



[Billing Code 4140-01-P]

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

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-2017>.

DATES:

Meeting: May 23, 2017, 9:00 a.m. to approximately 4:00 p.m. Eastern Daylight Time (EDT).

Registration for Onsite Meeting: Deadline is May 12, 2017.

Registration for Webcast: Deadline is May 23, 2017

Submission of Oral Public Statements: Deadline is May 12, 2017.

ADDRESSES:

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

Meeting Webpage: The preliminary agenda, registration, and other meeting materials are at <http://ntp.niehs.nih.gov/go/iccvamforum-2017>.

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: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM, a congressionally mandated committee, promotes the development and validation 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, 2017, 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 discussions of the proposed strategic roadmap to establish new approaches for evaluating the safety of chemicals and medical products in the United States. These new approaches are anticipated to increase confidence in alternative methods and improve their relevance to human health outcomes while maximizing efficiency and maintaining a commitment to replace, reduce, and refine animal use.

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 16 at <http://ntp.niehs.nih.gov/go/iccvamforum-2017>. Interested individuals are encouraged to visit this webpage 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-2017> by May 12, 2017, to facilitate planning for appropriate meeting space. Those planning to view the webcast must register at <http://ntp.niehs.nih.gov/go/iccvamforum->

2017; registration will be available through May 23, 2017. The URL for the webcast will be provided in the email confirming registration.

Visitor and security information for visitors to NIH 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: (919) 316-4668 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 with associated slides on topics relevant to ICCVAM's mission and topics under discussion including the U.S. strategic roadmap. The number and length of presentations may be limited based on available time. Submitters will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting public statements and/or associated slides should include their name, affiliation (if any), mailing address, telephone, email, and sponsoring organization (if any) with the document. National Toxicology Program guidelines for public statements are at http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

Persons wishing to present oral public statements are encouraged to indicate on the registration form whether their comments will focus on ICCVAM agency activities or the U.S. strategic roadmap. They should also email their statement to ICCVAMquestions@niehs.nih.gov by May 12, 2017, to allow time for review by NICEATM and ICCVAM and posting to the meeting page prior to the forum. Written statements may supplement and expand the oral presentation. Public statements will be distributed to NICEATM and ICCVAM members before the meeting.

Registration for oral public statements will be available onsite, although onsite registration and time allotted for these statements may be limited based on the number of individuals who register to make statements and available time. If registering onsite and reading from written text, please bring 20 copies of the statement for distribution and to supplement the record.

Persons wishing to present oral public statements are strongly encouraged to present their comments in person to facilitate effective interaction with ICCVAM members. However, there will also be the opportunity to present public statements by teleconference line. Persons who are unable to attend the meeting in person and wish to present oral public statements should email ICCVAMquestions@niehs.nih.gov by May 12, 2017 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 that 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 animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) establishes ICCVAM as a permanent interagency committee of the NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. ICCVAM acts to ensure that new and revised test methods are validated to meet the needs of federal agencies, increase the efficiency and effectiveness of federal agency test method review, and optimize utilization of scientific expertise outside the federal Government. Additional information about ICCVAM can be found at <http://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 testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at <http://ntp.niehs.nih.gov/go/niceatm>.

Dated: April 13, 2017

John R. Bucher,

Associate Director, National Toxicology Program

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