DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods; Notice of Public Meeting; Request for Public Input

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) will hold a public forum to share information and facilitate direct communication of ideas and suggestions from stakeholders. Interested persons may attend in person or view the meeting remotely by webcast. Time will be set aside for questions and public statements on the topics discussed. Registration is requested for both public attendance and oral statements, and required for remote access. Information about the meeting and registration are available at http://ntp.niehs.nih.gov/go/iccvamforum-2019.

DATES: Meeting: May 23, 2019, 9:00 a.m. to approximately 4:00 p.m. Eastern Daylight Time (EDT).

Registration for Onsite Meeting: Deadline is May 10, 2019.

Registration for Webcast: Deadline is May 23, 2019.

Submission of Oral Public Statements: Deadline is May 10, 2019.

ADDRESSES: Meeting Location: William H. Natcher Conference Center, National Institutes of Health, Bethesda, MD 20892.


FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); email: warren.casey@nih.gov; telephone: (984) 287–3118.

SUPPLEMENTARY INFORMATION: Background: ICCVAM, a congressionally mandated committee, has been charged with the evaluation of alternative testing strategies that protect human health and the environment while replacing, reducing, or refining animal use.

ICCVAM’s goals include promotion of national and international partnerships between governmental and nongovernmental groups, including academia, industry, advocacy groups, and other key stakeholders. To foster these partnerships ICCVAM initiated annual public forums in 2014 to share information and facilitate direct communication of ideas and suggestions from stakeholders (79 FR 25136).

This year’s meeting will be held on May 23, 2019, at the National Institutes of Health (NIH) in Bethesda, MD. The meeting will include presentations by NICEATM and ICCVAM members on current activities related to the development and validation of alternative test methods and approaches, including activities relevant to implementation of the strategic roadmap for establishing new approaches to evaluate the safety of chemicals and medical products in the United States (83 FR 7487).

Following each presentation, there will be an opportunity for participants to ask questions of the ICCVAM members. Instructions for submitting questions will be provided to remote participants prior to the webcast. The agenda will also include time for participants to make public oral statements relevant to the ICCVAM mission and current activities.

Preliminary Agenda and Other Meeting Information: The preliminary agenda, list of discussion topics, background materials, ICCVAM roster, and public statements submitted prior to the meeting will be posted by May 17 at http://ntp.niehs.nih.gov/go/iccvamforum-2019. Interested individuals are encouraged to visit this web page to stay abreast of the most current meeting information.

Meeting and Registration: This meeting is open to the public with time scheduled for questions and oral public statements following presentations from ICCVAM and NICEATM. The public may attend the meeting at NIH, where attendance is limited only by the space available, or view remotely by webcast. Those planning to attend the meeting in person are encouraged to register at http://ntp.niehs.nih.gov/go/iccvamforum-2019 by May 10, 2019, to facilitate planning for appropriate meeting space. Those planning to view the webcast must register at http://ntp.niehs.nih.gov/go/iccvamforum-2019 by May 23, 2019. The URL for the webcast will be provided in the email confirming registration.

Dated: April 8, 2019.

Ronald J. Livingston, Jr., Program Analyst, Office of Federal Advisory Committee Policy.

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NIH visitor and security information is available at http://www.nih.gov/about/visitor/index.htm. Individuals with disabilities who need accommodation to participate in this event should contact Dr. Elizabeth Maull at phone: (984) 287–3157 or email: maull@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Request for Oral Public Statements: Each presentation will be followed by an opportunity for participants to ask questions of the presenter. Attendees need not register in advance for the opportunity to ask questions or make comments specific to presentations. Instructions for submitting questions or comments will be provided to remote participants prior to the webcast.

In addition to time for questions or comments following each scheduled presentation, time will be allotted during the meeting for oral public statements. Prepared slides on topics relevant to ICCVAM’s mission will be available onsite, although onsite availability for oral public statements should email ICCVAMquestions@niehs.nih.gov by May 10, 2019 to arrange to present statements via teleconference line.

Responses to this notice are voluntary. No proprietary, classified, confidential, or sensitive information should be included in statements submitted in response to this notice or presented during the meeting. This request for input is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of such information.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 16 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. 285j–3) establishes ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences 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 http://ntp.niehs.nih.gov/go/iccvm.

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 examination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at http://ntp.niehs.nih.gov/go/niceatm.

Dated: April 8, 2019.

Brian R. Berridge, Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Medical Device for Vascular Dilation

A vascular dilator is commonly used in transcatheter cardiovascular intervention procedures. Commercially available vascular dilators have introducer sheaths with a finite thickness and mismatched diameter with the dilators. This causes uneven stretching of the trailing edge of the sheath and severe damage to the target vessels. This technology produces the specialized sheath with a shoulder that can be introduced percutaneously with an enhanced dilator into a broad range of diseased target vessels and chambers with reduced vascular injury. The shoulder helps to match the diameter of the introducer sheath so that there is a smooth transition between the dilator and the introducer sheath. The invention allows the dilator to be withdrawn in segments without disrupting the introducer sheath.