4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0892]

Agency Information Collection Activities; Proposed Collection; Comment Request; Communicating Composite Scores in Direct-to-Consumer Advertising

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, "Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising." This study is designed to explore how consumers understand and interpret composite endpoint scores in DTC ads.

DATES: Submit written or electronic 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:

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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.

Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising---(OMB Control Number 0910-NEW)

I. Regulatory Background

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 903(b)(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.

II. Composite Scores

To market their products, pharmaceutical companies must demonstrate to FDA the efficacy and safety of their drugs, typically through well-controlled clinical trials (Refs. 1 and 2). In some cases, drug efficacy can be measured by a single endpoint, such as high blood pressure (Ref. 3). Often, however, efficacy is measured by multiple endpoints that are sometimes combined into an overall score called a composite score (Refs. 4 and 5). For example, nasal allergy relief is measured by examining individual symptoms such as runny nose, congestion, nasal itchiness, and sneezing. Each symptom is measured on its own. An overall score is computed from the individual symptom measurements; if a drug has a significantly better overall score than the comparison group (e.g., placebo), it can be marketed for the relief of allergy symptoms. However, although a drug may have a significantly better score overall, it may not

have a significantly better score on a particular aspect (e.g., runny nose). Scientists and medical professionals have had training to understand the difference between composite score endpoints and single endpoints, but members of the general public may not understand the difference.

Given the frequency of DTC advertising, it is important to determine whether consumers understand composite scores as they are currently communicated and how best to communicate such scores to lay audiences in general. Because most DTC prescription drug ads do not explicitly state that they used composite scores to demonstrate efficacy or they provide little explanation of how these scores are calculated, it is also important to understand whether consumers recognize how composite scores are used for measuring drug efficacy.

Prior research on composite scores is scant. Therefore, in September 2011, FDA conducted a focus group study to better understand how consumers understand the concept of composite scores. Prior to the focus group, few participants had heard the term "composite score," none were aware of how the scores might be used in clinical trials, and most participants had difficulty correctly interpreting efficacy information that was based on composite scores. Once the moderator explained composite scores to participants, some reassessed their opinion of the advertised drug's effectiveness and said they thought that the information on effectiveness was "much less convincing," in many cases because it was unclear whether the drug would work for a particular symptom. As a result, some participants said they would want a drug ad to include more detailed information on the effectiveness of the drug on each component of the composite score. However, others felt that the ads already provided enough information on effectiveness and that adding more statistical details would make the ads more complicated, thus decreasing the likelihood that consumers would read them.

The focus group findings suggest that research is required to examine how the inclusion of increasingly detailed information affects understanding of composite scores and influences perceptions of efficacy. This is especially important given the many marketed prescription drugs that are based on composite outcomes.

We are aware of no quantitative research on best practices for communicating composite score information to consumers. One related area of research, communicating health-related information to consumers, offers two practical recommendations that are particularly relevant to communicating composite scores in DTC advertisements. First, because less-numerate and less-literate consumers may not understand the information as well, examining differences in comprehension of composite scores by numeracy- and literacy-relevant demographic characteristics such as education level and age is important (Refs. 6 and 7). Second, although the literature tends to suggest limiting the amount of information presented in advertisements (Refs. 7 to 9), examining the amount of detail that best facilitates comprehension of composite scores is warranted.

III. Research Purpose

Given the lack of research on consumer understanding of composite scores and how to best present this information in DTC advertisements, the main goal of the current research is to evaluate how consumers interpret and respond to DTC prescription drug advertising that includes benefit information based on composite scores. Specifically, this research will explore:

1. Whether consumers are aware of how efficacy is measured for specific drugs;
2. how well consumers comprehend the concept of composite scores;

3. whether exposure to DTC advertisements with composite endpoint benefit information influences consumers' perceptions of a drug's efficacy and risk; and
4. different methods for presenting composite endpoint benefit information in DTC ads to maximize consumer comprehension and informed decisionmaking.

The research will be conducted in two studies. Using a general population sample of adults, the first study will be a web-based survey, with a pre-post design, that will explore consumers' awareness of how efficacy is measured for drugs and consumers' comprehension of the concept of composite scores. The second study will be a randomized, controlled study conducted online using a web-based panel to examine whether exposure to DTC advertisements with composite endpoint benefit information influences consumers' perceptions of a drug's efficacy and risk, and how DTC advertisements can best deliver composite endpoint benefit information to maximize consumer comprehension and informed decisionmaking. Questionnaires for both studies are available upon request.

IV. Design Overview

Study 1. In this phase, individuals in a general population sample of 1,600 adults of varying education levels will answer an Internet survey designed to explore whether consumers recognize composite scores in DTC ads and their understanding of composite endpoint scores. The survey will be conducted with a probability-based consumer panel of U.S. adults.

As part of the survey, participants will view a print ad that contains claims based on composite scores and respond to questions about the ad to assess whether they recognized that composite scores were used. Other outcomes will include ad comprehension, perceived efficacy,

and perceived risk as they relate to their understanding of composite endpoint scores. We will also examine whether and in what ways participants' perceived efficacy and perceived risk change after they are given a definition and examples of composite scores. Questions will also explore consumers' understanding of how the effectiveness of drugs is measured in general.

This exploratory survey will not be used to test specific hypotheses. However, we will explore the differences in responses to the ad before and after information about composite scores is provided. We will also examine differences in the comprehension of the composite score concept and in the features of the ad by education level and age because literature suggests that less-educated and older consumers may not understand this type of information as well (Ref. 6).

Study 2. Unlike Study 1, Study 2 will be a randomized, controlled study. Study 2 will examine different ways to present the information that arises from a composite endpoint and different ways to explain the concept of a composite score (an educational intervention). Outcome measures will include consumers' awareness and comprehension of the composite score concept, perceived drug efficacy, and risk recall. Participants will be randomly assigned to experimental arms in a 3 x 2 design as shown in table 1.

Table 1.--Study Design for Study 2

	Information Presentation			
Educational Intervention	General Indication	List of Symptoms	Composite Definition	Total
Absent	Arm 1 (n=267)	Arm 2 (n=267)	Arm 3 (n=267)	801
Present	Arm 4 (n=267)	Arm 5 (n=267)	Arm 6 (n=267)	801
Total	534	534	534	1,602

This study will manipulate two variables: Three types of information presentations and the presence or absence of an educational intervention. In terms of information presentation, there are many aspects of composite endpoint scores that could be communicated and one research project cannot test them all. In this study, we have chosen to examine three different information presentations that may or may not help consumers understand the composite score concept. These different information presentations were chosen based on a review of the literature and a review of past DTC submissions.

The three different information presentations are described as follows:

General Indication. The first information presentation is the indication of the product. In this condition, participants will see the drug indication but will not see any explicit statement that the drug's benefits are based on a composite endpoint. This is a common way that composite scores are currently communicated. An example of this presentation is: "Drug A treats and helps prevent seasonal nasal allergy symptoms."

List of Symptoms. The next information presentation will include the drug indication and all of the symptoms that are used to make up the composite score. This condition, like the general indication condition, will not include an explicit statement referencing composite scores. This is also a common way that composite scores are currently communicated. An example of this presentation is: "Drug A treats and helps prevent seasonal nasal allergy symptoms: Congestion, runny nose, nasal stuffiness, nasal itching, and sneezing."

Composite Definition. The final information presentation will present the indication, describe that the drug's benefits are based on a composite endpoint, and explicitly define a composite score. To our knowledge, this would be a new way to communicate composite scores. An example of this presentation is: "Drug A treats and helps prevent seasonal nasal allergy

symptoms. Drug A's effectiveness is based on a composite score. A composite score is a single measure of how well a drug works based on a combination of factors. Drug A may not be as effective in addressing each factor individually."

We will also manipulate whether or not participants see a specific educational intervention. This intervention was developed from prior focus groups (OMB Control No. 0910-0677) where it was found to resonate with participants. It will feature the decathlon as an educational example of a composite score. For example, "Drug A's effectiveness is based on a composite score. A composite score is like a decathlon. In that event, athletes compete in 10 events, such as the long jump, the shot put, and the 50 yard dash. An athlete may not win all events, but if he or she wins some and performs well enough in others, he or she may be the winner based on a combination of scores for each event."

We will test whether the educational intervention, the information presentation, and the interaction of the two affect outcomes such as consumers' awareness and comprehension of the composite score concept; perceived drug efficacy; and risk recall. We will test whether numeracy and literacy moderates any significant relations.

The sample for the second study will include approximately 1,602 participants who have been diagnosed with seasonal allergies. The protocol will take place via the Internet. Participants will be randomly assigned to view one print ad for a fictitious prescription drug that treats seasonal allergies and will answer questions about it. The entire process is expected to take no longer than 20 minutes. This will be a one-time (rather than annual) collection of information.

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
Screeners, Study 1	3,200	1	3,200	0.03 (2 minutes)	96
Pretest, Study 1	200	1	200	0.33 (20 minutes)	66
Main Survey, Study 1	1,600	1	1,600	0.33 (20 minutes)	528
Screeners, Study 2	3,400	1	3,400	0.03 (2 minutes)	102
Pretest, Study 2	600	1	600	0.33 (20 minutes)	198
Main Study, Study 2	1,602	1	1,602	0.33 (20 minutes)	529
Total	10,602				1,519

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

The total respondent sample for this data collection is 10,602. For Study 1, we will sample 200 respondents for pretesting and 1,600 respondents for the full study. For Study 2, we will sample 600 respondents for pretesting and 1,602 participants for the full study. We estimate the response burden to be no more than 20 minutes, for a total burden, including screeners, of 1,519 hours.

V. 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. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Lipsky, M.S. and L.K. Sharp, "From Idea to Market: The Drug Approval Process," Journal of the American Board of Family Practitioners, vol. 14(5), pp. 362-367, 2001.

2. "Guidance for Industry: Postmarketing Studies and Clinical Trials--Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act," (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf), 2008.

3. Rutan, G.H., R.H. McDonald, and L.H. Kuller, "A Historical Perspective of Elevated Systolic vs. Diastolic Blood Pressure From an Epidemiological and Clinical Trial Viewpoint," Journal of Clinical Epidemiology, vol. 42(7), pp. 663-673, 1989.

4. Agency for Healthcare Research and Quality, "Combining Measures Into Composite or Summary Scores," (http://www.ahrq.gov/qual/perfmeasguide/), 2012.

5. American Medical Association, "Measures Development, Methodology, and Oversight Advisory Committee: Recommendations to PCPI Work Groups on Composite Measures," (http://www.ama-assn.org/resources/doc/cqi/composite-measures-framework.pdf), 2010.

6. Fagerlin, A. and E. Peters, "Quantitative Information," In: B. Fishoff, N.T. Brewer, and J.S. Downs (Eds.), Communicating Risks and Benefits: An Evidence-Based User Guide, Food and Drug Administration, U.S. Department of Health and Human Services, (http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm), 2011.

7. Peters, E., D. Vastfijall, P. Slovic, et al., "Numeracy and Decision Making," Psychological Science, vol. 17(5), pp. 407-413, 2006.

8. Gurmankin, A. D., J. Baron, and K. Armstrong, "The Effects of Numerical Statements of Risk on Trust and Comfort With Hypothetical Physician Risk Communication," Medical Decision Making, vol. 24(3), pp. 265-271, 2004.

9. Edwards, A., R. Thomas, R. Williams, et al., "Presenting Risk Information to People With Diabetes: Evaluating Effects and Preferences for Different Formats by a Web-Based Randomized Controlled Trial," Patient Education Counseling, vol. 63, pp. 336-349, 2006.

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