

animals for ocular safety testing. These evaluations included the following:

- A proposal for the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid and minimize pain and distress during in vivo ocular irritation testing.
- The in vivo low volume eye test (LVET).
- The use of the bovine corneal opacity and permeability (BCOP), the Cytosensor Microphysiometer® (CM), the isolated chicken eye (ICE), the isolated rabbit eye (IRE), and the hen's egg test—chorioallantoic membrane (HET-CAM) test methods for identifying moderate and mild ocular irritants and substances not labeled as ocular irritants.
- Nonanimal testing strategies that use the BCOP, CM, and/or EpiOcular™ (EO) test methods to assess the eye irritation potential of antimicrobial cleaning products to determine their appropriate U.S. Environmental Protection Agency ocular hazard classification.

The Panel report from this meeting is now available. The report contains (1) The Panel's evaluation of the validation status of the test methods and testing strategies and (2) the Panel's comments on the draft ICCVAM test method recommendations. NICEATM invites public comment on the Panel report. The report is available on the NICEATM-ICCVAM Web site at [http://iccvam.niehs.nih.gov/docs/ocutox\\_docs/OcularPRPrept2009.pdf](http://iccvam.niehs.nih.gov/docs/ocutox_docs/OcularPRPrept2009.pdf) or by contacting NICEATM at the address given below.

**DATES:** Written comments on the Panel report should be received by August 28, 2009.

**ADDRESSES:** NICEATM prefers that comments be submitted electronically by e-mail to [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Comments can also be submitted via the NICEATM-ICCVAM Web site at [http://iccvam.niehs.nih.gov/contact/FR\\_pubcomment.htm](http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm). Written comments can be sent by mail or fax to Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC 27709; (fax) 919-541-0947. Courier address: NIEHS, NICEATM, 530 Davis Drive, Room 2035, Durham, NC 27713.

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, (telephone) 919-541-2384, (fax) 919-541-0947 and (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

NICEATM announced the convening of an independent scientific peer review

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Independent Scientific Peer Review Panel Report: Evaluation of the Validation Status of Alternative Ocular Safety Testing Methods and Approaches: Notice of Availability and Request for Public Comments**

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

**ACTION:** Request for comments.

**SUMMARY:** NICEATM, in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), convened an independent international scientific peer review panel (hereafter, Panel) on May 19–21, 2009, to evaluate test methods and approaches with the potential to reduce and refine the use of

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panel to review and comment on the draft background review documents (BRDs) and summary review documents (SRDs) and draft recommendations, as well as the availability of the draft documents for public comment, in March 2009 (74 FR 14556). The Panel met in public session on May 19–21, 2009, at Consumer Product Safety Commission Headquarters in Bethesda, MD. The Panel reviewed the draft ICCVAM documents for completeness, errors, and omissions of any existing relevant data or information. The Panel then evaluated the information in the draft documents to determine the extent to which each of the applicable criteria for validation and acceptance of toxicological test methods (ICCVAM 2003) had been appropriately addressed. The Panel then considered the ICCVAM draft recommendations and commented on the extent that the recommendations were supported by the information provided in the draft BRDs or SRDs.

ICCVAM organized a 2005 symposium (70 FR 18037) on Minimizing Pain and Distress in Ocular Toxicity Testing where experts recommended that topical anesthetics and systemic analgesics should be routinely administered before *in vivo* ocular safety testing to avoid or minimize pain and distress that might occur during and after the initial application of test substances. The experts also recommended that systemic analgesics should routinely be administered when there are clinical signs indicative of pain or distress. The experts further recommended that humane endpoints to end a study early should be identified and used routinely. ICCVAM requested data (72 FR 26396), compiled available information on the use of topical anesthetics, systemic analgesics, and humane endpoints during *in vivo* ocular safety testing, and developed draft recommendations for implementing such practices.

In 2007, ICCVAM published (70 FR 66451) recommendations on the use of four *in vitro* test methods (BCOP, ICE, IRE, HET-CAM) for identifying ocular corrosives and severe irritants for hazard classification and labeling purposes. The ICCVAM recommendations were submitted to and accepted by ICCVAM member agencies (more information at [http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox/ocu\\_recommend.htm](http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox/ocu_recommend.htm)). One of the ICCVAM recommendations was to consider the validation status of these four *in vitro* ocular test methods for identifying mild and moderate ocular irritants and substances not classified as ocular irritants. NICEATM and ICCVAM requested data (72 FR 31582), compiled

available information, prepared draft BRDs assessing their current validation status for this purpose, and developed draft recommendations for their use.

In January 2008, a BRD titled, An *In Vitro* Approach for EPA Labeling of Anti-Microbial Cleaning Products, was submitted to NICEATM for review. This BRD, prepared by the Institute for *In Vitro* Sciences in collaboration with the Alternative Testing Working Group (comprised of seven consumer product companies [Clorox, Colgate Palmolive, Dial, EcoLabs, Johnson Diversey, Procter and Gamble, and SC Johnson]), proposes a testing strategy that uses the CM<sup>®</sup>, EpiOcular<sup>™</sup>, and BCOP test methods to assess the eye irritation potential of antimicrobial cleaning products and to determine appropriate EPA ocular hazard classification categories for such products. NICEATM and ICCVAM reviewed the BRD, requested additional data and information (73 FR 18535), and compiled draft recommendations and a draft ICCVAM SRD. ICCVAM also reviewed the validation status of the LVET, which is proposed as a reference test method to partially substantiate the validity of the *in vitro* test methods used in the test strategy.

#### Availability of the Peer Panel Report

The Panel's conclusions and recommendations are detailed in the Independent Scientific Peer Review Panel Report: Evaluation of the Validation Status of Alternative Ocular Safety Testing Methods and Approaches which is available along with the draft documents reviewed by the Panel and the draft ICCVAM test method recommendations at <http://iccvam.niehs.nih.gov/methods/ocutox/PeerPanel09.htm>.

#### Request for Public Comments

NICEATM invites the submission of written comments on the Panel report. When submitting written comments, please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). All comments received will be made publicly available via the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/methods/ocutox/PeerPanel09.htm>. ICCVAM will consider the Panel report along with public comments and comments made by the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) at their June 25–26, 2009 meeting (74 FR 19562) when finalizing test method recommendations. Final ICCVAM recommendations will be published in ICCVAM test method

evaluation reports, which will be forwarded to relevant Federal agencies for their consideration. The evaluation reports will also be available to the public on the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/methods/ocutox/ocutox.htm> and by request from NICEATM (see **ADDRESSES** above).

#### Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate 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 (42 U.S.C. 2851–3) 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 on their Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (67 FR 11358). SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the 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/> see "Advisory Board & Committees" (or directly at <http://ntp.niehs.nih.gov/go/167>).

#### Reference

ICCVAM. 2003. ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods. NIH Publication No. 03–4508. Research Triangle Park, NC: NIEHS. Available at: <http://iccvam.niehs.nih.gov>.

Dated: July 3, 2009.

**John R. Bucher,**

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