

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Dental & Craniofacial Research; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Dental & Craniofacial Research, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

*Date:* May 28–29, 2015.

*Time:* May 28, 2015, 12:00 p.m. to 5:40 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 30, Room 117, NIH Campus, Bethesda, MD 20892.

*Time:* May 29, 2015, 8:00 a.m. to Adjournment.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 30, Room 117, NIH Campus, Bethesda, MD 20892

*Contact Person:* Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, Natl Inst of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892, (301) 594–4805.

Information is also available on the Institute's/Center's home page: <http://www.nidcr.nih.gov/about/CouncilCommittees.asp>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: March 31, 2015.

**David Clary,**  
Program Analyst, Office of Federal Advisory Committee Policy.

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**BILLING CODE 4140–01–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 May 6, 2015.

**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](mailto: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](mailto: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