(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 25, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

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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); Availability of a Second Expert Panel Request 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), DHHS.

ACTION: Report availability and request for comments.

SUMMARY: NICEATM announces availability of the report ''The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Expert Panel Evaluation of the draft Background Review Document Addendum for In Vitro Test Methods For Identifying Ocular Corrosives And Severe Irritants.'' 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: Comments should be sent by mail, fax, or e-mail to the address given below by December 2, 2005.

FOR FURTHER INFORMATION CONTACT: Dr. Raymond Tice at NICEATM, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–4482, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov*.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 2004, NICEATM released draft background review documents (BRDs) that provided information about the current validation status of 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 from the January 2005 meeting (''first expert panel report'') was released in March 2005 and is 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 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.

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 **Federal Register** (Vol. 70, No. 142, pg. 43149, July 26, 2005). NICEATM subsequently announced a second meeting of an expert panel by teleconference on September 19, 2005 in the **Federal Register** (Vol. 70, No. 174, pg. 53676, September 9, 2005). The second expert panel report is a product of the teleconference meeting and is being made available for public comment. ICCVAM will consider the first and second 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 test method recommendations for these methods.

Request for Comments

NICEATM invites the submission of written comments on the second expert panel report. When submitting written comments please include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail 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 agency representatives for their consideration prior to the development of final ICCVAM recommendations on these test methods.

An ICCVAM test method evaluation report, which includes the ICCVAM test method 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 fifteen Federal regulatory and research agencies that use or gerate 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/PLI06545.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: October 25, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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