4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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 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, "Spousal Influence on Consumer Understanding of and Response to Direct-To-Consumer (DTC) Prescription Drug Advertisements." This study will examine differences between consumers viewing prescription drug ads with a spouse or partner versus alone through empirical research.

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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

Spousal Influence on Consumer Understanding of and Response to DTC 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 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.

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 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 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. 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 × 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.

Preliminary 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 draft 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	Break	Couples engage in a 5-minute semistructured conversation related to the advertising stimuli
4	Consumer completes postquestionnaire	Consumer and spouse complete postquestionnaire separately (spouse completes selected measures)

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 3.--Estimated Annual Reporting Burden[1]

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.

Dated: November 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-26918 Filed 11/13/2014 at 8:45 am; Publication Date: 11/14/2014]