4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3543]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Information in Direct-to-Consumer Television 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 oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Quantitative Information in Direct-to-Consumer Television 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, 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.

Quantitative Information in Direct-to-Consumer Television Advertisements

OMB Control Number 0910-NEW

I. Background

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.

A previous FDA study found that simple quantitative information could be conveyed in direct-to-consumer (DTC) television ads in ways that increased consumer's knowledge about the drug (OMB control number 0910-0663, "Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs") (Ref. 1). However, this research only tested simple information (e.g., one clinical trial, comparison to placebo). Drug information can be much more complicated (e.g., complicated endpoints, multiple study arms). The following studies are designed to address the question of whether consumers can use more complicated information when assessing prescription drug information in television DTC ads. These studies will build on previous research by: (1) Examining more complicated quantitative information, (2) examining

quantitative information for both benefits and risks, and (3) examining how visuals designed to represent efficacy interact with quantitative information.

The objective of this project is to test consumers' understanding of quantitative information about prescription drugs in DTC television ads. In study 1, we plan to examine experimentally the presence and complexity of quantitative benefit and risk information in DTC television ads (table 1). We hypothesize that, replicating past studies, adding simple quantitative information about benefits and risks will lead to increased understanding among consumers. We will test whether adding complex quantitative information results in the same outcomes as simple quantitative information or whether it is too much quantitative information for consumers to process. In study 2, we plan to examine experimentally the presence of quantitative benefit information and how the ad visually represents efficacy (by having no images, images that accurately reflect the improvement in health that could be expected with treatment, or images that overstate the improvement in health that could be expected with treatment (table 2)). We hypothesize that overstated images of improvement will lead consumers to overestimate the drug's efficacy; however, adding a quantitative claim may moderate this effect. To test these hypotheses, we will conduct inferential statistical tests such as analysis of variance (ANOVA). With the sample sizes described in this document, we will have sufficient power to detect small- to medium-sized effects in each study.

All participants will be 60 years of age or older. We will exclude individuals who work in health care or marketing. We selected a sample of participants 60 years and older to increase the likelihood that participants will be interested in the fictitious study drug and therefore motivated to pay attention to the ad during the study. The studies will be conducted with an Internet panel.

In both studies, participants will be randomly assigned to one experimental condition and view the corresponding television ad. The ad will be for a fictitious drug to treat cataracts. The ads will be created and pretested to ensure that consumers perceive different levels of complexity across the ads in study 1 and different levels of image accuracy in study 2. "Pretests for a Study on Quantitative Information in Direct-to-Consumer Television Advertisements" was submitted under OMB control number 0910-0695. After viewing the ad twice, participants will complete a questionnaire that assesses consumers' understanding of the drug information, their retention of the information, and their perceptions of the drug. We will also measure covariates such as demographics and numeracy. The questionnaires are available upon request.

Table 1.--Study 1 Design

		Quantitative Risk Claim		
		No	Yes: General (e.g., Side effects that occur in 10% or less of people who take Drug X include…)	Yes: Specific (e.g., Side effects that occur in [6-10%, 1-5%, and less than 1%] of people who take Drug X include…)
QuantitativeEfficacy Claim	No			
	Yes: Single outcome (e.g., 52% of people with cataracts improved their vision to 20/40 while taking Drug X compared to 23% without Drug X. [starting at an average baseline of 20/70])			
	Yes: Multiple outcomes (e.g., 52% of people with cataracts improved their vision to 20/40 while taking Drug X compared to 23% without Drug X. [starting at an average baseline of 20/70]. With Drug X, people could see an average of 85 letters on a 100-letter eye chart, compared to 73 letters without Drug X.)			

Table 2.--Study 2 Design

		Images of Improvement		
		None	Accurate improvement in health conveyed in images	Overstated improvement in health conveyed in images
Quantitative Benefit Claim	No			
	Yes (Single outcome)			

In the **Federal Register** of October 13, 2015 (80 FR 61433), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four public comments were received. Two comments called for direct-to-consumer prescription drug advertising to be banned. These comments are outside the scope of the current project. Other comments and their responses follow.

(Comment 1) The first suggestion was that FDA should research the health literacy of approved patient labeling before conducting research on DTC television advertising.

(Response) FDA has a program of research that includes studies on both patient labeling and DTC television advertising (Refs. 1 to 3). This study extends previous research and addresses issues unique to DTC television advertising (e.g., visual representations of efficacy) (Ref. 1). The public is exposed to information about prescription drugs via DTC television advertising and this advertising has a public health impact (Refs. 4 and 5). We disagree that there is a need for approved patient labeling research to be conducted before we study issues unique to DTC television advertising.

(Comment 2) The second suggestion is to consider that because low numeracy individuals are not well-represented in online panels we should implement mechanisms to help validate results across health-literate populations.

(Response) We agree that numeracy may be a crucial variable in this study. We have added a second measure of numeracy (subjective numeracy) and a question on health literacy. We will use these measures to determine whether and how numeracy and health literacy affect our results. If our sample has few individuals with low numeracy, we will note this as a limitation.

(Comment 3) The third suggestion is to use a mixed-method approach, recruiting limited-literacy and low socioeconomic participants for in-person administration of the study and using the Internet panel to gather a broad sample.

(Response) We acknowledge that Internet administration is not perfect and have chosen this method to maximize our budget. We will permit the survey to be taken on a variety of devices. We are excluding phones because the stimuli cannot be fully viewed on a very small screen.

(Comment 4) The fourth suggestion is to use frequencies rather than percentages in the questionnaire.

(Response) A recent review of the literature did not support the view that frequencies are more widely understood than percentages (Ref. 6). This review included two studies conducted in the context of DTC advertising (Refs. 1 and 7). Given these findings, we plan to use percentages in the questionnaire.

(Comment 5) The fifth suggestion is to include a single-item health literacy question to the screener.

(Response) We agree this is an important measure and have added it to the questionnaire.

(Comment 6) This comment requests further rationale for the selection of an older patient population and its impact on the generalizability of study findings to advertisements targeted for younger patient populations.

(Response) Advertising studies often recruit participants who have or who are at risk for the medical condition being advertised to increase interest in the ad and motivation to pay attention to the ad. Older participants are more likely to be at risk for cataracts. In addition, older adults use more prescription drugs and watch more television than younger adults do (Refs. 8 and 9). We will note that the study is not broadly generalizable when we report our findings.

(Comment 7) This comment suggests including a video compatibility test to verify that participants can view the videos and precluding participants from taking the survey using a smartphone device.

(Response) We have added a video compatibility test to the study and will preclude participants from using phones.

(Comment 8) This comment also sought clarification on which stimuli from study 1 will be used in study 2.

(Response) The benefit information in study 2 will be the "simple" claim from study 1. Study 2 will not include quantitative risk information. This means that the same ad will be used in the "simple quantitative benefit claim/no quantitative risk claim" condition in study 1 and the "quantitative benefit claim/no images of improvement" condition in study 2.

(Comment 9) This comment expresses concern that adding complex benefit information in study 1 may cause the content to become unmanageable and suggests adding study arms with more of fewer risks and benefits to assess this.

(Response) Based on this comment and peer reviewer feedback, we will manipulate the complexity of quantitative efficacy claim by adding a second benefit outcome. We have revised the study design tables to reflect this (see tables 1 and 2). The number of risks will be constant but we will manipulate whether and how the frequencies of the risks are presented.

(Comment 10) This comment recommended holding all other aspects outside the variable being tested be held constant across the different treatments.

(Response) We agree with this recommendation. We will create one ad that will be the basis of all the stimuli. We will manipulate this base ad by adding quantitative benefit information, quantitative risk information, and/or images of improvement to create the different experimental conditions, while leaving other factors constant.

(Comment 11) This comment recommends using scales with a neutral midpoint.

(Response) There are advantages and disadvantages to including midpoints in scales (Refs. 10 and 11). Based on responses from similar studies, we have decided to use scales without a midpoint. Instead, we have included a "don't know" option for some items that may make participants' responses easier to interpret than a neutral midpoint would.

(Comment 12) This comment noted that without the stimuli it was difficult to tell whether the battery of questions measuring efficacy accuracy was redundant or inapplicable.

(Response) We did not create the stimuli before the public notice so that the public and peer review comments, along with cognitive interviews and pretesting, could inform the creation of the stimuli. Based on peer review, we refined our efficacy claims. We tailored the efficacy accuracy items to reflect the new claims. Some of these questions are designed to measure participants' gist understanding of the drugs' efficacy likelihood and magnitude (Ref. 12). They are not redundant with the questions designed to measure participants' verbatim understanding of

the drugs' efficacy likelihood and magnitude. As in previous research, participants in the control condition will not have the information to answer all the accuracy questions (Ref. 1). Instead, this condition serves as a baseline with which to compare the experimental conditions. We added a "don't know" option so that these participants can report that they do not know the answer.

(Comment 13) This comment suggested reordering questions so that the perception and intention questions appeared before the questions about efficacy and risk information.

(Response) Based on peer review, we moved the gist questions before the accuracy questions, but we did not move intentions and perceptions before gist and accuracy. We understand the value in getting obtaining intentions and perceptions unbiased by the other measures. However, we put the gist and accuracy measures first because they are our primary measures; therefore, we want to decrease potential memory decay and ensure the gist and accuracy measures are not biased.

(Comment 14) This comment questioned whether three risk claim accuracy questions in study 1 were redundant with each other and how the stimulus will list frequencies for the risks.

(Response) We updated table 1 to show how risks will be described in each condition. The terms "least common" and "most common" will not be used in the ads. The questions are not redundant. One question (previously Q17) asks participants to report the frequency for each risk. The other two questions (previously Q20 and Q21) ask participants whether they got the "gist" of how common the risks are. If participants are able to understand the gist of the information, then those in the two quantitative risk information conditions should be able to report that the most common risks had a frequency of roughly 10 percent and participants in the

specific quantitative risk information condition should be able to report that the least common risks had a frequency of roughly 1 percent. We will cognitively test and pretest these items.

(Comment 15) This comment suggests adding "don't know" options to the perceived efficacy and risk questions.

(Response) We added a "don't know" option to the questions that ask participants to compare the advertised drug's risks and benefits to other treatments.

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

Table 3.--Estimated Annual Reporting Burden[1]--Study 1

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Sample outgo	15,130				
Number to complete the screener (10%)	1,513	1	1,513	0.05 (3 minutes)	76
Number eligible for survey (70%)	1,059				
Number to complete the survey (85%)	900	1	900	0.33 (20 minutes)	297
Total			2,413		373

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

Table 4.--Estimated Annual Reporting Burden[1]--Study 2

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Sample outgo	15,130				
Number to complete the screener (10%)	1,513	1	1,513	0.05 (3 minutes)	75.65
Number eligible for survey (70%)	1,059				
Number to complete the survey (85%)	900	1	900	0.33 (20 minutes)	297
Total			2,413		372.65

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

II. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. O'Donoghue, A.C., H.W. Sullivan, K.J. Aikin, et al., "Presenting Efficacy Information in Direct-To-Consumer Prescription Drug Advertisements," Patient Education and Counseling, 95(2):271-280, 2014.

2. Boudewyns, V., A.C. O'Donoghue, B. Kelly, et al., "Influence of Patient Medication Information Format on Comprehension and Application of Medication Information: A Randomized, Controlled Experiment," Patient Education and Counseling, 98(12):1592-1599, 2015.

3. Kish-Doto, J., M. Scales, P. Equino-Medina, et al., "Preferences for Patient Medication Information: What Do Patients Want?" Journal of Health Communication, 19(suppl 2):77-88, 2014.

4. Brownfield, E.D., J.M. Bernhardt, J.L. Phan, et al., "Direct-To-Consumer Drug Advertisements on Network Television: An Exploration of Quantity, Frequency, and Placement," Journal of Health Communication, 9(6):491-497, 2004.

5. Niederdeppe, J., S. Byrne, R.J. Avery, et al., "Direct-To-Consumer Television Advertising Exposure, Diagnosis With High Cholesterol, and Statin Use," Journal of General Internal Medicine, 28(7):886-893, 2013.

6. Zipkin, D.A., C.A. Umscheid, N.L. Keating, et al., "Evidence-Based Risk Communication: A Systematic Review," Annals of Internal Medicine, 161:270-280, 2014.

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

8. Zhong, W., H. Maradit-Kremers, J.L. St. Sauver, et al., "Age and Sex Patterns of Drug Prescribing in a Defined American Population," Mayo Clinic Proceedings, 88(7):697-707, 2013.

9. Depp, C.A., D.A. Schkade, W.K. Thompson, et al., "Age, Affective Experience, and Television Use," American Journal of Preventive Medicine, 39:173-178, 2010.

10. Moors, G., "Exploring the Effect of a Middle Response Category on Response Style in Attitude Measurement," Quality & Quantity, 42(6):779-794, 2008.

11. Sturgis, P., C. Roberts, and P. Smith, "Middle Alternatives Revisited: How the Neither/Nor Response Acts as a Way of Saying “I Don’t Know?” Sociological Methods & Research, 43(1):15-38, 2014.

12. Reyna, V.F., "How People Make Decisions That Involve Risk: A Dual-Process Approach," Current Directions in Psychological Science,13:60-66, 2004.

Dated: March 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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