



**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Predictive Models for Acute Oral Systemic Toxicity; Notice of Meeting; Registration Information**

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces the workshop “Predictive Models for Acute Oral System Toxicity.” Workshop attendees will discuss development of in silico models for acute oral system toxicity and the next steps to encourage appropriate use of these models in regulatory contexts. Interested persons may attend in person or view the meeting remotely by webcast. Registration is requested to attend in person and required to view the webcast. Information about the workshop and registration links are available at <http://ntp.niehs.nih.gov/go/atwksp-2018>.

**DATES:**

Meeting: April 11-12, 2018; from 9:00 a.m. to approximately 5:00 p.m. Eastern Daylight Time (EDT) on April 11 and from 8:30 a.m. to approximately 3:00 p.m. EDT on April 12, 2018.

Registration for Onsite Meeting: Deadline is April 6, 2018.

Registration for Webcast: Deadline is April 12, 2018.

**ADDRESSES:**

Meeting Location: Natcher Conference Center, National Institutes of Health, Bethesda, MD 20984.

Meeting Web page: Registration links and other information are available at <http://ntp.niehs.nih.gov/go/atwksp-2018>.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Deputy Director, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), at telephone: (984) 287-3150 or email: [nicole.kleinstreuer@nih.gov](mailto:nicole.kleinstreuer@nih.gov).

#### SUPPLEMENTARY INFORMATION:

**Background:** The development of test methods that reduce or replace animal use for acute toxicity tests required by regulatory authorities is one of ICCVAM's high priority activities. To this end, the ICCVAM Acute Toxicity Workgroup, with support from NICEATM, sponsored a global project to develop *in silico* models of acute oral systemic toxicity that predict five specific endpoints identified by regulatory agencies. These endpoints included identification of "very toxic" chemicals (LD50 less than 50 mg/kg), "nontoxic" chemicals (LD50 greater than or equal to 2000 mg/kg), and point estimates for LD50s, and categorization of toxicity hazard using the U.S. Environmental Protection Agency's and United Nations Globally Harmonized System of Classification and Labelling's classification schemes. NICEATM invited scientists to develop and submit *in silico* models that predict any or all of these endpoints. This workshop will provide an opportunity for project participants to present their submitted models. Workshop participants will also discuss development of a consensus model for predicting acute oral toxicity as well as next steps needed to encourage appropriate use of these models in

regulatory contexts.

**Workshop and Registration:** The workshop is open to the public, free of charge, with attendance limited only by space available. Webcast viewing will be offered for all plenary presentation sessions. Links to registration and additional information about the workshop are available at <http://ntp.niehs.nih.gov/go/atwksp-2018>. Individuals planning to attend the workshop in person should register by April 6, 2018. Walk-in registration will be available only as space permits. Registration is required to view the webcast and will be open through the end of the workshop. The URL for the webcast will be provided in the email confirming registration.

Security information for visitors to NIH is available at <https://www.nih.gov/about-nih/visitor-information>. Individuals with disabilities who need accommodation to participate in this event should contact Dr. Elizabeth Maull at telephone: (984) 287-3157 or email: [maull@niehs.nih.gov](mailto: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.

**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. 2851-3)

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 <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 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: February 9, 2018.

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