FOR FURTHER INFORMATION CONTACT: William Lewallen, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 301–796–3810, *William.Lewallen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The ICH, formerly known as the International Conference on Harmonisation, was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory requirements for safety and effectiveness. One of the goals of harmonization is to identify and then reduce regional differences in technical regulatory requirements for pharmaceutical products while preserving a consistently high standard for drug efficacy, safety, and quality. In 2015, the ICH was reformed to establish ICH as a true global initiative that expands beyond the previous ICH members. More involvement from regulators around the world is expected, as they join counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH observers and regulatory members. Expanded involvement is also anticipated from global regulated pharmaceutical industry parties, joining as ICH observers and industry members. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development, and their regulation.

ICH guidelines are developed following a five-step process. In Step 1, experts from the different ICH regions work together to prepare a consensus draft of the Step 1 Technical Document. The Step 1 Technical Document is submitted to the ICH Assembly to request endorsement under Step 2a of the process. Step 2b is a ''Regulators only'' step in which the ICH regulatory members review the Step 2a Final Technical Document and take any actions, which might include revisions that they deem necessary, to develop the draft ''Guideline.'' Step 3 of the process begins with the public consultation process conducted by each of the ICH regulatory members in their respective regions, and this step concludes with completion and acceptance of any revisions that need to be made to the Step 2b draft guideline in response to public comments. Adoption of the new guideline occurs in Step 4. Following adoption, the harmonized guideline moves to Step 5, the final step of the process when it is implemented by each of the regulatory members in their respective regions. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions since 1990. More information on the current ICH process and structure can be found at the following website: *http://www.ich.org.* (FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.)

The topics for discussion at this public meeting include the current guidelines under development under the ICH.

II. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by October 28, 2019. To register for the public meeting, please visit the following website: *https://www.eventbrite.ca/e/health-canada-us-fda-joint-consultation-on-ich-tickets-63004743885.* 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 meeting must register by October 28, 2019, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

The agenda for the public meeting will be made available on the internet at: *http://wcms-internet.fda.gov/drugs/news-events-human-drugs/health-canada-and-united-states-food-and-drug-administration-joint-regional-consultation* approximately 2 weeks in advance of the meeting.

If you need special accommodations due to a disability, please contact William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 21, 2019.

Requests for Oral Presentations: If you wish to make a presentation during the public comment session, please contact William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 28, 2019. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. If selected for presentation, any presentation materials must be emailed to William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 28, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: To register to attend via webcast, please visit the following website: *https://www.eventbrite.ca/e/health-canada-us-fda-joint-consultation-on-ich-tickets-63004743885.*

Dated: October 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22760 Filed 10–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0370, FDA–2013–N–0065, FDA–2012–N–0427, FDA–2012–N–0536, FDA–2012–N–0873, FDA–2015–N–3662, FDA–2012–N–0976, FDA–2013–N–0297, FDA–2011–D–0893, and FDA–2019–N–1265]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Export of Medical Devices; Foreign Letters of Approval	0910–0264	8/31/2022
Registration of Food Facilities	0910–0502	8/31/2022
Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002	0910–0510	8/31/2022
Medical Device User Fee Cover Sheet—Form FDA 3601	0910–0511	8/31/2022
Bar Code Label Requirement for Human Drug Products and Biological Products	0910–0537	8/31/2022
Guidance on Reagents for Detection of Specific Novel Influenza A Viruses	0910–0584	8/31/2022
Guidance: Emergency Use Authorization of Medical Products and Related Authorities	0910–0595	8/31/2022
Production, Storage, and Transportation of Shell Eggs (preventing *Salmonella* Enteritidis (SE))	0910–0660	8/31/2022
Center for Devices and Radiological Health Appeals Processes	0910–0738	8/31/2022
Food Labeling: Nutrition Facts Label and Supplement Facts Labels	0910–0813	8/31/2022

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22803 Filed 10–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Brain Tumors, Neuro-sequalae of Cancer Treatments and Neurodegeneration.

Date: November 5, 2019.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7846, Bethesda, MD 20892, 301–827–7238 *zhaow@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Brain Disorders and Related Neurosciences.

Date: November 7–8, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott-Residence Inn Bethesda, 7355 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Vilen A. Movsesyan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040M, MSC 7806, Bethesda, MD 20892, 301–402–7278, *movsesyanv@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR17–094: Maximizing Investigators' Research Award (R35).

Date: November 12, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Methode Bacanamwo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, Bethesda, MD 20892, 301–827–7088, *methode.bacanamwo@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 11, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–22709 Filed 10–17–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel PAR–16–412: NIAID Resource-Related Research Projects (R24).

Date: November 13, 2019.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute for Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, Program Management and Operations Branch, Scientific Review Program, National Institute for Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, RM 3E71, Rockville, MD 20852, 301–761–3100, *cruza@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)