ICH Assembly is responsible for the endorsement of draft guidelines and adoption of final guidelines. FDA publishes ICH guidelines as FDA guidances.

ICH S9 (2010) was a significant advance in harmonizing anticancer drug development. Implementation of ICH S9 (2010) has revealed areas that are open to broad and divergent interpretation by both regulatory authorities and industry. For this reason, an Implementation Working Group (IWG) was formed in October 2014 to provide additional clarity about anticancer pharmaceutical development. The questions and answers developed by the IWG are intended to facilitate the implementation of ICH S9 (2010), as well as to continue progress in the 3Rs of Reduction, Refinement, and Replacement in the use of animals.

In the **Federal Register** of September 19, 2016 (81 FR 64178), FDA published a notice announcing the availability of a draft guidance entitled ''S9 Nonclinical Evaluation for Anticancer Pharmaceuticals—Questions and Answers.'' The notice gave interested persons an opportunity to submit comments by November 18, 2016.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in June 2016.

The guidance provides recommendations on development of anticancer pharmaceuticals, including small molecule and biotechnology-derived products. The questions and answers are intended to provide clarity and to facilitate a harmonized approach to the implementation of ICH S9 (2010). Since the publication of the draft questions and answers and receipt of public comments, some questions were combined for brevity and clarity or were deleted as redundant or due to lack of harmonization. Several areas of particular importance include additional clarity around the scope of the guidance, additional recommendations regarding development of antibody-drug conjugates, and the need for recovery animals in general toxicology studies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''S9 Nonclinical Evaluation for Anticancer Pharmaceuticals—Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the document at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: June 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12975 Filed 6–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Immunity in the Elderly (R01).

Date: July 9–10, 2018.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, LD30, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Julio Aliberti, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852, 301–761–7322, *alibertijc@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Maintaining Immunity after Immunization (U01).

Date: July 11–12, 2018.

Time: 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Geetanjali Bansal, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G49, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, (240) 669–5073, *geetanjali.bansal@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project (P01).

Date: July 11, 2018.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Raymond R. Schleef, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3E61, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5019, *schleefrr@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)

Dated: June 12, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12921 Filed 6–15–18; 8:45 am]

BILLING CODE 4140–01–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; PAR: Selected Topics in Transfusion Medicine.

Date: June 28–29, 2018.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, *Katherine_Malinda@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: July 10, 2018.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shalanda A. Bynum, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, *bynumsa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Convergent Neuroscience: From Genomic Association to Causation.

Date: July 10, 2018.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jana Drgonova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–827–2549, *jdrgonova@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Neuroscience Assay, Diagnostics and Animal Model Development.

Date: July 12–13, 2018.

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

Agenda: To review and evaluate grant applications.

Place: The Crown Plaza Seattle Hotel, 1113 6th Ave., Seattle, WA 98101.

Contact Person: Susan Gillmor, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1730, *susan.gillmor@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Center for Neuroscience and Regenerative Medicine Program.

Date: July 12, 2018.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chittari V. Shivakumar, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–408–9098, *chittari.shivakumar@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Review: Understanding and Modifying Temporal Dynamics of Coordinated Neural Activity.

Date: July 12, 2018.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jana Drgonova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–827–2549, *jdrgonova@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Integrative Neuroscience.

Date: July 12, 2018.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892–7814, 301–435–1787, *borzanj@csr.nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group; International and Cooperative Projects—1 Study Section.

Date: July 13, 2018.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.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: June 12, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12920 Filed 6–15–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Chemical Facility Anti-Terrorism Standards Personnel Surety Program

AGENCY: National Protection and Programs Directorate (NPPD), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; revision of information collection request: 1670–0029.

SUMMARY: The DHS NPPD Office of Infrastructure Protection (IP), Infrastructure Security Compliance Division (ISCD) will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. NPPD previously published this ICR, in the **Federal Register** on December 27, 2017, for a 60-day public comment period.

In this notice NPPD is responding to seven commenters that submitted comments in response to the 60-day notice previously published for this ICR and soliciting public comment concerning this ICR for an additional 30 days.

DATES: Comments are encouraged and will be accepted until July 18, 2018.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to OMB Desk Officer, Department of Homeland Security, National Protection and Programs Directorate and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.* All submissions must include the words ''Department of Homeland Security'' and the OMB Control Number 1670–0029.

Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

Comments that include trade secrets, confidential commercial or financial information, Chemical-terrorism Vulnerability Information (CVI), Sensitive Security Information (SSI), or Protected Critical Infrastructure Information (PCII) should not be submitted to the public regulatory docket. Please submit such comments separately from other comments in response to this notice. Comments containing trade secrets, confidential commercial or financial information, CVI, SSI, or PCII should be appropriately marked and packaged in