EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form	70	1	3/60	4
Data Use Agreement	70	1	3/60	4
Medical Office Information Form	70	35	5/60	205
Data Files Submission	70	1	1	70
Total	NA	NA	NA	283

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	70	4	$52.58	$210
Data Use Agreement	70	4	52.58	210
Medical Office Information Form	70	205	52.58	10,779
Data Files Submission	70	70	52.58	3,680
Total	NA	213	NA	14,880

* Mean hourly wage rate of $52.58 for Medical and Health Services Managers (SOC code 11–9111) was obtained from the May 2016 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at *https://www.bls.gov/oes/current/oes119111.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–15751 Filed 7–23–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2017–0084; Docket Number NIOSH–298]

Final National Occupational Research Agenda for Construction

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final *National Occupational Research Agenda for Construction.*

DATES: The final document was published on July 17, 2018.

ADDRESSES: The document may be obtained at the following link: *https://www.cdc.gov/niosh/nora/councils/const/agenda.html.*

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H, (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On September 27, 2017, NIOSH published a request for public review in the **Federal Register** [82 FR 45027] of the draft version of the *National Occupational Research Agenda for Construction.* All comments received were reviewed and addressed where appropriate.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–15741 Filed 7–23–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Public Health Preparedness and Response, (BSC, OPHPR)

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, Office of Public Health Preparedness and Response, (BSC, OPHPR). This meeting is open to the public, limited only by 1,500 web conference lines. Public participants should pre-register for the meeting as described below.

The public is welcome to view/listen to the meeting via Adobe Connect. Pre-

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-*