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, 301–796–1122, *Christopher.Toscano@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Although multiple drugs are known to cause hearing loss, otic and vestibular toxicities remain a neglected component in routine drug development. In drug safety evaluations, comparative clinical assessments for auditory and vestibular systems between animals and humans remain largely unexplored. The objective of this public workshop is to identify the challenges involved in the translation of toxicities from animal toxicology studies to clinical trials, to highlight potential endpoints that can be used in nonclinical and clinical phases of drug development, and to provide a platform for engaging discussions to improve safety assessments for ototoxic drugs. This public workshop will bring together regulatory medical and toxicologist reviewers, veterinary and clinical neurologists, and experts in evaluating auditory and vestibular endpoints.

II. Topics for Discussion at the Public Workshop

A regulatory perspective of drug development and the occurrence of otic and vestibular toxicity will be presented, with a focus on the current regulatory recommendations on assessment of the auditory and vestibular systems in clinical and nonclinical studies. Relevant endpoints of vestibular and auditory function (clinical evaluation, non-invasive electrophysiological measurements, and histopathology) will be discussed from a clinical and nonclinical perspective. The public workshop will end with an open platform discussion between the audience and panelists regarding the adequacy of the current evaluation and potential future approaches towards improving safety assessments for agents impacting auditory and vestibular functions. We support the principles of the ''3Rs,'' to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if it they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website to register: *https://www.eventbrite.com/e/fda-public-workshop-regulatory-perspectives-on-*

otic-vestibular-toxicity-tickets-47223962142. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 20, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

For any participant in need of sign language interpretation, please send an email request to *Interpreting.Services@oc.fda.gov.* For all other reasonable accommodations, please contact FDA's Office of Equal Employment Opportunity at 301–796–9400.

Streaming webcast of the public workshop: This public workshop will also be webcast at *https://collaboration.fda.gov/ovtw/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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.

[FR Doc. 2018–15779 Filed 7–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2647 for ''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.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: 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