4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title, "Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements." Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements--(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.

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 advertisement (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 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 direct-to-consumer (DTC) and healthcare-directed professional advertising for prescription drugs.

Design Overview and Procedure

The design consists of two pretests and a main study. We will conduct two sequential pretest waves prior to main data collection. The purpose the pretests are to: (1) Ensure the stimuli are understandable and viewable; (2) identify and address any challenges to embedding the stimuli within the online survey; and (3) ensure the study questions are appropriate and meet the study's goals. Participants in the pretests will be randomly assigned to one of two versions of an ad. One version will present information about the price of the product relative to a competitor for the same indication (Price Comparison). 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 (Price Comparison + Additional Context).

Participants in Pretest 1 will be consumers (n = 400) who self-identify as having been diagnosed with diabetes. Pretest 2 will be conducted with physicians (n = 1,000) who are General Practitioners (e.g., Family Practice, General Practice, Internal Medicine) and Specialists (e.g., Endocrinology, Pain Management). Pretest 2 has a two-fold purpose. In addition to the measurement and stimuli verification issues identified above, we will also conduct an experiment to evaluate the impact of incentive level (level 1 vs. level 2) and study sponsorship (FDA vs.

Public Health Agency) disclosure on physician response rates (see Exhibit 1). Pretest 2 will therefore provide a comparison of recruitment approaches, identify ways to optimize response rates, and provide a "dry run" of experimental study recruitment procedures.

Exhibit 1.--Pretest 2 Design, Incentive Level by Study Sponsorship by Type of Ad

Type of Ad						
		Price Comparison		Price Comparison + Additional Context		Total
Study Sponsor		FDA	Public Health Agency	FDA	Public Health Agency	
Incentive Level	Level 1	125	125	125	125	500
	Level 2	125	125	125	125	500
Total		250	250	250	250	1,000

In the main study phase, physician (n = 1440) and consumer (n = 1,500) participants will be randomly assigned to view one of three possible versions of a DTC or professional ad for a fictitious prescription drug for diabetic neuropathy and will be asked to complete an online survey to assess their perceptions and understanding of product safety and efficacy, perceptions and understanding of the additional contextual information, perceptions of comparative safety and efficacy, perceptions of the comparator product, and intention to seek more information about the product (see Exhibit 2). This sample size will provide us with sufficient power to detect small-to-medium sized effects.

In addition to the Price Comparison and Price Comparison + Additional Context ads used in pretesting, a third ad 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.

Exhibit 2.--Main Study Design

Type of Price Comparison				
Sample	Price Comparison	Price Comparison + Additional Context	Price Information Only (No comparison/control)	Total
Consumers (DTC ad)	500	500	500	1,500
Physicians (Professional ad)	480	480	480	1,440
Total	980	980	980	2,940

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, pharmaceutical, 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.

In the Federal Register of May 7, 2014 (79 FR 26255), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two submissions were received; one from Ms. Lenisse Lippert of Quality Matrix Solutions, and one from AbbVie biopharmaceutical company, which contained multiple comments. We summarize and respond to these comments below.

(Comment 1 from Lenisse Lippert, Quality Matrix Solutions) "I would like to participate in the industry feedback on a proposed study to better understand direct-to-consumer advertisements that compare drug pricing, and how that information affects a consumer's perception of a drug's overall safety and efficacy versus the comparator product."

(Response) We thank Ms. Lippert for her comment.

(Comment 2 from AbbVie) To prevent fatigue, online market research surveys do not generally exceed 20 minutes. Given that FDA is trying to make the most of their survey opportunity by asking many questions, it would be wise to place the meatier pricing related questions earlier in the survey when respondents are still engaged.

(Response) We take the survey length very seriously. We are sensitive to issues regarding respondent fatigue and its impact upon completion rates and thus have placed items that are most likely to be influenced by respondent fatigue (open-ended questions) at the beginning of the survey. We have employed similar online surveys on several previous studies,

and we have obtained high completion rates, typically 90 percent or higher. For example, on a recent study (Experimental Study: Examination of Corrective Direct-to-Consumer Television Advertising [OMB control number 0910-0737]), we had a pool of 1,071 eligible respondents, and only 14 of those respondents failed to complete the survey. We anticipate that the completion rate for this study will be similar.

(Comment 3 from AbbVie) In both surveys, respondents are asked many questions about product X that appear positively stated. Therefore, there is a risk of a bias by asking the critical pricing and language questions after the respondent has already been exposed to many product X questions and supposed attributes. To avoid bias, the most critical questions should appear as up front in the surveys as possible.

(Response) Of greatest interest to FDA is the question of whether presence or absence of price comparison information and contextual information influences outcomes such as perceptions of comparative safety and efficacy, perceptions of the comparator product, and intentions to seek more information about the advertised product. Placing pricing related questions near the beginning of the survey would likely bias participants to think about pricing information more than they would under natural conditions, which may influence their responses to the aforementioned critical dependent variables. Although current question ordering may bias responses to pricing related questions, we believe this outcome is less consequential than the reverse, as suggested in this comment. Consequently, we intend to retain the current order of questions in the survey.

(Comment 4 from AbbVie) It is unclear if the drug examples (X and Y) are real world medicines that could be taken by the patient respondents. If so, do respondents need to be aware of each product? If they need not be aware, you will need to balance the samples for any

differences between cells. In addition, the cells will also need to be balanced for current drug usage to prevent additional bias.

(Response) We have constructed a fictional product for use in this study to control for effects that might result as a consequence of having taken the product in the past. The comparator is a real product. We will measure participants' experience with medication for this condition, prior exposure to advertising for the comparator, and prior experience taking the comparator. Responses to these questions can be used as covariates in analysis.

(Comment 5 from AbbVie) The questions on the physician survey should be at a higher level language versus the general population. We note the questions in the patient questionnaire seem to vary in reading level required to comprehend them. We recommend that FDA review the questions for consistency so as not [to] introduce a reading bias.

(Response) We appreciate this comment. We have conducted cognitive interviews (OMB control number 0910-0695) to refine and improve the survey questions. We will also be conducting two rounds of pretesting which will provide an additional opportunity to identify and remove questions that do not function as intended, further refining the questionnaire prior to the main study. These activities include consideration of language level and whether it is appropriate for the participants being surveyed.

(Comment 6 from AbbVie) We recommend this ad explicitly present contextual information that the two drugs may not be comparable in terms of efficacy and safety (i.e., the products are not interchangeable) notwithstanding price comparisons. This would permit FDA to assess whether it has provided enough contextual information so that the audience understands that the products are not interchangeable. Consequently, there would be a response choice in the questionnaire that allows a respondent to acknowledge the products are not interchangeable.

AbbVie suggests that an option be added that reads, "The brochure left the impression that Drug X's efficacy (and safety) should not be compared to Drug Y's; the products are not interchangeable."

(Response) The context language is based on feedback from the cognitive interviews. We appreciate the comment and have added a question to assess participants' attitudes about the context with regard to interchangeability of the products being compared.

(Comment 7 from AbbVie) It is not clear what type of cost information is being presented in these ads. We suggest that the advertisement should make clear what costs are being presented, for what doses, and over what time frames so that readers are comparing 'apples to apples' when viewing the ads. If study budget allows, it would be ideal to test a variety of cost information.

(Response) The price comparison is for the same indication on a yearly basis. We agree that it would be informative to expand the study to test a variety of cost information but do not have the resources to do so.

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

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

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
Sample outgo (pretests and main survey)	41,110	==	==	==	==
Screener completes	7,400	1	7,400	0.03 (2 minutes)	222
Eligible	4,933	==	==	==	==
Completes, Pretests Phase 1	400	1	400	0.5 (30 minutes)	200
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: March 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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