DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM): International Workshop on Alternative Methods To Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), Department of Health and Human Services.

ACTION: Announcement of a workshop.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM announce an upcoming "International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions." The workshop will bring together an international group of scientific experts from government, industry, and academia to review the current state of the science, availability, and future need for alternative methods that can reduce, refine, and replace the use of animals for human and veterinary vaccine post-licensing potency and safety testing. Plenary and breakout sessions will address current U.S. and international regulatory requirements, currently available alternatives, and future research, development, and validation activities needed to further advance the use of alternative methods for vaccine post-licensing potency and safety testing. This workshop is free and open

to the public with attendance limited only by the space available. Abstracts for scientific posters for display at the workshop are also invited (*see* **SUPPLEMENTARY INFORMATION**).

DATES: The workshop will be held on September 14–16, 2010. Sessions will begin at 8:30 a.m. and end at approximately 5 p.m. on all days. The deadline for submission of poster abstracts is July 29, 2010. Individuals who plan to attend are asked to register in advance (by August 30, 2010) with NICEATM.

ADDRESSES: The workshop will be held at the William H. Natcher Conference Center, 45 Center Drive, NIH Campus, Bethesda, MD 20892. Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, should contact 919–541–2475 voice, 919–541–4644 TTY (text telephone), through the Federal TTY Relay System at 800–877–8339, or e-mail to *niehsoeeo@niehs.nih.gov.* Requests should be made at least 14 days in advance of the event.

FOR FURTHER INFORMATION CONTACT: Correspondence should be sent by mail, fax, or e-mail to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD K2–16, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Vaccines represent a vital and cost-effective tool in the prevention of infectious diseases in humans and animals. Regulatory authorities require post-licensing potency and safety testing of human and veterinary vaccines to ensure their effectiveness and minimize potential adverse health effects. Because some of these tests require large numbers of laboratory animals that may experience unrelieved pain and distress, the development and validation of alternative methods that can reduce, refine, and replace the use of animals for vaccine potency and safety testing is one of ICCVAM's four highest priorities. The workshop goals are to (1) review the state of the science of alternative methods that are currently available and/or accepted for use that can reduce, refine (less pain and distress), and replace animal use in vaccine potency and safety testing, and discuss ways to promote their implementation; (2) identify knowledge and data gaps that should be addressed to develop alternative methods that can further reduce, refine, and/or replace the use of animals in vaccine potency and safety testing; and (3) identify and prioritize research, development, and validation efforts needed to address these knowledge and data gaps in order to advance alternative methods for vaccine potency and safety testing while ensuring the protection of human and animal health.

Preliminary Workshop Agenda

Day 1 Tuesday, September 14, 2010

- Welcome and Introduction of Workshop Goals and Objectives
- Overview of Public Health Needs and Regulatory Requirements for Vaccine Safety and Potency Testing
- Replacement Methods for Vaccine Potency Testing: Current State of the Science
- Breakout Groups: Non-animal Replacement Methods for Vaccine Potency Testing
- Human Vaccines
- Veterinary Vaccines

Day 2 Wednesday, September 15, 2010

- Refinement Alternatives: Using Serological Methods to Avoid Challenge Testing
- Refinement Alternatives: Using Earlier Humane Endpoints to Avoid or Minimize Animal Pain and Distress in Vaccine Potency Challenge Testing
- Reduction Alternatives: Strategies to Further Reduce Animal Numbers for Vaccine Potency Testing
- Breakout Groups: Refinement and Reduction of Animal Use for Vaccine Potency Testing
  - Human Vaccines
  - Veterinary Vaccines

Day 3 Thursday, September 16, 2010

- Vaccine Post-licensing Safety Testing: Reduction, Refinement and Replacement Methods and Strategies
- Breakout Groups: Post-license Vaccine Safety Testing: Alternative Strategies for the Replacement, Refinement, and Reduction of Animals
  - Human Vaccines
  - Veterinary Vaccines
- Closing Comments

Registration

Registration information, tentative agenda, and additional meeting information are available on the workshop Web site (*http://iccvam.niehs.nih.gov/meetings/BiologicsWksp-2010/BiologicsWksp.htm*) and upon request from NICEATM (*see* **FOR FURTHER INFORMATION CONTACT**).

Call for Abstracts

ICCVAM and NICEATM invite the submission of abstracts for scientific posters to be displayed during this workshop. Posters should address current research, development, validation, and/or regulatory acceptance of alternative methods that may reduce, refine, and/or replace the use of animals in vaccine potency or vaccine post-licensing safety testing. The body of the abstract must be limited to 400 words or fewer. Key references relevant to the abstract may be included after the abstract body. However, the length of the abstract and references should not exceed one page. All submissions should be at least 12-point font and all margins for the document should be no less than one inch. Title information should include names of all authors and associated institutions. The name and contact information (*i.e.,* address, phone number, fax number, e-mail address) for the corresponding or senior author should be provided at the end of the abstract.

A statement indicating whether animals or humans were used in studies described in the poster must accompany all abstracts. All abstracts that involve studies using animals or animal tissues should be accompanied by a statement by the senior author certifying that all animal use was carried out in accordance with applicable laws, regulations, and guidelines, and that the studies were approved by the appropriate Institutional Animal Care and Use Committee or equivalent. A statement that all human studies were conducted in accordance with applicable laws, regulations, and guidelines, and that the studies were approved by the appropriate Institutional Review Board or equivalent must accompany any abstracts that involve studies using humans.

Abstracts must be submitted by e-mail to *niceatm@niehs.nih.gov.* The deadline for abstract submission is close of business on July 29, 2010. ICCVAM and NICEATM will review the submitted abstracts. The corresponding author will be notified of the abstract's acceptance approximately five weeks prior to the workshop. Guidelines for poster presentations will be sent to corresponding authors along with the notification of acceptance.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 U.S. Federal regulatory and research agencies that require, use, or generate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability, and promotes the scientific validation and regulatory acceptance of toxicological test methods

that more accurately assess the safety and health hazards of chemicals and products and that refine (less pain and distress), reduce, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–2, 2851–5 [2000]), available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and coordinates international validation studies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM, guidelines for nomination of test methods for validation studies, and guidelines for submission of test methods for ICCVAM evaluation are available at *http://iccvam.niehs.nih.gov.*

Dated: April 30, 2010.

John R. Bucher,

Associate Director, National Toxicology Program.

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