DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH) Notice of an Expert Panel Meeting To Assess the Current Validation Status of In Vitro Testing Methods for Identifying Potential Ocular Irritants; Request for Comments

Summary

Notice is hereby given of a meeting sponsored by the NIEHS and the National Toxicology Program (NTP), and organized by 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). At this meeting, an expert panel (''Panel'') will assess the current validation status and develop recommendations for further validation of in vitro test methods proposed for identifying substances that may cause serious eye damage. The meeting will take place on January 11–12, 2005, from 8:30 a.m. to 5 p.m., at the National Institutes of Health (NIH), Natcher Center, Bethesda, MD. The meeting is open to the public with attendance limited only by the space available.

Evaluation of In Vitro Ocular Test Methods Background

In August 2003, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) recommended that ICCVAM review the validation status of screening test methods that could be used to identify severe and irreversible ocular effects and carry out appropriate reviews of these test methods. In October 2003, the U.S. Environmental Protection Agency nominated several ocular-related activities to ICCVAM including evaluation of the validation status of four in vitro ocular toxicity test methods for screening for severe/irreversible ocular effects: (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. ICCVAM endorsed the review of the methods as a high priority and recommended that Background Review Documents be developed for each method by NICEATM in collaboration with the ICCVAM Ocular Toxicity Working Group. ICCVAM also

recommended that an expert panel be convened to independently review the validation status of these methods and the proposed, standardized, test method protocols.

A request for public comment on the nomination of these and other ocular toxicity test methods and related activities and a request for data on chemicals evaluated by in vitro or in vivo ocular irritancy test methods was previously published in the **Federal Register** (Vol. 69, No. 57, pp. 13859–13861, March 24, 2004, available at *http://iccvam.niehs.nih.gov/*). Additionally, NICEATM solicited the nomination of scientific experts for independent expert panel evaluations and/or reviews of in vitro testing methods for identifying potential ocular irritants through the **Federal Register** (Vol. 69, No. 77, pg. 21565, April 21, 2004, available at *http://iccvam.niehs.nih.gov/*). This notice also announced that ICCVAM and NICEATM would coordinate an expert panel meeting to evaluate in vitro ocular test methods for their ability to detect severe and irreversible ocular irritants. No additional methods for identifying severe/irreversible ocular effects other than the four named above were identified in response to the **Federal Register** notices.

NICEATM has prepared Background Review Documents (BRDs) on the four test methods nominated by the EPA (BCOP, HET-CAM, IRE and ICE). Each of the BRDs contains comprehensive summaries of available data, analyses of the accuracy and reliability of the available test method protocols, and related information characterizing the current validation status of these assays. At this meeting, the Panel will review each of the four BRDs and develop conclusions and recommendations on the following:

- The current usefulness and limitations of the test methods for identifying severe/irreversible ocular irritants and corrosives.
- The adequacy of the specific protocols recommended for future validation and testing studies.
- The adequacy of recommended test method validation studies.
- The adequacy and appropriateness of substances recommended for future validation studies.

Agenda

The public meeting will take place January 11–12, 2005, at the NIH Campus, Natcher Center, Bethesda, MD (a map of the NIH Campus and other visitor information are available at *http://www.nih.gov/about/visitor/index.htm*). The meeting will begin at 8:30 a.m. each day and conclude at approximately 5 p.m. A preliminary agenda is given below. A detailed agenda and roster of the expert panel members will be available two weeks prior to the meeting on the ICCVAM/NICETATM Web site (*http://iccvam.niehs.nih.gov*) or by contacting NICEATM (contact information below). Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NICEATM at least seven business days in advance of the meeting.

On the morning of January 11th, there will be a brief orientation on ICCVAM and the ICCVAM test method review process, followed by the Panel's evaluation of the BRDs for the ICE and BCOP assays. It is anticipated that review of the HET–CAM assay will continue on the morning of January 12th after which the review of the BRD for the IRE assay will take place. The Panel will evaluate the current status of each of the four different types of in vitro assays and develop recommendations regarding their future validation and use.

Availability of Background Review Documents

NICEATM has prepared four BRDs, one for each of the assays being evaluated. Copies of each BRD can be obtained on the ICCVAM/NICEATM Web site at *http://iccvam.niehs.nih.gov,* or by contacting NICEATM, NIEHS, PO Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–3398, (fax) 919–541–0947, (email) *iccvam@niehs.nih.gov.*

Request for Comments

NICEATM invites the submission of written comments on each of the BRDs. When submitting written comments please include appropriate contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable). Written comments and additional information should be sent by mail, fax, or email to Dr. William Stokes, Director of NICEATM, at the address listed above not later than December 30, 2004. Written comments will be placed on the ICCVAM/NICEATM website and made available to the Panel, ICCVAM agency representatives and experts, and attendees at the meeting.

The meeting is open to the public and time will be provided for the presentation of public oral comments at designated times during the peer review. Members of the public who wish to present oral statements at the meeting (one speaker per organization) should contact NICEATM (at the address above) no later than noon on January 5, 2005. Speakers will be assigned on a consecutive basis and up to seven minutes will be allotted per speaker. Persons registering to make comments are asked to provide a written copy of their statement by January 5th, so that copies can be distributed to the Panel prior to the meeting or if this is not possible to bring 40 copies to the meeting. Written statements can supplement and expand the oral presentation. Each speaker is asked to provide contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable) when registering to make oral comments.

Summary minutes and a final report of the Panel will be available following the meeting at the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov*).

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee charged with the technical review and evaluation of new, revised, and alternative test methods applicable for specific regulatory uses. The committee is composed of representatives from 15 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 that refine, reduce, or 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: October 21, 2004.

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