

information and obtain early input from the public on a potential framework for how sponsors may voluntarily change the approved conditions of use of medically important antimicrobial drugs used in or on the medicated feed of food-producing animals to establish an appropriately defined duration of use for those indications that currently have an undefined duration of use. The concept paper does not contain recommendations and does not constitute draft or final guidance by FDA. It should not be used for any purpose other than to facilitate public comment. FDA intends to consider all information and comments received on the concept paper before issuing draft guidance for additional comment.

We are specifically interested in receiving public comments on the following questions:

1. Are the potential timeframes outlined in the concept paper reasonable to achieve the goals described in the concept paper? If not, are there specific scientific or administrative barriers that would prevent sponsors from meeting these timeframes?

2. Are the potential processes for revising the applications described in the concept paper reasonable? If not, what specific adjustments could be made to improve these processes?

3. Are there other factors we should consider regarding this potential framework? If so, what are they?

III. Electronic Access

Persons with access to the internet may obtain the concept paper at either <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry> or <https://www.regulations.gov>.

Dated: January 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-00189 Filed 1-8-21; 8:45 am]

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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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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 HHS-NIH-CDC-SBIR PHS 2021-1 Phase I: Reagents for Immunologic Analysis of Non-Mammalian and Underrepresented Mammalian Models (Topic 094) (For SBIRs Phase I)

Date: January 28, 2021.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240-669-5067, kelly.hudspeth@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HHS-NIH-CDC-SBIR PHS 2021-1 Phase II: Reagents for Immunologic Analysis of Non-Mammalian and Underrepresented Mammalian Models (Topic 094) (For SBIRs Phase II).

Date: January 29, 2021.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240-669-5067, kelly.hudspeth@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: January 5, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-00219 Filed 1-8-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Communities of Practice Webinar on Non-Animal Approaches for Mixtures Assessment; Notice of Public Webinar; Registration Information

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces a public webinar “Non-animal Approaches for Mixtures Assessment.” The webinar is organized on behalf of ICCVAM by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Interested persons may participate via WebEx. Time will be allotted for questions from the audience. Information about the webinar and registration are available at <https://ntp.niehs.nih.gov/go/commprac-2021>.

DATES:

Webinar: January 26, 2021, 9:00 a.m. to approximately 11:00 a.m. EST.

Registration for Webinar: January 4, 2021, until 11:00 a.m. EST January 26, 2021.

Registration to view the webinar is required.

ADDRESSES: Webinar web page <https://ntp.niehs.nih.gov/go/commprac-2021>.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Acting Director, NICEATM, Division of NTP, NIEHS, P.O. Box 12233, K2-16 Research Triangle Park, NC 27709. Phone: 984-287-3150, Email: Nicole.kleinstreuer@nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2032, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM promotes the development and validation of toxicity testing methods that protect human health and the environment while replacing, reducing, or refining animal use. ICCVAM also provides guidance to test method developers and facilitates collaborations that promote the development of new test methods. To address these goals, ICCVAM will hold a Communities of Practice webinar on “Non-animal Approaches for Mixtures Assessment.”

While most available toxicity data are for single chemicals, humans are often

exposed to chemicals as mixtures. Assessing the safety of a mixture is a complex process that requires consideration of both the toxicity of each chemical component of the mixture and the potential for interaction among the components to affect toxicity of the overall mixture. Additionally, most alternative methods and approaches used for assessing chemical safety are developed and evaluated using single chemicals. This can result in lack of clarity about whether a method is appropriate to use for assessing toxicity of a particular mixture.

This webinar will discuss new approach methodologies for assessing exposure to, and potential hazards associated with, chemical mixtures. Key insights and ongoing activities will be described in three presentations featuring speakers from U.S. federal research and regulatory agencies. The preliminary agenda and additional information about presentations will be posted at <https://ntp.niehs.nih.gov/go/commprac-2021> as available.

Webinar and Registration: This webinar is open to the public with time scheduled for questions by participants following each presentation. Registration for the webinar is required and will be open from January 4, 2021, through 11:00 a.m. EST on January 26, 2021. Registration is available at <https://ntp.niehs.nih.gov/go/commprac-2021>. Interested individuals are encouraged to visit this web page to stay abreast of the most current webinar information. Registrants will receive instructions on how to access and participate in the webinar in the email confirming their registration.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 17 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of

alternative test methods. Additional information about ICCVAM can be found at <https://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at <https://ntp.niehs.nih.gov/go/niceatm>.

Dated: January 6, 2021.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2021-00227 Filed 1-8-21; 8:45 am]

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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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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; HHS-NIH-CDC-SBIR PHS 2021-1 Phase I: Improving Technologies to Make Large-scale High Titer Phage Preps (Topic 95).

Date: February 5, 2021.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20892-9823, (240) 669-5023, fdesilva@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS-NIH-CDC-SBIR PHS 2018-1 Phase II: Improving Technologies to Make Large-scale High Titer Phage Preps (Topic 95).

Date: February 5, 2021.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E72A, Rockville, MD 20892-9823, (240) 669-5023, fdesilva@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: January 5, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-00222 Filed 1-8-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Council of Councils, January 29, 2021, 10:00 a.m. to 05:00 p.m., a virtual meeting, which was published in the **Federal Register** on November 25, 2020, 85 FR 75342.

The meeting notice is amended to change the open session meeting end time as follows: The open session will now be held from 11:00 a.m. to 3:50 p.m.

Dated: January 5, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-00221 Filed 1-8-21; 8:45 am]

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