

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 FDA intends to consider all information and comments received on the concept paper before issuing draft guidance for additional comment.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.*

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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](mailto: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](mailto: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.*

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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](mailto: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