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); Announcement of Expert Panel Meeting To Evaluate Revised Analyses and Proposed Reference Substances for In Vitro Test Methods for Identifying Ocular Corrosives and Severe Irritants

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

ACTION: Meeting announcement and opportunity for public comment.

SUMMARY: NICEATM announces a second meeting of an expert panel by teleconference on September 19, 2005, to evaluate (1) revised accuracy and reliability analyses of four *in vitro* test methods proposed for detecting ocular corrosives and severe irritants and (2) a revised list of proposed reference substances for validation studies on *in vitro* test methods for identifying ocular corrosives and severe irritants. The four *in vitro* test methods under consideration are the (1) Bovine Corneal Opacity and Permeability (BCOP) assay, (2) Hen's Egg Test—Chorion Allantoic Membrane (HET–CAM), (3) Isolated Rabbit Eye (IRE) assay, and (4) Isolated Chicken Eye (ICE) assay. The revised analyses and revised list of proposed reference substances are available in an addendum to the draft Background Review Documents (BRDs) for the four methods (available at *http://iccvam.niehs.nih.gov/methods/ocudocs/reanalysis.htm*). A previous **Federal Register** notice solicited public comment on the revised analyses and revised list of proposed reference substances (Vol. 70, No. 142, pg. 43149, July 26, 2005). Comments submitted in response to the July 26, 2005 **Federal Register** notice will be considered at the expert panel meeting and do not need to be resubmitted. The public is invited to attend the teleconference and will be provided with an opportunity to make oral comments during the public comment period. Interested individuals can attend the meeting via a phone line or in person at the NIEHS campus (see **ADDRESSES** below). Participation is limited only by the number of phone lines available and by the number of available seats at the teleconference site. Additional meeting information may be obtained on the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov*) or by contacting NICEATM (see **ADDRESSES** below).

DATES: The expert panel meeting will be held via teleconference on Monday, September 19, 2005, beginning at 9 a.m. eastern daylight time (e.d.t.) and continuing until adjournment (approximately 12 p.m. e.d.t.).

Requests to attend the meeting via the telephone or in person must be received no later than September 12, 2005, to ensure access (see **ADDRESSES** below). We encourage all individuals who plan to attend this meeting to register online at the NICEATM Web site (*http://iccvam.niehs.nih.gov/*), but requests may also be submitted by e-mail, telephone, fax, or through hand delivery/courier (see **ADDRESSES** below).

Persons wishing to make oral comments during the teleconference must notify NICEATM no later than September 12, 2005 (see **ADDRESSES** below). In lieu of oral comments, individuals may provide written comments for distribution to the expert panel prior to the meeting. Written comments should be received by September 15, 2005, in order to enable consideration by the expert panel prior to the meeting.

Persons with disabilities, such as those who need sign language interpreters and/or other reasonable accommodation to participate in this meeting at NIEHS, are asked to notify NICEATM by September 8, 2005.

ADDRESSES: The teleconference will originate from Room 3162, 3rd Floor, NIEHS, 79 T.W. Alexander Drive, Bldg. 4401, Research Triangle Park, NC. A government-approved photo ID is required to access the meeting.

Correspondence should be sent by mail, fax, e-mail, or through hand delivery/courier to Dr. Raymond Tice at NICEATM, NIEHS, PO Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–4482, (fax) 919–541–0947, (e-mail) *niceatmcomments@niehs.nih.gov.* Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3129, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 2004, NICEATM released draft BRDs that provided information about the current validation status of the four *in vitro* test methods for detecting ocular corrosives and severe irritants (**Federal Register**, Vol. 69, No. 212, pp. 64081–64082, November 3, 2004). In conjunction with ICCVAM, NICEATM convened an expert panel meeting on January 11–12, 2005, to independently assess the validation status of the four *in vitro* test methods. The expert panel report and background information for this meeting are available at *http://iccvam.niehs.nih.gov/methods/eyeirrit.htm.* Public comments at the meeting indicated that additional data could be made available that had not been provided in response to earlier requests for data announced in the **Federal Register** in March (Vol. 69, No. 57, pp. 13859–13861, March 24, 2004) and November 2004). The expert panel recommended that NICEATM conduct a reanalysis of the accuracy and reliability of each test method that would include these data. In response to this recommendation, NICEATM published a notice in the **Federal Register** (Vol. 70, No. 38, pp. 9661–9662, February 28, 2005) requesting additional *in vitro* data on these four *in vitro* ocular irritancy test methods, corresponding *in vivo* rabbit eye test method data, as well as any human ocular exposure/injury data (either from ethical human studies or accidental exposure). Subsequently, NICEATM received additional *in vitro* and *in vivo* data that were used for the

revised accuracy and reliability analyses and considered in revising the list of proposed reference substances.

In preparation for this teleconference, NICEATM released the revised accuracy and reliability analyses and the revised list of proposed reference substances as an addendum to the draft BRDs and announced its availability in the July 26, 2006 **Federal Register** notice. Following the expert panel teleconference, a second expert panel report will be published and made available for public comment. ICCVAM will consider both expert panel reports, other relevant background materials, and all comments received from the public and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on this topic in finalizing ICCVAM recommendations for these test methods.

Opportunity for Public Comment

Public comments may be made on the revised accuracy and reliability analyses for BCOP, HET–CAM, ICE, and IRE and on the proposed list of reference substances. In lieu of oral comments, individuals may provide written comments for distribution to the expert panel prior to the meeting. Written comments should be received no later than September 15, 2005, to enable consideration by the expert panel prior to the meeting. Written comments received in response to the July 26, 2005 **Federal Register** notice announcing availability of the addendum to the draft BRDs do not need to be resubmitted. If written comments are submitted, appropriate contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable) should be included. Written comments will be posted on the NICEATM/ICCVAM Web site and made available to the expert panel and the ICCVAM. Persons wishing to make oral comments during the teleconference (one speaker per organization) must notify NICEATM by no later than September 12, 2005. Speakers will be assigned on a consecutive basis and comments will be limited to no more than four minutes per speaker. Due to logistical issues it may not be possible for persons who do not pre-register to make oral comments.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 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, and replace animal use. The ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the 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 Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: *http://www.iccvam.niehs.nih.gov.*

Dated: August 30, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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