DEPARTMENT OF HEALTH AND HUMAN SERVICES

International Workshop on Alternative Methods for Human and Veterinary Rabies Vaccine Testing: State of the Science and Planning the Way Forward

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

ACTION: Announcement of a Workshop; Call for Abstract Submissions.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces an ''International Workshop on Alternative Methods for Human and Veterinary Rabies Vaccine Testing: State of the Science and Planning The Way Forward.'' This workshop will bring together scientists from government, industry, and academia to review the current state of the science and validation status of methods and approaches that may reduce, refine, or replace animal use in human and veterinary rabies vaccine potency testing, and to develop an implementation strategy to achieve global acceptance and use of these alternatives. Attendance is open to the public at no charge and limited only by the available space. Abstracts for scientific posters for display at the workshop are also invited (see **SUPPLEMENTARY INFORMATION**).

DATES: The workshop is scheduled for October 11–13, 2011. Sessions will begin at 8:30 a.m. each day and end at approximately 6 p.m. on October 11 and 12 and at 12 p.m. on October 13. The deadline for registration is September 30, 2011. Due to U.S. Department of Agriculture (USDA) security requirements, onsite registration at the workshop will not be available. The deadline for submission of poster abstracts is September 16, 2011.

ADDRESSES: The workshop will be held at the Center for Veterinary Biologics at the USDA National Centers for Animal Health, 1920 Dayton Avenue, Ames, Iowa 50010. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Debbie McCarley at voice telephone: 919–541–2384 or e-mail: *mccarley@niehs.nih.gov.* TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least 5 business days in advance of the event.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.* Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

Rabies is one of the oldest known zoonotic diseases and is responsible for at least 55,000 human deaths worldwide each year (World Health Organization [WHO], 2010). Rabies vaccines serve a vital role in preventing further deaths and controlling the disease in certain animal populations. An estimated 15 million people receive post-exposure vaccine prophylaxis each year due to actual or suspected exposures to the rabies virus. In the United States and other developed countries, rabies vaccines have effectively eliminated domestic rabies virus strains. Prior to the release of each production lot of vaccine, regulatory authorities require demonstration of potency and safety. Potency and safety testing of rabies vaccines requires large numbers of laboratory animals and involves significant pain and distress. New

methods and approaches are sought that (1) are more humane and use fewer or no animals; (2) are faster, less expensive, and more accurate; and (3) are safer for laboratory workers.

A recent international workshop organized by NICEATM, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and its international partners identified rabies vaccines as one of the three highest priorities for future research, development, and validation of alternative test methods that could further reduce, refine, and ultimately replace animal use for potency and safety testing. Organizing an international workshop to assess the current state of the science and way forward for alternative methods for rabies vaccine potency testing was identified as a high priority. Based on recent scientific and technological advances, several alternative approaches to rabies vaccine potency testing have been proposed or are currently available. This international workshop will bring together scientific experts from government, industry, and academia to review these methods and to define efforts necessary to achieve global acceptance and implementation. The workshop is organized by NICEATM, ICCVAM, the European Centre for the Validation of Alternative Methods (ECVAM), the Japanese Center for the Validation of Alternative Methods (JaCVAM), and Health Canada.

Preliminary Workshop Agenda

Day 1 Tuesday, October 11, 2011

- Welcome and Overview of Workshop Goals and Objectives
- Rabies Vaccines for Humans and Animals: Public Health Perspectives
- Current Requirements and Guidance on Product-Specific Validation of Alternatives for Veterinary Rabies Vaccine Potency Testing
- Current Requirements and Guidance on Product-Specific Validation of Alternatives for Human Rabies Vaccine Potency Testing
- International Guidelines for Rabies Vaccine Potency Testing
  - WHO
  - World Organisation for Animal Health (OIE)
- Incorporating Reduction, Refinement, and Replacement (the ''3Rs'') Into Human and Veterinary Rabies Vaccine Potency Testing: An Industry Perspective
- Critical Analysis of the *In Vivo* Potency Challenge Test for Inactivated Rabies Vaccines
- Serological Methods for Human and Veterinary Rabies Vaccine Potency Testing: Overview and Validation Status
- *In Vitro* Antigen Quantification Assays for Rabies Vaccine Potency Testing
- Application of Consistency Parameters and Integrated Approaches to Reduce and Replace Animal Use for Rabies Vaccine Potency Testing
- Vaccine Adjuvants and their Impact on Antigen Quantification Methods
- Current NIH Research on Improved Rabies Vaccines

Day 2 Wednesday, October 12, 2011

- Breakout Session #1: Serologic Methods for Rabies Vaccine Potency Testing
- Breakout Session #2: Non-Animal Approaches to Rabies Vaccine Potency Testing: Antigen Quantification and Integrated Approaches

Day 3 Thursday, October 13, 2011

- Breakout Session #2 (continued): Non-Animal Approaches to Rabies Vaccine Potency Testing: Antigen Quantification and Integrated Approaches
- Breakout Session #3: The *In Vivo* Potency Challenge Test for Inactivated Rabies Vaccines: Refinement and Reduction Opportunities
- Closing Session: Review of Workshop Conclusions and Recommendations

Registration

Registration information, tentative agenda, and additional meeting information are available on the workshop Web site (*http://iccvam.niehs.nih.gov/meetings/RabiesVaccWksp-2011/RabiesVaccWksp.htm*) and upon request from NICEATM (see **FOR FURTHER INFORMATION CONTACT**).

Call for Abstracts

NICEATM and ICCVAM 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 for human or veterinary rabies vaccine potency testing. The body of the abstract is not to exceed 400 words. 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 the names of all authors and associated institutions. The name, address, phone number, fax number, and email address for the corresponding or senior author should be provided at the end of the abstract.

Abstracts must include the following information, when applicable: (1) A statement indicating whether animals or humans were used in studies, (2) a statement by the senior author certifying that use of animals or animal tissues 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, and (3) 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.

Abstracts must be submitted by e-mail to *niceatm@niehs.nih.gov.* The deadline for abstract submission is September 16, 2011. The corresponding author will be notified regarding the abstract's acceptance within 10 working days of the submission deadline. Guidelines for poster presentations will be sent to the corresponding authors.

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. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) 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 conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on the

NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov).*

References

WHO. 2010. Rabies vaccines: WHO Position paper. Weekly Epidemiological Record 85(32):309–320.

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John R. Bucher,

Associate Director, National Toxicology Program.

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