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**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, Director of NICEATM, (phone) 919-541-2384, (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

On January 11 and 12, 2005, NICEATM and ICCVAM held an expert panel meeting to evaluate the validation status for four *in vitro* ocular test methods nominated by the EPA: (1) The Bovine Corneal Opacity and Permeability (BCOP) test; (2) the Hen's Egg Test—Chorion Allantoic Membrane (HET-CAM); (3) the Isolated Rabbit Eye (IRE) test; and (4) the Isolated Chicken Eye (ICE) test. At this meeting, the expert panel reviewed the Background Review Document (BRD) for each method and was asked to:

- Evaluate the extent and adequacy that each method's BRD addresses the applicable ICCVAM validation and acceptance criteria based on available information and data, or will address the criteria in proposed studies, focused on identifying ocular corrosives and severe irritants in a tiered testing strategy.

- Develop conclusions and recommendations on:
  - The current usefulness and limitations of each of the four test methods for identifying ocular corrosives and severe/irreversible irritants.
  - The test method protocol that should be used for future testing and validation studies.
  - The adequacy of proposed optimization and/or validation studies.
  - The adequacy of reference substances proposed for future validation studies.

The expert panel's conclusions and recommendations on the four test methods are described in "The ICCVAM Expert Panel Evaluation of the Current Validation Status of *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants".

Prior to the expert panel meeting, NICEATM issued several **Federal Register** notices to (1) request public comment on the EPA nomination of ocular toxicity test methods and related activities and request data on chemicals evaluated by *in vitro* or *in vivo* ocular irritancy test methods (**Federal Register**, Vol. 69, No. 57, pp. 13859-13861,

March 24, 2004, available at <http://iccvam.niehs.nih.gov/>); (2) request the nomination of scientific experts to serve on the expert panel (**Federal Register**, Vol. 69, No. 77, pg. 21565, April 21, 2004, available at <http://iccvam.niehs.nih.gov/>); and (3) request public comments on the BRDs prepared by NICEATM for each of the four test methods (**Federal Register**, Vol. 69, No. 212, pp. 64081-64082, November 3, 2004, and public comments are available at <http://iccvam.niehs.nih.gov/>).

**Request for Comments**

NICEATM invites the submission of written comments on the expert panel report. When submitting written comments please include appropriate contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable). All written comments received by the deadline listed above will be posted on the ICCVAM/NICEATM Web site and made available to ICCVAM.

ICCVAM will consider the expert panel report and any written public comments received on that report as it prepares final ICCVAM test method recommendations for the four *in vitro* ocular test methods. An ICCVAM test method evaluation report, which includes the ICCVAM recommendations, will be forwarded to appropriate Federal agencies for their consideration. This report also will be available to the public on the ICCVAM/NICEATM Web site and by request to NICEATM.

**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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Toxicology Program; National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of Expert Panel Report on the Evaluation of the Current Validation Status of *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants**

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Availability of report and request for comments.

**SUMMARY:** The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of a report entitled, "The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Expert Panel Evaluation of the Current Validation Status of *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants." The NICEATM invites public comment on the expert panel report. Copies of the expert panel report may be obtained on the ICCVAM/NICEATM Web site at <http://iccvam.niehs.nih.gov>, or by contacting NICEATM at the address given below.

**DATES:** Written comments and additional information should be received by noon on May 5, 2005.

**ADDRESSES:** Comments and additional information should be sent by mail, fax, or e-mail to Dr. William S. Stokes, Director of NICEATM, at NICEATM,

Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: <http://iccvam.niehs.nih.gov>.

Dated: March 9, 2005.

**Samuel Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

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