Comment from Eli Lilly) Q20 is ambiguous and unclear. Rephrasing or deletion is recommended.

(Response) In our cognitive interviews, some participants had difficulty understanding the meaning of the introductory phrase “In these thoughts”. Due to the ambiguity of Q20 as a whole, we will remove this item from the questionnaire.

(Comment from Eli Lilly) Q21 instructions could bias respondents to evaluate each statement as risk-related. Consider rephrasing to, “The following statements describe how people deal with various situations.”

(Response) The Q21 battery is a validated scale specifically designed to measure attitudes toward risk (Ref. 7). Respondents are meant to evaluate the statements as though they are risk-related. Therefore, we will retain the Q21 battery.

(Comment from Eli Lilly) The scale for Q25 should be made consistent with other scales to ensure internal consistency. A scale with a midpoint is recommended.

(Response) When developing the questionnaires, we included a number of questions from existing multi-items scales. The number and format of response options differed from scale to scale (e.g., 6-points vs. 10-points, fully labelled vs. anchors-only, etc.). We will revise the Likert-type response scales so that the number of levels and labeling formats across questions is consistent.

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described in Table 3, 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 3.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretesting					
Number to Complete the Screener	700	1	700	0.08 (5 minutes)	56
Number of Completes	120	1	120	1	120
Main Study					
Number to Complete the Screener	4,060	1	4,060	0.08 (5 minutes)	325
Number of Completes	792	1	792	1	792
Total					1,293

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

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 all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Reis, H., and C. Judd, Handbook of Research Methods in Social and Personality Psychology, 2nd Ed. New York: Cambridge University Press (2014).
2. Kerig, P. K., and D. H. Baucom, (Eds.). Couple Observational Coding Systems, Mahwah, NJ: Erlbaum (2004).

3. Bakeman, R., Behavioral Observation and Coding, In H.T. Reis & C.M. Judd (Eds.) Handbook of Research Methods in Social and Personality Psychology, pp. 138-159. New York: Cambridge University Press (2000).
4. Ewart, C.K., C. B. Taylor, H.C. Kraemer, and W. S. Agras. "High Blood Pressure and Marital Discord: Not Being Nasty Matters More Than Being Nice," Health Psychology, 10, pp. 155-163 (1991).
5. Spitzberg, B.H., and W. R. Cupach, Handbook of Interpersonal Competence Research, NY: Springer-Verlag (1989).
6. Gottman, J.M., What Predicts Divorce? The Relationship Between Marital Processes and Marital Outcomes. Hillsdale, NJ: Erlbaum (1994).
7. Rohrmann, B., "Risk Attitude Scales: Concepts, Questionnaires, Utilizations [Project Report]," University of Melbourne, Australia. Retrieved from <http://www.rohrmannresearch.net/pdfs/rohrmann-racreport.pdf> (2005).

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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