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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 Reverse Toxicokinetics; Notice of Public Webinar and Registration Information

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces a public webinar "Reverse Toxicokinetics: Using In Vitro Data to Estimate Exposures that Could Be Associated with Adverse Effects In Vivo." The webinar is organized on behalf of ICCVAM by the National Toxicology Program Interagency Center for the Evaluation Alternative Toxicological Methods (NICEATM) and hosted by the Environmental Protection Agency's National Center for Computational Toxicology (NCCT). Interested persons may participate via Adobe® Connect™. Time is allotted for questions from participants.

DATES:

Webinar: January 27, 2015, 1:00 p.m. to approximately 2:30 p.m. Eastern Standard Time (EST).

Registration for Webinar: December 3, 2014, until 2:30 p.m. January 27, 2015.

ADDRESSES:

Webinar Webpage: http://ntp.niehs.nih.gov/go/ivive-webinar.

FOR FURTHER INFORMATION CONTACT: Dr. Warren S. Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (919) 316-4729.

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 the communities of practice webinar "Reverse Toxicokinetics: Using In Vitro Data to Estimate Exposures that Could Be Associated with Adverse Effects In Vivo."

Many commercial and environmental chemicals lack toxicity data necessary for users and risk assessors to make fully informed decisions about potential health effects. Generating these data using high throughput in vitro cell- or biochemical-based tests would be faster and less expensive than testing in animals; tests that use human cells or cellular components would also potentially be more relevant to human health. However, correlating test chemical concentrations that produce effects in vitro to exposure levels that cause toxicity in vivo is complicated, since factors that can significantly influence toxicity in vivo (such as plasma protein binding and metabolic clearance) are often not replicated in in vitro assays. Mathematical models known as reverse toxicokinetic

models provide a framework for making these correlations. Reverse toxicokinetic models provide an estimate of the exposure level that would result in a blood concentration equal to a chemical concentration causing an in vitro adverse outcome.

The ICCVAM webinar will feature presentations by two experts in the development and application of reverse toxicokinetic models to high throughput screening data: John Wambaugh, Ph.D., physical scientist at NCCT, and Barbara Wetmore, Ph.D., senior research investigator at the Hamner Institutes for Health Sciences. Their presentations will provide an overview of the development of reverse toxicokinetic models and discuss the consideration of population variability and sensitive subpopulations in the use of these models.

Webinar and Registration: This webinar is open to the public with time scheduled following each presentation for questions by participants. Registration for the webinar is required and is open from December 3, 2014, through 2:30 p.m. on January 27, 2015. A link to registration is available at http://ntp.niehs.nih.gov/go/ivive-webinar. Registrants will receive instructions on how to access and participate in the webinar in the email confirming their registration.

The preliminary agenda is available at http://ntp.niehs.nih.gov/go/ivive-webinar. Interested individuals are encouraged to visit this webpage to stay abreast of the most current webinar information.

Individuals with disabilities who need accommodation to participate in this event should contact Ms. LaCresha Styles at phone: (919) 541–3282 or email: styles.lacresha@epa.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 15 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences and provides the authority for ICCVAM's involvement in activities relevant to the development of new and revised toxicological tests.

ICCVAM conducts technical evaluations of new, revised, and alternative test methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of test methods that both 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. ICCVAM acts to ensure that new and revised test methods are validated to meet the needs of federal agencies, to increase the efficiency and effectiveness of federal agency test method review, and to 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 activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and

strategies 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: December 5, 2014

John R. Bucher, Ph.D.

Associate Director, National Toxicology Program

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