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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2406]

Agency Information Collection Activities; Proposed Collection; Comment Request; Market Claims in Direct-to-Consumer Prescription Drug Print Ads

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, “Market Claims in Direct-to-Consumer Prescription Drug Print Ads.” This study will examine the impact of market claim information in direct-to-consumer (DTC) print advertising for prescription drugs.

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.

Market Claims in Direct-to-Consumer Prescription Drug Print Ads

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(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.

The marketing literature divides product attributes (“cues”) into intrinsic and extrinsic. Intrinsic cues are physical characteristics of the product (e.g., size, shape), whereas extrinsic cues are product-related but not part of the product (e.g., price and brand name) (Refs. 1, 2). Research has found that both intrinsic and extrinsic cues can influence perceptions of product quality (Ref. 3). Consumers may rely on product cues in the absence of explicit quality information. The objective quality of prescription drugs is not easily obtained from promotional claims in DTC ads; thus consumers may rely upon extrinsic cues to inform their decisions. Market claims such as “#1 prescribed” and “new” may act as extrinsic cues about the product’s quality, independent of the product’s intrinsic characteristics. Prior research has found that market leadership claims can affect consumer beliefs about product efficacy, as well as their beliefs about doctors’ judgments about product efficacy (Ref. 4). One limitation of these prior studies is the lack of quantitative information about product efficacy in the information provided to respondents. Research indicates that providing consumers with efficacy information generally improves understanding and facilitates decisionmaking (Refs. 5, 6). Efficacy information may moderate

the effect of the extrinsic cue by providing insight into characteristics that would otherwise be unknown. Other research has shown that consumers are able to use information about efficacy to inform judgments about the product (Refs. 6, 7).

The Office of Prescription Drug Promotion plans to investigate, through empirical research, the impact of market claims on prescription drug product perceptions with and without quantitative information about product efficacy. This will be investigated in DTC print advertising for prescription drugs.

The project consists of two parts; a main study and a followup study. Pretesting will be conducted to assess and identify problems with the questionnaire, stimuli, and procedures. Participants will be consumers who self-identify as having been diagnosed with diabetes. All participants will be 18 years of age or older. We will exclude individuals from the consumer sample who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Recruitment and administration of the study will take place over the Internet. Participation is estimated to take no more than 30 minutes.

In the main study, participants will be randomly assigned to view one of nine possible versions of an ad, as depicted in table 1. The two variables of interest are type of market claim (#1 Prescribed, New) and level of efficacy information (high, low, or none). Efficacy information will be operationalized in the form of simple quantitative information (for example, product X can provide 50 percent relief for up to 60 percent of patients). We will investigate memory, perception, and understanding of product risks and benefits; perception and understanding of the market claim; perception of product quality; perceptions of product acceptance by doctor, intention to seek more information about the product; and perceptions of trust/skepticism regarding product claims and the sponsor. 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.

		#1 Prescribed	New	None (control)
Efficacy Level Information	High	A	B	C
	Low	D	E	F
	None (control)	G	H	I

The followup study will examine the tradeoff between efficacy level and market share claim using decision analysis techniques. Participants will be asked to choose between two different DTC print ads over 48 trials. One set of DTC ads will feature the two claims from the main study. The other set of DTC ads will depict 48 different levels of product efficacy. Participants will be asked to choose one product on one or more dependent measures.

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

Table 2: Estimated Burden¹

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
Sample outgo (pretests and main survey)	16,384	==	==	==	==
Screener completes	1,638	1	1,638	.03 (2 minutes)	49
Eligible	1,556	==	==	==	==
Completes, Pretest 1	252	1	252	.5 (30 minutes)	126
Completes, Pretest 2	252	1	252	.5 (30 minutes)	126
Completes, Main Study	495	1	495	.5 (30 minutes)	248
Completes, Pretest 3	108	1	108	.25 (15 minutes)	27
Completes, Followup Study	216	1	216	.25 (15 minutes)	54
Total	==	==	==	==	630

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>.

1. Lee, M. and Y. C. Lou, "Consumer Reliance on Intrinsic and Extrinsic Cues in Product Evaluations: A Conjoint Approach," Journal of Applied Business Research, 12(1), pp. 21-29 (2011).
2. Teas, R. K. and S. Agarwal, "The Effects of Extrinsic Product Cues on Consumers' Perceptions of Quality, Sacrifice, and Value," Journal of the Academy of Marketing Science, 28(2), pp. 278-290 (2000).
3. Rao, A. R. and K. B. Monroe, "The Effect of Price, Brand Name, and Store Name on Buyers' Perceptions of Product Quality: An Integrative Review," Journal of Marketing Research, pp. 351-357 (1989).
4. Mitra, A., J. L. Swasy, and K. J. Aikin, "How Do Consumers Interpret Market Leadership Claims in Direct-to-Consumer Advertising of Prescription Drugs?" Advances in Consumer Research, 33, pp. 381-387 (2006).
5. O'Donoghue, A., H. K. Sullivan, D. Aikin, R. Chowdhury, et al., "Presenting Efficacy Information in Direct to Consumer Prescription Drug Advertisements," Patient Education Counsel, 95(2), pp. 271-80 (2014).
6. Schwartz, L. M., S. Woloshin, and H. G. Welch, "Using a Drug Facts Box to Communicate Drug Benefits and Harmstwo Randomized Trials," Annals of Internal Medicine, 150(8), pp. 516-527 (2009).

7. Sullivan, H. W., A. C. O'Donoghue, and K. J. Aikin, "Presenting Quantitative Information About Placebo Rates to Patients," JAMA Internal Medicine, doi: 10.1001/jamainternmed.2013.10399 (2013).

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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