Dated: March 11, 2005.

Cassandra Isom,

Program Administrator, Office of Science Education, National Institutes of Health.

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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); Request for Data on Non-Animal Methods and Approaches for Determining Skin and Eye Irritation Potential of Antimicrobial Cleaning Product Formulations; Request for Nominations for an Independent Expert Panel

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

ACTION: Request for data and nomination of panelists.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM are requesting the submission of data that would assist in evaluating the validation status of non-animal methods and approaches used for determining the skin and eye irritation potential of antimicrobial cleaning product formulations to meet regulatory hazard classification and labeling purposes. Additionally, NICEATM is also requesting the nomination of scientists for consideration as potential members of an independent scientific expert panel (''Panel'') to evaluate the proposed methods and approaches. The ICCVAM will consider the conclusions and recommendations from the Panel in developing its recommendations on the validation status of these methods.

DATES: Nominations and data should be received by noon on May 5, 2005.

ADDRESSES: Nominations and data should be sent by mail, fax, or email to Dr. William S. Stokes, Director of NICEATM at NICEATM, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.* Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director of NICEATM, (phone) 919–541–2384, (fax) 919–541–0947, (email) *niceatm@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

In June 2004, the Environmental Protection Agency (EPA) asked ICCVAM to evaluate the validation status of proposed non-animal approaches for determining the skin and eye irritation potential of antimicrobial cleaning product formulations for meeting regulatory hazard classification and labeling requirements. ICCVAM considered the EPA's request and recommended that the evaluation of these non-animal approaches proceed as a high priority. ICCVAM agreed to work with the EPA and representatives of its Pesticide Program Dialogue Committee (PPDC) to help assure that the submission provided to ICCVAM contains all relevant information, data, and appropriate analyses as described in the ''ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods'' (NIH publication 03–4508). The NICEATM on behalf of ICCVAM plans to convene an independent scientific expert panel to review the submission, develop conclusions on the validation status of these methods, and make recommendations about the usefulness and limitations of these methods for their intended purpose. The date for the expert panel meeting has not been determined but will be announced in a future **Federal Register** notice.

Request for Data

Data, the nomination of experts, and other information submitted in response to this notice should be sent to NICEATM at the address given above. Data received by the deadline will be made available on the ICCVAM/NICEATM Web site at *http://iccvam.niehs.nih.gov* and considered by the Panel and ICCVAM.

When submitting data or information on protocols, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable). NICEATM prefers the submission of raw untransformed data in addition to any summary data including the submission of copies of pages from applicable study notebooks and/or study reports, if available. *In vivo* and *in vitro* data for each substance are preferred. Post-marketing surveillance data, ethical human studies, and accidental exposure reports also are sought when available and applicable. Each submission for a chemical or product should preferably include the following information when available:

- Common and trade name.
- Chemical Abstracts Service Registry Number (CASRN) for each ingredient of a formulation, and the percent composition of each ingredient.
- Chemical structure.
- Chemical class.
- Product class.
- Commercial source.
- Test protocol used for either *in vivo* or *in vitro* testing.
- The extent to which the study complies with national/international Good Laboratory Practice (GLP) guidelines.
- Date and testing organization.

Request for the Nomination of Scientists for the Expert Panel

NICEATM invites the nomination of scientists with relevant knowledge and experience that can serve on the Panel to evaluate *in vitro* dermal and ocular toxicity test methods. Areas of relevant expertise include, but are not limited to: human and animal dermatotoxicology/ophthalmology with an emphasis on evaluation and treatment of chemical injuries, *in vivo* dermal/ocular toxicity testing, *in vitro* dermal/ocular toxicology, 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. NICEATM and ICCVAM will also consider nominations previously submitted in response to a request for scientific experts for the evaluation of *in vitro* ocular test methods (**Federal Register**, Vol. 69, No. 57, pp. 13859–13861, March 24, 2004, available at *http://iccvam.niehs.nih.gov/)* and do not need to be resubmitted.

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, or 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 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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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, NIEHS, P. O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.* Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director of NICEATM, (phone) 919–541–2384, (e-mail) *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