

- Case reports or series of case reports
- Cross-sectional studies/surveys
  - Prospective or retrospective (all applicable study types)
- For harms, we will start by searching for existing systematic reviews of interventions used during pregnancy, postpartum, or breastfeeding, regardless of their indication (*i.e.*, for any disease/condition, not only primary headaches). We will not enforce a date restriction when screening for eligible systematic reviews, but when multiple eligible systematic reviews exist for a certain drug/class of drugs, we will use the most recent or most complete one.
  - We will subsequently search for, and include, large primary studies of interventions not adequately covered by the existing systematic reviews of harms. The specific eligibility criteria (particularly pertaining to study design, minimum sample size, and publication date) will be determined based on available EPC resources, the number of interventions without adequate existing systematic reviews, and the volume of potentially eligible studies.
  - For harms, we will also search the U.S. Food and Drug Administration, other international equivalent agencies, and pharmacopoeia.

Dated: November 19, 2019.

Virginia Mackay-Smith,  
Associate Director.

[FR Doc. 2019-25414 Filed 11-21-19; 8:45 am]

BILLING CODE 4160-90-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC); Notice of Charter Renewal

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of charter renewal.

**SUMMARY:** This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 5, 2021.

#### FOR FURTHER INFORMATION CONTACT:

Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Department of Health and Human Services, 4770 Buford Highway NE, Mailstop F-63, Atlanta, Georgia 30341, telephone (770) 488-1430; email address [GCattledge@cdc.gov](mailto:GCattledge@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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.

#### Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019-25352 Filed 11-21-19; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, Center for Preparedness and Response (BSC, CPR); (Formerly Known as the Board of Scientific Counselors, Office of Public Health Preparedness and Response (BSC, OPHPR)); Notice of Charter Renewal

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of charter renewal.

**SUMMARY:** This gives notice under (specific statutes and regulations citations and) the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, Center for Preparedness and Response (BSC, CPR); (formerly known as the Board of Scientific Counselors, Office of Public Health Preparedness and Response (BSC, OPHPR)), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 5, 2021.

#### FOR FURTHER INFORMATION CONTACT:

Kimberly Lochner, ScD, Designated Federal Officer, BSC, CPR, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road NE,

Mailstop H21-6, Atlanta, Georgia 30329-4027, telephone (404) 718-3420; Email address [KDL4@cdc.gov](mailto:KDL4@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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.

#### Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019-25354 Filed 11-21-19; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID); (Formerly Known as the Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID)); Notice of Charter Renewal

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of charter renewal.

**SUMMARY:** This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID); (formerly known as the Board of Scientific Counselors, Office of Infectious Diseases, (BSC, OID)), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through October 31, 2021.

#### FOR FURTHER INFORMATION CONTACT:

Sarah Wiley, MPH, Designated Federal Officer, BSC, DDID, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road NE, Mailstop H24-12, Atlanta, Georgia 30329-4027, telephone (404) 639-2100; email address [SWiley@cdc.gov](mailto:SWiley@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2019-25353 Filed 11-21-19; 8:45 am]

BILLING CODE 4163-18-P

**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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, 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).

*Date:* February 19-20, 2020.

*Time:* 8:00 a.m.-5:00 p.m., EST.

*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](mailto:nturner@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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 Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2019-25351 Filed 11-21-19; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-1147]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 December 23, 2019.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0541. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [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.

**Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition**

*OMB Control Number 0910-0541—Extension*

As an integral part of our decision making process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions,

including allowing notifications for food contact substances to become effective; approving food additive petitions, color additive petitions, generally recognized as safe affirmation petitions, and requests for exemption from regulation as a food additive; and approving actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. We have provided guidance that contains sample formats to help industry submit a claim of categorical exclusion (CE) or an environmental assessment (EA) to the Center for Food Safety and Applied Nutrition (CFSAN). The document entitled “Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition” identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of CE and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations.

*Description of Respondents:* The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of June 25, 2019 (84 FR 29864), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows: