4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, "Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing." This study is designed to use eye tracking technology to explore how consumers view direct-to-consumer (DTC) prescription drug advertisements (ads) that include text regarding risk information and reporting side effects and that vary in the amount of distracting audio and visual content during the presentation of the risk information.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing--(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.

Current regulations require that a major statement of the risks of prescription drugs be included in at least the audio of DTC television ads. FDA has proposed including the risk information in DTC television ads in superimposed text as well as in the audio (75 FR 15376, "Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner"). In addition, Title IX of the Food and Drug Administration Amendments Act (Pub. L. 110-85) required a study to determine if the statement "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088" (the MedWatch statement) is appropriate for inclusion in DTC television ads. These communications have been tested separately by FDA. The first study found that participants were better able to recall the drug risks when they were presented in superimposed text as well as in audio (OMB Control Number 0910-0634, "Experimental Evaluation of the Impact of Distraction"). The second study found that the inclusion of the MedWatch statement does not interfere with participants' understanding of the risk information (OMB Control Number 0910-

0652,"Experimental Study: Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs"). Thus, these two new communications may appear in future DTC television ads. However, they have not been examined together.

In addition, questions continue to arise about the use of potentially distracting images and sounds during the major statement of risks in DTC television ads. The first study referenced above found no differences among ads that differed in the affective tone of static, non-moving visuals presented during the major statement of risks. Previous research has shown that factors such as multiple scene changes and music in advertising can be distracting. However, the effects of this kind of distraction during the major statement of risks on consumers' perceptions and risk recall has not been tested in the presence of risk reinforcing superimposed text.

This project is designed to use eye tracking technology to determine how these communications in DTC ads are perceived and the impact of distraction. Eye tracking technology is an effective method to determine the extent to which consumers attend to risk information presented in DTC television ads. This technology allows researchers to unobtrusively detect and measure where a participant looks while viewing a television ad and for how long, and the pattern of their eye movements may indicate attention to and processing of information in the ad.

We plan to collect descriptive eye tracking data on participants' attention to (1) the superimposed text during the major statement of risk information and (2) the MedWatch statement. Further, we plan to examine experimentally the effect of distraction. We hypothesize that distracting audio and visuals during the major statement will decrease risk recall, risk perceptions, and attention to superimposed text risk information. To test these hypotheses, 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.

We plan to conduct one 60-minute pilot study with 30 participants and one 30-minute main study with 300 participants. All participants will be 18 years of age or older who self-identify as needing to lose more than 30 pounds. We will exclude individuals who work in healthcare or marketing or who wear bifocals or hard contact lenses. The studies will be conducted in person in at least five different cities across the United States.

The pilot study and main study will have the same design and will follow the same procedure. Participants will be randomly assigned to one of three test conditions (low, medium, and high distraction in a DTC television ad). The ad will be for a fictitious weight loss prescription drug. The ads are currently being created and pretested to ensure that consumers perceive different levels of distraction across the ads (OMB Control Number 0910-0695, "Stimuli Development and Pretests for an Attentional Effects Study"). For instance, as the distraction level increases, the number of scene changes and on-screen activity during the major statement will increase.

We will explain the study procedure to participants and calibrate the eye tracking device. To collect eye tracking data, we will use an unobtrusive computer-interfaced eye tracker with a minimum speed of 60 Hertz. The test images will be shown on a computer monitor with a minimum size of 20 inches and a minimum display resolution of 1,280 × 1,024. To simulate normal television ad viewing, participants will watch a 2 to 5 minute video clip followed by a series of three ads. One of the ads will be the study ad. The video clip and non-study ads will be unrelated to health. The order of the ads will be counterbalanced, and only eye tracking data

from the study ad will be analyzed. Next, participants will complete a questionnaire that assesses risk perceptions, risk recall, recall of the MedWatch statement, and covariates such as demographics and health literacy. In the pilot study, participants will also answer questions as part of a debriefing interview to assess the study design and questionnaire. The questionnaire is available upon request.

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

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

Eye Tracking Study of DTC Prescription Drug Advertisement Viewing	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pilot study screener	200	1	200	0.03 (2 minutes)	6
Main study screener	2,000	1	2,000	0.03 (2 minutes)	60
Pilot study	30	1	30	1	30
Main study	300	1	300	0.50 (30 minutes)	150
Total					246

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

Dated: November 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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