

Background Information on ICCVAM, NICEATM, and SACATM

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. 285l-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 for validation studies and technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM-ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established in response to the ICCVAM Authorization Act [Section 285l-3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

References

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Dated: August 3, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011-20537 Filed 8-11-11; 8:45 am]

BILLING CODE 4140-01-P

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.

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

References

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

Dated: August 3, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011–20540 Filed 8–11–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice To Change Catalog of Federal Domestic Assistance (CFDA) Number

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice provides public announcement of CDC's intent to award two awards to eligible applicants of State or Territorial Public Health Newborn Bloodspot Screening Programs. These activities are proposed by the above-mentioned grantees in their FY 2011 applications submitted under funding opportunity CDC–RFA–EH11–001, “Program to Support New Implementation of State or Territorial Public Health Laboratory Capacity for Newborn Bloodspot Screening of Severe Combined Immune Deficiency (SCID) (U01), ” Catalog of Federal Domestic Assistance Number (CFDA): 93.070. Approximately \$900,000 in funding will be awarded to the grantees for the implementation of newborn screening for SCID.

Accordingly, CDC adds the following information to the previously published funding opportunity announcement of EH11–001:

Authority: Authorized under Section 301 of the Public Health Service Act, [42 U.S.C. 241], as amended.

CFDA #: 93.070 Environmental Public Health Emergency Response.

Award Information

Type of Award: New Competing Cooperative Agreement.

Approximate Total Current Fiscal Year ACA Funding: \$900,000.

Anticipated Number of Awards: 2.
Fiscal Year Funds: 2011.

Anticipated Award Date: September 1, 2011.

Application Selection Process

Funding will be awarded to applicants based on results from the peer review panel ranking recommendations.

Funding Authority

CDC will add the authority to that which is reflected in the published Funding Opportunity CDC–RFA–EH11–001. The revised funding authority language will read:

—Authorized under Section 301 of the Public Health Service Act, [42 U.S.C. 241], as amended.

DATES: The effective date for this action is the date of publication of this Notice and remains in effect until the expiration of the project period of the funded applications.

FOR FURTHER INFORMATION CONTACT: Beth Gardner, Extramural Team Lead, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Hwy., Atlanta, GA 30341, telephone (770) 488–0572, e-mail Bgardner@cdc.gov.

SUPPLEMENTARY INFORMATION: None.

Dated: August 3, 2011.

James Stephens,

Director of the Office of Science Quality, Centers for Disease Control and Prevention.

[FR Doc. 2011–20507 Filed 8–11–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 76 FR 47189–47190, dated August 4, 2011) is amended to reflect the reorganization of the Center for Global Health, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows: After the title and functional statements for the Division of Global Disease Detection and Emergency Response (CWJ), insert the following:

Global Immunization Division (CWK). The Global Immunization Division (GID) protects the health of Americans and global citizens by preventing

disease, disability, and death worldwide from vaccine-preventable diseases. In carrying out its mission, GID: (1) Provides national leadership and coordination of the CGH efforts to eradicate polio, control or eliminate measles, strengthen routine immunization programs, introduce new and under-utilized vaccines, and promote safe injection practices, in collaboration with international organizations and CDC Centers/Institute/Offices; (2) provides short- and long-term consultation and technical assistance to the WHO, UNICEF, and foreign countries involved in global immunization activities and participates in international advisory group meetings on immunization issues; (3) administers grants to WHO, Pan American Health Organization (PAHO), UNICEF, and other international partners as appropriate for the provision of technical, programmatic, and laboratory support, and vaccine procurement for initiatives to support global immunization targets; (4) designs and participates in international research, monitoring, and evaluation projects to increase the effectiveness of immunization strategies as may be developed; (5) develops strategies to improve the technical skills and problem-solving abilities of program managers and health care workers in other countries; (6) refines strategies developed for the eradication or control of vaccine-preventable diseases in the Western Hemisphere for implementation in other parts of the world; (7) assists other countries, WHO, and other partners to improve surveillance for polio, measles, and other vaccine preventable diseases (VPDs); (8) prepares articles based on findings for publication in international professional journals and presentation at international conferences; (9) collaborates with other countries, WHO, UNICEF, and advocacy groups to ensure the availability of sufficient funds to purchase an adequate supply of polio, measles, and other vaccines, and funds for technical support for use in eradication and control efforts; and (10) provides technical and operational leadership for CDC's activities in support of the immunization initiatives such as Global Alliance for Vaccines and Immunization and the Global Immunization Vision and Strategies.

Office of the Director (CWK1). (1) Provides leadership, management, and oversight for all division activities; (2) provides coordination of budgeting and liaison with CGH, and FMO on budget and spending; (3) provides coordination and oversight of the division's