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the **Federal Register** of September 19, 2016 (81 FR 64178), FDA published a notice announcing the availability of a draft guidance entitled ''S9 Nonclinical Evaluation for Anticancer Pharmaceuticals—Questions and Answers.''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.