4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Comparative Price Information in Direct-to-Consumer and Professional 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 "Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements." This study will investigate the impact of price comparison information in direct-to-consumer (DTC) and health care professional 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, 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.

Comparative Price Information in Direct-to-Consumer and Professional 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 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.

By their very nature, medical and health decisions are comparative (e.g., treat versus not treat). For consumers, these decisions may include the use of prescription drug products versus over the counter products versus herbal supplements, as well as one prescription brand versus another prescription brand. Similarly, advertising is often comparative. In prescription drug advertising, sponsors are permitted to include truthful, non-misleading information about the price of their products in promotion. This may extend to price comparison information, wherein sponsors may include information about the price of a competing product in order to make advantageous claims. Currently, when price comparisons are made, the ad should also include context that the two drugs may not be comparable in terms of efficacy and safety and that the acquisition costs presented do not necessarily reflect the actual prices paid by consumers, pharmacies, or third party payers. Despite the inclusion of this additional information, there is concern that adding contextual information about efficacy or safety is not sufficient to correct the impression that the products are interchangeable and that price is the main factor to consider. The Office of Prescription Drug Promotion (OPDP) plans to investigate, through empirical research, the impact of price comparison information and additional contextual information on

prescription drug product perceptions. This will be investigated in DTC and healthcare-directed professional advertising for prescription drugs.

We will investigate perceptions about overall drug safety and efficacy and perceptions of the comparator product. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described in this document, we will have sufficient power to detect small-to-medium sized effects in the main study.

Participants will be consumers who self-identify as having been diagnosed with diabetes and physicians who are General Practitioners (e.g., Family Practice, General Practice, Internal Medicine) and Specialists (e.g., Endocrinology, Pain Management). 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 approximately 30 minutes.

Physician and consumer participants will be randomly assigned to view one of three possible versions of an ad (DTC or professional), as depicted in table 1. One version will present information about the price of the product relative to a competitor for the same indication (price comparison information). Another version will present this information with additional contextual information that the two drugs may not be comparable in terms of efficacy and safety and that the acquisition costs do not necessarily reflect actual prices paid. A third version will have a claim about the price of the product but will not present information about the price relative to a competitor, and will act as a control.

After viewing the ad, participants will respond to questions about information in the ad. Preliminary measures are designed to assess perception and understanding of product safety and efficacy; perception and understanding of the additional contextual information; perceptions of comparative safety and efficacy; and intention to seek more information about the product. The questionnaire is available upon request.

Table 1.--Study Design

	Type of Price Comparison		
Sample	Price information only	Price information + Additional context	No comparison information (Control)
Consumers (DTC ad)			
Physicians (Professional ad)			

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Sample outgo (pretests and main survey)	41,110	--	--	--	--
Screener completes	7,400	1	7,400	.03 (2 minutes)	222
Eligible	4,933	--	--	--	--
Completes, Pretests Phase 1	400	1	400	0.5 (30 minutes)	200

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Completes, Pretest Phase 2	1,000	1	1,000	0.5 (30 minutes)	500
Completes, Main Study	2,940	1	2,940	0.5 (30 minutes)	1,470
Total					2,392

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

Dated: May 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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