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