DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Request for Ocular Irritancy Test Data From Human, Rabbit, and In Vitro Studies Using Standardized Testing Methods

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

ACTION: Request for submission of relevant data.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM are collaborating with the European Centre for the Validation of Alternative Methods (ECVAM) to evaluate the validation status of *in vitro* test methods for assessing the ocular irritation potential of substances. On behalf of the ICCVAM, NICEATM requests data on substances tested for ocular irritancy in humans, rabbits, and/or in vitro. These data will be used to: (1) Review the state-of-the-science in regard to the availability of accurate and reliable *in vitro* test methods for assessing the range of potential ocular irritation activity, including whether ocular damage is reversible or not and (2) expand NICEATM's high-quality ocular toxicity database. *In vitro* test methods for which data are sought include, but are not limited to: (1) The Bovine Corneal Opacity and Permeability (BCOP) test, (2) the Isolated Rabbit Eye (IRE) test, (3) the Isolated Chicken Eye (ICE) test, and (4) the Hen's Egg Test—Chorioallantoic Membrane (HET–CAM).

DATES: Data should be received by July 23, 2007. Data received after this date will be considered as feasible.

ADDRESSES: 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 be submitted electronically at the ICCVAM–NICEATM Web site: *http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm* or by e-mail, mail, or fax.

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 October 2003, the U.S. Environmental Protection Agency (EPA) submitted to ICCVAM a nomination with several activities related to reducing, replacing, and refining the use of rabbits in the current *in vivo* eye irritation test method (**Federal Register** Vol. 69, No. 57, pp 13859–13861, March 24, 2004). In response to this nomination, ICCVAM completed an evaluation of the validation status of the BCOP, ICE, IRE, and HET–CAM test methods for identifying severe (irreversible) ocular irritants/corrosives using the United Nations Globally

Harmonized System of Classification and Labeling of Chemicals (GHS), the EPA, and the European Union hazard classification systems. NICEATM and ICCVAM prepared a comprehensive background review document (BRD) on each of the four *in vitro* test methods. Each BRD included an analysis of test method performance (i.e., reliability and relevance) as compared to the *in vivo* rabbit eye reference test method, based on all available data. ICCVAM developed recommendations on the usefulness and limitations of these *in vitro* test methods for identifying ocular corrosives/severe irritants after considering the BRDs, comments received from the public and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), and comments and recommendations received from an independent expert panel (**Federal Register** Vol. 70, No. 53, pp 13513–13514, March 21, 2005 and Vol. 70, No. 211, p 66451, November 2, 2005).

ICCVAM is now reviewing the validation status of these and other *in vitro* test methods for identifying nonsevere ocular irritants (i.e., those that induce reversible ocular damage) and non-irritants.

Request for Data

As part of the review process, NICEATM requests the submission of data from substances tested for ocular irritancy in humans, rabbits, and/or *in vitro*. Data received by July 23, 2007 will be compiled and added to the database maintained by NICEATM and utilized where appropriate in the evaluation of *in vitro* ocular irritation test methods. Data received after this date will also be considered and used where applicable for future evaluation activities. All information submitted in response to this notice will be made publicly available upon request to NICEATM.

When submitting substance and protocol information/test 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 data to 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 vitro* test protocol used.
- Rabbit eye test protocol used.
- Human eye test protocol used.
- Individual animal/human 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.

Additional information on the submission of data may be obtained at *http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox.htm.*

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 (42 U.S.C. 285l–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 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 is available on the following Web site: *http://iccvam.niehs.nih.gov.*

Dated: May 25, 2007.

Samuel H. Wilson,

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

[FR Doc. E7–10966 Filed 6–6–07; 8:45 am]

BILLING CODE 4140–01–P