DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0902]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug Product Labeling; Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prescription Drug Product Labeling; Medication Guide Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On April 30, 2012, the Agency submitted a proposed collection of information entitled ''Prescription Drug Product Labeling; Medication Guide Requirements'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0393. The approval expires on January 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0892]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 June 13, 2013.

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, ''Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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.

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(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.

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 (Ref. 1) (see section 505 of the FD&C Act; 21 U.S.C. 355). In some cases, drug efficacy can be measured by a single endpoint, such as high blood pressure (Ref. 2). Often, however, efficacy is measured by multiple endpoints that are sometimes combined into an overall score called a composite score (Ref. 3). 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 investigate whether consumers understand 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 (OMB control number 0910–0677) 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 scores.

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. 4 and 5). Second, although the literature tends to suggest limiting the amount of information presented in advertisements (Ref. 5 to 7), 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:

- Whether consumers are aware of how efficacy is measured for specific drugs;
- How well consumers comprehend the concept of composite scores;
- Whether exposure to DTC advertisements with composite scores influence consumers' perceptions of a drug's efficacy and risk; and
- Different methods for presenting composite scores in DTC ads to maximize consumer comprehension and informed decision making.

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 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 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 about the outcome measures. 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. 4).

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 score 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 3×2 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=290)	Arm 2 (n=290)	Arm 3 (n=290)	870
Present	Arm 4 (n=290)	Arm 5 (n=290)	Arm 6 (n=290)	870
Total	580	580	580	1,740

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 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 score. 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 score, 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 symptoms. 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 number 0910–0677) where it was found to resonate with participants. In these focus groups, medical examples were confusing, so non-medical examples were explored. This example 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 performs well enough in some events, 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 moderate any significant relations.

The sample for the second study will include approximately 1,740 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.

In the **Federal Register** of August 23, 2012 (77 FR 51027), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received four public submissions. One submission discussed bird flu, and another submission discussed graphic warnings on cigarette packages. Both of these comments are outside the scope of the present project and will not be discussed further. In the following section, we outline the observations and suggestions raised in the other two submissions and provide our responses:

(Comment 1) One comment mentioned the respondents who were identified as screeners, wondering who these individuals were and what their roles will be.

(Response) These individuals are members of the Internet panel who are screened for participation. They originate from the same source as participants who complete the whole survey but either do not meet the criteria in the screener or choose not to participate in the study.

(Comment 2) One comment mentioned that ensuring adequate power is an important consideration.

(Response) We agree that power analysis is critical to ensure that participants' time is used wisely and that the research meets high standards of rigor. We have conducted power analyses to do this.

(Comment 3) One comment questioned whether the understanding of composite scores is more applicable to print or video ads and suggested that we ensure we are delivering the sample ad in the medium consumers will be most likely to use.

(Response) Because this is the first study to our knowledge that specifically examines the understanding of composite scores, we have chosen to examine them in the context of magazine ads. Magazine ads for prescription drugs are common. Pending the results of the current research, we may examine the issues in video format.

(Comment 4) One comment mentioned that we have not addressed the issue of non-response.

(Response) We will perform a non-response analysis to determine whether respondents were biased in the direction of any demographic characteristics.

(Comment 5) The comment suggested that because FDA conducted focus groups on the understanding of composite scores there is no need to conduct quantitative research.

(Response) FDA respectfully disagrees. Focus groups are small, qualitative interviews among a group of individuals. Focus groups are composed of individuals who are not representative of any population, and the number of people queried is too small to draw firm conclusions. The value of focus group research is the exploration of topics for potential future study, to determine what language people use to discuss topics, and to strengthen the details of future quantitative research that may be conducted by FDA. What we learned from the focus groups on composite scores is that there is a need for research to determine how widespread misconceptions are and whether there are methods available to remedy them. To gain confidence in our qualitative findings, more quantitative measures are necessary.

(Comment 6) This comment suggested that because a health care professional is involved in the prescribing of prescription drugs, the misunderstanding of composite scores is mitigated.

(Response) We agree that the health care professional is the prescriber and that the consumer or patient has a layer of protection before consuming prescription drugs. However, direct-to-consumer advertising is directed at consumers before they talk to their health care professionals—in fact, driving consumers to their health care professionals is a primary goal of DTC ads. If sponsors choose to communicate with consumers in such a manner, then it makes sense to examine the understandability of their messages.

(Comment 7) This comment stated that because the meaning of composite scores in serious medical conditions may differ from that in allergy situations, FDA should take care in not generalizing beyond what the results suggest in the nasal allergy category.

(Response) We agree. Because we have designed only two studies to examine this issue, we have by necessity chosen one medical condition for each. We will be cautious in applying the findings of our research.

(Comment 8) This comment suggested leveraging the brief summary to improve consumer understanding of composite scores. They suggest including a signal, such as an asterisk, to information in the brief summary about composite scores. They also suggest that the brief summary draft guidance could include language about what the proper

explanation of composite scores could be.

(Response) This comment appears to address the draft guidance ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,'' and is thus beyond the scope of this project. We encourage the commenter to consider submitting comments to the docket for that guidance, Docket No. 2004D–0042. Comments can be made to any guidance at any time.

(Comment 9) This comment requests that FDA publish a strategic plan that clearly shows which studies are independent and which are connected to each other. This comment also suggests that FDA publish in a timely manner the results of studies posted on the Office of Prescription Drug Promotion Web page.

(Response) We agree that timely results should be made available to the public. In the last few years, we have had an increase in the number of research studies and they are all in various states of development. We will publicize them as results become available. We agree the Web page should be updated and are constantly working to make that happen. Please note that this study is the first to explore composite scores and does not build on any prior research from our office.

(Comment 10) This comment suggests that an assessment of drug effectiveness and risk recall is outside the scope of the stated interest in the study and that information on this study is being collected elsewhere.

(Response) Assessment of effectiveness and risk information are within the scope of our stated interests in composite scores. Anything that is included in a DTC ad has the potential to influence the balance of risks and benefits that must be considered when a consumer makes the decision to speak with their health care professional about a prescription drug. Perceptions of effectiveness are central to issues of understanding composite scores because inappropriate presentations of composite scores overstate the efficacy of the drug. FDA is always concerned about the communication of risks in DTC promotion. Therefore, it is important to understand if variations in the presentation of composite scores influence the understanding of risks as well. Nonetheless, we are not collecting information on how composite scores may affect risk and benefit accuracy in other studies.

(Comment 11) This comment requests that the results of this study, which address print ads, not be broadly applied to other forms of advertising such as Web sites, smart phones, and social media.

(Response) We have chosen to investigate the concept of composite scores in a static print medium. The concepts we are exploring in this research apply to any similar medium, including static elements of Web sites.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Phase 1					
Informed Consent	1,800	1	1,800	0.03	54
Pretest	200	1	200	0.30	60
Main study	1,600	1	1,600	0.30	480
Phase 2					
Informed Consent	2,202	1	2,202	0.03	66
Pretest	462	1	462	0.30	139
Main study	1,740	1	1,740	0.30	522
Total					1,321

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

V. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 in this reference section, but FDA is 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, pp. 362–367, 2001.

2. Rutan, G. H., R.cH. 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, pp. 663–673, 1989.

3. The Physician Consortium for Performance Improvement (PCPI) convened by the 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.

4. 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's Guide,* Food and Drug Administration, U.S. Department of Health and Human Services, (*http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm*), 2011.

5. Peters, E., D. Vastfijall, P. Slovic, et al., ''Numeracy and Decision Making,'' *Psychological Science,* vol. 17, pp. 407–413, 2006.

6. 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, pp. 265–271, 2004.

7. 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.

Dated: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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