meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018–17042 Filed 8–8–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Name of Committee: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Dates: October 16–October 18, 2018.

Time: 8:00 a.m.–5:00 p.m., EDT.

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, VA 22314.

Agenda: The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and occupational health-related grant applications.

For Further Information Contact: Nina Turner, Ph.D., Scientific Review Officer, NIOSH, 1095 Willowdale Road, Morgantown, WV 26506, (304) 285–5976; *nturner@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0558]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Disclosures in Professional and Consumer Prescription Drug Promotion

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 (PRA).

DATES: Fax written comments on the collection of information by September 10, 2018.

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 ''Disclosures in Professional and Consumer Prescription Drug Promotion.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Disclosures in Professional and Consumer Prescription Drug Promotion

OMB Control Number 0910–NEW

I. 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 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (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.

FDA regulates prescription drug advertising and promotional labeling directed to healthcare professionals (HCPs) and consumers (section 502(a) and (n), respectively, of the FD&C Act (21 U.S.C. 352(a) and (n))). In the course of promoting their products, pharmaceutical sponsors (sponsors) may present a variety of information including the indication, details about the administration of the product, efficacy information, and clinical trial data. To present often complicated information concisely, sponsors may not include relevant information in the body of the text or visual display of the claim. Additionally, sponsors may not always present limitations to the claim in the main body of the text or display. In these cases, sponsors typically include disclosures of information somewhere in the promotional piece.

There is limited published research on disclosures in prescription drug promotion, either directed to consumers or to HCPs. The use of disclosures is one method of communicating information to HCPs and consumers about scientific and clinical data, the limitations of that data, and practical utility of that information. These disclosures may influence HCP and consumer comprehension and decision making, and may affect how and what treatment HCPs prescribe for their patients. Previous research on the effectiveness of disclosures has been conducted primarily in the dietary supplement arena (Refs. 1–4). Thus, the proposed research will examine the effectiveness of clear and conspicuous disclosures in prescription drug promotion directed to both populations. The purpose of our study is to determine how useful disclosures regarding prescription drug information are when presented prominently and adjacent to claims.[1] Specifically, are HCPs and consumers able to use disclosures to effectively frame information in efficacy claims in prescription drug promotion?

To address this research question, we have designed a set of studies that cover both consumers and HCPs, as well as three presentations addressing different

[1] The Federal Trade Commission (FTC), which regulates the advertising of non-prescription drug products as well as other non-FDA regulated products (*e.g.,* package goods, cars, etc.) issued a specific position on disclosures (Ref. 5) for the advertising it regulates. Specifically, FTC explains that disclosures must be ''clear and conspicuous''; in other words, in understandable language, located near the claim to be further clarified, and not hidden or minimized by small font or other distractions.