DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP), NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM): Scientific Workshop on Alternative Methods To Refine, Reduce, or Replace the Mouse LD_{50} Assay for Botulinum Toxin Testing; Request for In Vivo and In Vitro Data

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

ACTION: Workshop announcement and data request.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM announce an upcoming ''ICCVAM/NICEATM/ECVAM Scientific Workshop on Alternative Methods to Refine, Reduce, or Replace the Mouse LD_{50} Assay for Botulinum Toxin Testing.'' The workshop is being co-organized by ICCVAM, NICEATM, and the European Centre for the Validation of Alternative Methods (ECVAM). This workshop is open to the public with attendance limited only by the space available. ICCVAM and NICEATM also invite the submission of (1) data from botulinum toxin test methods and (2) abstracts for scientific posters for display at the workshop (discussed more under ''Supplemental Information'').

DATES: The workshop will be held on November 13 and 14, 2006. Sessions for both days will begin at approximately 8:30 a.m. and end at approximately 5 p.m. The deadline for submission of an abstract is September 29, 2006. The deadline for submission of data is October 20, 2006.

Individuals who plan to attend the workshop are strongly encouraged to register in advance (by October 30, 2006) with NICEATM. Registration information, an agenda, and additional information will be available on the workshop Web site (*http://iccvam.niehs.nih.gov/methods/biolodocs/biolowkshp/wkshpinfo.htm*) and upon request from NICEATM (see ''**FOR FURTHER INFORMATION CONTACT**'' above).

ADDRESSES: The workshop will be held at the Crowne Plaza Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910. 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 7 days in advance of the event.

FOR FURTHER INFORMATION CONTACT: Correspondence should be addressed to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

In October 2005, the Humane Society of the United States (HSUS) submitted a nomination to NICEATM to organize a workshop to evaluate the state-of-the-science for potential alternatives to the mouse LD_{50} assay for botulinum toxin potency testing. The HSUS nomination is available at *http://iccvam.niehs.nih.gov*. See ''Nominations and Submissions.'' ICCVAM considered the nomination and supported, with a high priority, the concept of a workshop to discuss alternative methods and approaches that might reduce, refine, or replace the use of animals for botulinum toxin potency testing. The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) discussed this nomination at its meeting on December 12, 2005, and concurred with ICCVAM. The goals of the workshop are to (1) review the state-of-the-science and current status of alternative methods that may refine (less pain and distress), reduce, or replace the use of mice for botulinum toxin testing and (2) identify priorities for research, development, and validation efforts needed to advance the use of alternative methods for botulinum toxicity testing.

Preliminary Workshop Agenda

Day 1 Monday, November 13, 2006

- Welcome and Introduction of Workshop Goals and Objectives.
- Session 1 Overview of Public Health Needs for Botulinum Toxin Testing and Regulatory Requirements.
- Session 2 Current Understanding and Knowledge Gaps for Botulinum Toxin.
- Session 3 Potential Replacement of Animal Use for Botulinum Toxin Potency Testing.

Day 2 Tuesday, November 14, 2006

- Session 4 Refinement (Less Pain and Distress) of Animal Use for Botulinum Toxin Potency Testing.
- Session 5 Reduction of Animal Use For *In Vivo* Botulinum Testing.
- Session 6 Wrap-up of Panel Discussions.

Call for Abstracts

ICCVAM and NICEATM invite the submission of abstracts for scientific posters to be displayed during the workshop. Posters should address current developments and/or the validation status of alternative test methods for *in vivo* botulinum toxin tests and their potential to reduce, refine, or replace the use of the mouse LD_{50} assay. The body of the abstract is limited to 400 words or less and 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 in at least 12-point font and all margins for the document should be no smaller than one inch. Title information should include the names of all authors and their affiliations. 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 from the senior author certifying that all animal use was carried out in accordance with applicable laws, regulations, and guidelines, and that the appropriate Institutional Animal Care and Use Committee approved the studies. All abstracts that involve studies using humans should be accompanied by a statement from the senior author certifying that all human use was conducted in accordance with applicable laws, regulations, and guidelines, and that the appropriate Institutional Review Board approved the studies.

Abstracts should be submitted by e-mail to *niceatm@niehs.nih.gov.* The deadline for abstract submission is close of business on September 29, 2006. ICCVAM and NICEATM will review the submitted abstracts. The corresponding author will be notified of the abstract's acceptance, along with guidelines for the poster format, approximately five weeks prior to the workshop.

Request for Data

NICEATM invites the submission of data and information from *in vivo* botulinum toxin testing and *ex vivo* and *in vitro* test methods being used or evaluated as potential alternatives to the mouse assay for botulinum toxin testing. The deadline for data submission is October 20, 2006. These data will be provided to the workshop participants and workshop panels for their review and consideration during workshop discussions. A similar request for data was announced previously (**Federal Register**, Vol. 71, No. 18, pp. 4603–4604, January 27, 2006, available at *http://iccvam.niehs.nih.gov/*).

When submitting chemical and protocol information/test data, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable). NICEATM prefers data to be submitted as copies of pages from study notebooks and/or study reports, if available. Raw data and analyses available in electronic format may also be submitted. Each submission should preferably include the following information, as appropriate:

- Specific type of botulinum neurotoxin tested (e.g., Clostridium botulinum neurotoxin type A).
- *In vivo* potency test protocol used and test results.
- Individual animal responses, including time of onset of specific clinical signs and death.
- Alternative *ex vivo* or *in vitro* test protocol used and test results.
- The extent to which the study complied with national or international Good Laboratory Practice guidelines.
- Date of the study.
- The organization that conducted the study

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 U.S. Federal regulatory and research agencies that 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 hazards of chemicals and products and that refine, reduce, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–2, 2851–5 [2000]) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM–related activities. 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 can be found at the ICCVAM–NICEATM Web site (*http://iccvam.niehs.nih.gov*).

SACATM provides external advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings can be found at *http://ntp.niehs.nih.gov/go/167.*

Dated: August 7, 2006.

David A. Schwartz,

Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E6–13525 Filed 8–16–06; 8:45 am]

BILLING CODE 4140–01–P