

irritation, such as the Bovine Corneal Opacity and Permeability (BCOP) test, the Cytosensor Microphysiometer (CM) test, and the EpiOcular test, and data supporting the accuracy and reproducibility of these methods.

DATES: Submit nominations and data by May 19, 2008. Data submitted after this date will be considered in the evaluation, if feasible.

ADDRESSES: Submit nominations and data to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC-17, Research Triangle Park, NC, 27709, (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. Responses can also be submitted electronically via the ICCVAM-NICEATM Web site (http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm).

FOR FURTHER INFORMATION CONTACT:

Other correspondence should be directed to Dr. William S. Stokes (919-541-2384 or niceatm@niehs.nih.gov).

SUPPLEMENTARY INFORMATION:

Background

In June 2004, the EPA Office of Pesticide Programs informed NICEATM that they were developing, via a subgroup of the Pesticide Program Dialogue Committee, a non-animal assessment approach for evaluating eye irritation potential and labeling requirements for AMCPs. Subsequently, the EPA in collaboration with the Alternative Testing Working Group (ATWG) developed a non-animal approach for this limited group of products. The ATWG is comprised of seven consumer product companies (Clorox, Colgate Palmolive, Dial, EcoLabs, Johnson Diversey, Procter & Gamble, and SC Johnson). The Institute for *In Vitro* Sciences, Inc. (IIVS), which coordinated the EPA-ATWG collaboration, performed additional testing to complete parallel sets of *in vivo* and *in vitro* data, and prepared a background review document (BRD) describing the final approach. More information concerning this submission is available at: <http://iccvam.niehs.nih.gov/methods/ocutox/AMCP.htm>.

In January 2008, IIVS submitted the BRD, *An In Vitro Approach for EPA Toxicity Labeling of Anti-Microbial Cleaning Products*, to NICEATM. The EPA and the ATWG requested that NICEATM and ICCVAM use information within the BRD to conduct a technical review of the proposed approach to determine whether ICCVAM could assure the EPA, with a

reasonable degree of certainty, that the approach would be useful for making labeling decisions for AMCPs that appropriately inform the user.

NICEATM and ICCVAM are now conducting a preliminary evaluation of the submission to determine its completeness and adherence to ICCVAM guidelines, which are available at http://iccvam.niehs.nih.gov/SuppDocs/SubGuidelines/SD_subg034508.pdf. If they decide to move forward with an evaluation, NICEATM and ICCVAM will convene an independent peer review panel to review the validation status of the proposed approach.

Request for Nominations of Scientific Experts

NICEATM requests nominations of scientists with relevant knowledge and experience to serve on the peer review panel should it be convened. Areas of relevant expertise include, but are not limited to:

- Biostatistics
- Human and veterinary

ophthalmology, with an emphasis on evaluation and treatment of chemical injuries

- *In vivo* ocular toxicity testing
- *In vitro* ocular toxicology
- Test method validation

Each nomination should include the nominee's name, affiliation, contact information (i.e., mailing address, e-mail address, telephone and fax numbers), curriculum vitae, and a brief summary of relevant experience and qualifications. Nominations previously submitted to NICEATM in response to an earlier request for scientific experts for a possible peer panel review of *in vitro* ocular test methods used to evaluate AMCPs (**Federal Register** Vol. 70, No. 53, pp. 13512-13513, available at <http://iccvam.niehs.nih.gov>) do not need to be resubmitted.

Request for Data

NICEATM invites the submission of relevant data and information on AMCPs or related substances obtained from (1) human testing or experience including reports from accidental exposures, (2) rabbits using the standard eye test or the low volume eye test (LVET), and (3) *in vitro* test methods for assessing ocular irritation, such as the Bovine Corneal Opacity and Permeability (BCOP) test, the Cytosensor Microphysiometer (CM) test, and the EpiOcular test, including data supporting the accuracy and reproducibility of these methods.

Although data can be accepted at any time, data received by May 19, 2008 will be considered during the ICCVAM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Non-Animal Methods and Approach for Evaluating Eye Irritation Potential for Antimicrobial Cleaning Products (AMCPs): Request for Nominations for an Independent Expert Panel and Submission of Relevant Data

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

ACTION: Request nominations for an independent expert panel and submission of relevant data.

SUMMARY: At the request of the U.S. Environmental Protection Agency (EPA), the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is planning to assess the validation status of a proposed non-animal approach for evaluating the eye irritation potential of AMCPs that meets hazard classification and labeling requirements. On behalf of ICCVAM, NICEATM requests:

1. Nominations of expert scientists to serve as members of an independent peer review panel.
2. Submission of relevant data and information on AMCPs or related substances obtained from (1) human testing or experience including reports from accidental exposures, (2) rabbits using the standard eye test or the low volume eye test (LVET), and (3) *in vitro* test methods for assessing ocular

evaluation process. Relevant data received after this date will be considered during the ICCVAM evaluation process, if feasible. All information submitted in response to this notice will be made publicly available and may be incorporated into future NICEATM and ICCVAM reports and publications as appropriate.

When submitting data, 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 that data be submitted as copies of pages from study notebooks and/or study reports, if available. Raw data and analyses available in electronic format may also be submitted. Each submission for a substance should preferably include the following information, as appropriate:

- Common and trade name
- Chemical Abstracts Service Registry Number (CASRN)
- Chemical and/or product class
- Commercial source
- *In vivo* or *in vitro* test protocol used
- Individual animal or *in vitro* responses at each observation time (i.e., raw data)
- The extent to which the study complied with national/international Good Laboratory Practice (GLP) guidelines
- Date and testing organization
- Physical and chemical properties (e.g. molecular weight, pH, water solubility, etc.)

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 (42 U.S.C. 2851–3, available at (http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf) 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 Federal agencies. Additional

information about ICCVAM and NICEATM is available on the following Web site: <http://iccvam.niehs.nih.gov>.

Dated: March 24, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

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