registration is required by clicking the links below.

Web ID: https://adobeconnect.cdc.gov/e3pmwd6fhge/event/registration.html.

Dial in number: 888–790–3293 (100 seats).

Participant code: 3762458.

DATES: The meeting will be held on August 30, 2018, 2:00 p.m. to 5:00 p.m., EDT.

ADDRESSES: Web Conference.

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Office of Science and Public Health Practice, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop D–44, Atlanta, Georgia 30333, Telephone: (404) 639–7450; Fax: (404) 471–8772; Email: OPHPR.BSC. Questions@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review for OPHPR scientific programs. For additional information about the Board, please visit: http://www.cdc.gov/phpr/science/counselors.htm.

Matters to be considered: The agenda will include briefings and BSC deliberation on the following topics:

• Interval updates from OPHPR Divisions and Offices including responses to issues raised by the Board during the May 2018 in-person BSC meeting; updates from the Biological Agent Containment working group; and proposed agenda items for the October 29–30 2018 in-person BSC meeting. Agenda items are subject to change as priorities dictate.

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 A. Berger, Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018–15781 Filed 7–23–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Regulatory Perspectives on Otic and Vestibular Toxicity: Challenges in Translating Animal Studies to Human Risk Assessment; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Regulatory Perspectives on Otic and Vestibular Toxicity: Challenges in Translating Animal Studies to Human Risk Assessment.” The purpose of the public workshop is to identify the challenges involved in the translation of toxicities from animal studies to clinical trials, to highlight potential endpoints that can be used in both nonclinical and clinical phases of drug development, and to provide a platform for engaging discussions to improve safety assessments for drugs impacting auditory and vestibular functions. This public workshop will bring together regulatory medical and toxicologist reviewers, veterinary and clinical neurologists, and experts in evaluating auditory and vestibular endpoints.

DATES: The public workshop will be held on August 21, 2018, from 9 a.m. until 12 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Deepa B. Rao, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4235, Silver Spring, MD 20993, 240–402–6544, Deepa.Rao@fda.hhs.gov or Christopher D. Toscano, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4145, Silver Spring, MD 20993, 301–796–
Food and Drug Administration
[Docket No. FDA–2018–D–2647]

Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development.” This draft guidance describes FDA’s current recommendations regarding how to optimize and standardize dietary management in clinical trials for the development of drugs treating inborn errors of metabolism (IEM) for which dietary management is a key component of patients’ metabolic control. Optimizing dietary management in these patients before entry into and during the clinical trial(s) is essential to providing an accurate evaluation of the efficacy of new drug products.

DATES: Submit either electronic or written comments on the draft guidance by September 24, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

DISTRIBUTION: Submit written/paper submissions as detailed in “Instructions.”

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 18, 2018.

Leslie Kux,
Associate Commissioner for Policy.

For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the