

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), National Toxicology Program (NTP); Request for Nominations of Scientific Experts for Independent Expert Panel Evaluations and/or other Reviews of In Vitro Testing Methods for Identifying Potential Ocular Irritants****Summary**

The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is seeking nominations of scientific experts to evaluate the validation status of in vitro test methods for determining the potential ocular irritancy of chemicals and other substances. The experts will serve on future independent expert panel(s) or participate at other similar meetings and provide input on the usefulness, limitations, accuracy, and reliability of test methods proposed for identifying whether and to what extent substances may cause reversible or irreversible eye damage. The initial review activity will evaluate test methods that may be used to identify severe irreversible ocular irritation/corrosion. Applicable test methods anticipated for review include, but are not limited to: (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. Details about future meetings to evaluate the validation status of in vitro ocular toxicity test methods, including the date, location and availability of background documents, will be announced in the **Federal Register** and posted on the ICCVAM/NICEATM website (<http://iccvam.niehs.nih.gov>).

Request for Nominations of Experts

NICEATM invites nominations of scientists with relevant knowledge and experience that can serve on independent expert panels or participate at other similar meetings to evaluate in vitro ocular toxicity test methods. Areas of relevant expertise include, but are not limited to: human and animal ophthalmology, with an emphasis on evaluation and treatment of chemical injuries; in vivo ocular toxicity testing; in vitro ocular

toxicology (particularly experience with BCOP, IRE, ICE, and/or HET-CAM); test method validation; and biostatistics. Each nomination should include the person's name, affiliation, contact information (*i.e.*, mailing address, e-mail address, telephone and fax numbers), a brief summary of relevant experience and qualifications, and curriculum vitae, if possible. Nominations should be sent to NICEATM by mail, fax, or e-mail within 45 days of the publication date of this notice. Correspondence should be directed to Dr. William Stokes, Director, NICEATM, NIEHS, 79 T.W. Alexander Dr., MD EC-17, P.O. Box 12233, Research Triangle Park, NC 27709; telephone: 919-541-2384; fax: 919-541-0947; e-mail: iccvam@niehs.nih.gov.

SUPPLEMENTARY INFORMATION: In August 2003, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) recommended that ICCVAM evaluate certain in vitro test methods for ocular toxicity that could be used to identify substances that cause irreversible ocular damage. The SACATM recommended that NICEATM and ICCVAM prepare a background review document and convene a workshop or other appropriate review activity. In October 2003, EPA submitted a nomination to ICCVAM that included a request to: (1) Review the validation status of four in vitro ocular test methods with the potential to screen chemicals for severe eye irritation or corrosion (BCOP, IRE, ICE, HET-CAM); (2) review the state of the science for other in vitro methods for assessing moderate or mild eye irritation; (3) obtain good quality in vivo eye irritation/corrosion reference data; and (4) to review ways to alleviate pain and suffering which might arise from current in vivo eye irritation testing. ICCVAM endorsed this nomination as a high priority. NICEATM published a **Federal Register** notice on March 24, 2004 (Vol. 69, No. 57, pages 13959-13861) inviting public comment on the nomination and related activities.

NICEATM is preparing Background Review Documents on in vitro ocular test methods that will contain comprehensive summaries of available data, an analysis of the accuracy and reliability of available test method protocols, and related information characterizing the current validation status of these assays. NICEATM requested data on ocular irritancy for chemicals tested using in vivo and in vitro test methods in the March 24 **Federal Register** notice. Applicable data received in response to this notice will

be included in the Background Review Documents and used to assess the performance of in vitro ocular toxicity test methods. Conclusions and recommendations from independent evaluations will be made publicly available and considered by ICCVAM in developing its recommendations on in vitro ocular toxicity test methods. ICCVAM recommendations will address the usefulness and limitations of the test methods for regulatory testing purposes and may include recommended standardized protocols, performance standards, and reference chemicals for future validation studies.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information. ICCVAM promotes the development, validation, regulatory acceptance, and national and international harmonization of toxicological test methods that more accurately assess the safety or hazards of chemicals and products; and test methods 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>) established ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific support for ICCVAM and 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://iccvam.niehs.nih.gov>.

Dated: April 9, 2004.

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[FR Doc. 04-9032 Filed 4-20-04; 8:45 am]

BILLING CODE 4140-01-P