
DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Toxicology Program (NTP), NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Request for Data on the Use of Topical Anesthetics and Systemic Analgesics for In Vivo Eye Irritation Testing**

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

ACTION: Request for data on the use of topical anesthetics and systemic analgesics for in vivo ocular irritation testing.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM request the submission of data and information on the use of topical anesthetics and systemic analgesics for alleviating pain and distress in rabbits during eye irritation testing. They also request the submission of information about other procedures and strategies that may reduce or eliminate pain and distress associated with *in vivo* eye irritation methods.

DATES: Data should be received by June 25, 2007.

ADDRESSES: Data should be sent by mail, fax, or e-mail to Dr. William S. Stokes, Director, NICEATM, 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.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, NICEATM Director, (phone) 919-541-2384 or niceatm@niehs.nih.gov.

SUPPLEMENTARY INFORMATION**Background**

The U.S. Environmental Protection Agency (EPA) nominated to ICCVAM several activities relevant to reducing, replacing, or refining the use of rabbits in the current *in vivo* eye irritation test method (**Federal Register** Vol. 69, No. 57, pages 13859-13861, March 24,

2004). One activity is to review ways to alleviate pain and suffering that might arise from current *in vivo* eye irritation testing. ICCVAM endorsed this activity with a high priority and recommended that NICEATM review the data currently available on the use of topical anesthetics and/or systemic analgesics to reduce animal pain and distress.

As part of this review, NICEATM requests the submission of data from completed studies on the use of topical anesthetics and/or systemic analgesics for *in vivo* ocular irritancy testing. These data will be used to evaluate the validation status of the use of topical anesthetics and/or analgesics to reduce pain and distress for *in vivo* testing situations. ICCVAM and NICEATM also request the submission of information and data from *in vivo* methods, procedures, and/or strategies that may reduce or eliminate the pain and suffering associated with current *in vivo* eye irritation methods.

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) 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. Additional information about NICEATM and ICCVAM can be found at the following Web site: <http://iccvam.niehs.nih.gov>.

Dated: April 30, 2007.

Samuel H. Wilson,

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

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