DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0373]

Agency Information Collection Activities; Proposed Collection; Comment Request; Risk and Benefit Perception Scale Development

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 a study, Risk and Benefit Perception Scale Development. The study is designed to test different ways of measuring consumers' benefit and risk perceptions after exposure to direct-to-consumer (DTC) prescription drug advertising.

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.

Risk and Benefit Perception Scale Development--(OMB Control Number 0910-New)

FDA requires that prescription drug advertisements be balanced in their presentation of risk and benefit information. Patients receive information on drugs not only from their doctors and pharmacies, through patient labeling and FDA-mandated medication guides, but also online, on social networks and via DTC television and print advertising. Moreover, research suggests that consumers struggle with the concepts of risk and efficacy (Ref. 1) and often overestimate drug efficacy (Ref. 2). As a result, it is important for FDA to understand and accurately measure how consumers are making sense of this information and how it impacts decisions related to prescription drugs.

FDA's Office of Prescription Drug Promotion has an active research program that investigates how DTC advertising influences consumer knowledge, perceptions, and behavior. Consequently, FDA needs a pool of reliable and valid measurement items for assessing consumers' drug risk and benefit perceptions--as well as other elements of prescription drug decision making--consistently across studies. The purpose of this project is to create that measurement pool, thus increasing the rigor and efficiency of FDA's research.

Design: This research will be conducted in two stages.

Stage 1: Pretests

The purpose of the first study stage is to pretest the candidate measurement items to assess their psychometric properties and identify any measurement challenges (e.g., misinterpretation, lack of variance). We also will use the pretest to examine factors that may affect future study results and analyses (e.g., response scale midpoints, moderating variables).

We will conduct two sequential pretest waves (n=500 per wave; n=1,000 total) with the following target populations: (a) Individuals diagnosed with chronic pain; and (b) individuals

diagnosed with hypertension. Each participant will be randomly assigned to view either a print ad or a television ad for a fictitious prescription drug indicated to treat chronic pain; or hypertension and will be asked to complete a brief online survey assessing their benefit/risk recall, benefit/risk perceptions, and attitudes toward the drug. Based on the pretest findings, we will revise and remove candidate items prior to full-scale testing. The pretest study design is outlined in Exhibit 1.

Exhibit 1.--Pretest Study Design

Wave	Medical Condition		
	Chronic Pain	Hypertension	
Wave 1	n=250	n=250	500
Wave 2	n=250	n=250	500
Total	500	500	1,000

Stage 2: Iterative Tests

In the second stage, we will conduct four sequential waves of iterative testing to fully assess the measurement properties of the candidate items and create the final pool of measurements. We will conduct the first two waves with members of the target populations (hypertension and chronic pain) to refine the measurement items for those groups and the second two waves with members of the general population who do not have the target health conditions to determine if measurement reliability and validity change when the advertised drug addresses a condition that study participants do not have (n=2,500 per wave; n=10,000).

Each participant will be randomly assigned to view either a print or television ad for a fictitious prescription drug for hypertension or chronic pain and will be asked to complete a brief online survey assessing their benefit/risk recall, benefit/risk perceptions, and attitudes toward the drug. In the first two waves, participants will view an ad that matches the sample's medical condition (chronic pain or hypertension). In the final two waves, half of the general population

sample will be exposed to the chronic pain stimuli, and half will be exposed to the high blood pressure stimuli.

The first two waves are outlined in Exhibit 2, and the final two waves are outlined in Exhibit 3.

Exhibit 2.--Iterative Testing Design; Illness Population Sample

Wave 1									
Chronic Pain Ad					Hypertension Ad				
Ad Type	Drug Risk Level	Drug Benefit Level		Control	Ad Type	Drug Risk Level	Drug Benefit Level		Control
		High	Low				High	Low	
Print	High	n=125	n=125	n=125	Print	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	
Television	High	n=125	n=125	n=125	Television	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	
Wave 2									
Chronic Pain Ad					Hypertension Ad				
Ad Type	Drug Risk Level	Drug Benefit Level		Control	Ad Type	Drug Risk Level	Drug Benefit Level		Control
		High	Low				High	Low	
Print	High	n=125	n=125	n=125	Print	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	
Television	High	n=125	n=125	n=125	Television	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	

Exhibit 3.--Iterative Testing Design; General Population Sample

Wave 3									
Chronic Pain Ad					Hypertension Ad				
Ad Type	Drug Risk Level	Drug Benefit Level		Control	Ad Type	Drug Risk Level	Drug Benefit Level		Control
		High	Low				High	Low	
Print	High	n=125	n=125	n=125	Print	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	
Television	High	n=125	n=125	n=125	Television	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	
Wave 4									
Chronic Pain Ad					Hypertension Ad				
Ad Type	Drug Risk Level	Drug Benefit Level		Control	Ad Type	Drug Risk Level	Drug Benefit Level		Control
		High	Low				High	Low	

Print	High	n=125	n=125	n=125	Print	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	
Television	High	n=125	n=125	n=125	Television	High	n=125	n=125	n=125
	Low	n=125	n=125			Low	n=125	n=125	

Participants and Burden Hours and General Methods:

Participants will be randomly assigned to view one version of a fictitious prescription drug ad (print or television). The drug risks and benefits in each ad will be manipulated into high or low conditions, creating four different ad versions: high benefit/high risk, high benefit/low risk, low benefit/high risk, and low benefit/low risk. There also will be a control condition in which the ad does not contain any risk or benefit information (reminder ad). The fictitious prescription drugs will be modeled on real drugs used to treat the same conditions and created with the input of medical experts.

During the study, we will expose participants to one of these fictitious ads and ask them to answer a series of questions about the fictitious drug. The questions represent the candidate measures we are testing in this study, and we will examine which measures are most sensitive/accurate in capturing participants' perceptions of the advertised drug. (For example, an accurate measure should detect different perceptions in a participant who sees a high benefit/high risk ad versus a participant who sees a low benefit/low risk ad.) We have designed the study and selected sample sizes (described previously) so that we will have sufficient statistical power to detect small-to-medium sized differences between the candidate measures and the ability to refine and re-test measures to ensure their accuracy.

For both the pretests and iterative tests, the questionnaire is expected to last no more than 20 minutes (the questionnaire is available upon request). This will be a one-time (rather than annual) collection of information. FDA estimates the burden of this collection of information as follows:

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Screener	22,000	1	22,000	0.03 (2 minutes)	660
Pretest	1,000	1	1,000	0.33 (20 minutes)	330
Main Study	10,000	1	10,000	0.33 (20 minutes)	3,300
Total					4,290

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

References

1. Lipkus, I. M. "Numeric, Verbal, and Visual Formats of Conveying Health Risks: Suggested Best Practices and Future Recommendations." Medical Decision Making, 27(5), 696-713 (2007).

2. Aikin, K. J., J. L. Swasy, and A. C.Braman. "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs--Summary of FDA Survey Research Results." Food and Drug Administration, Center for Drug Evaluation and Research, 19 (2004).

Dated: April 14, 2014.

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