DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 2, 2011

RADM William S. Stokes
Director
NICEATM
National Toxicology Program
PO Box 12233, EC-17
Research Triangle Park, NC 27709

Dear Dr. Stokes:

The US Food and Drug Administration (FDA) has reviewed the following ICCVAM test method validation reports. These were sent to the FDA in a letter dated September 7, 2010, from Dr. Linda Birnbaum, Director of NIEHS. FDA has the following comments:

1. ICCVAM Test Method Evaluation Report: "**Recommendations for Routine Use of Topical Anesthetics, Systemic Analgesics, and Humane Endpoints to Avoid or Minimize Pain and Distress in Ocular Safety Testing**"

   FDA no longer requires Draize ocular irritation/corrosion tests for regulatory approval of FDA-test articles. However, in principle, FDA supports the use of topical anesthetics or systemic analgesics, if use of these products does not compromise the validity of the test results.

2. ICCVAM Test Method Evaluation Report: "**Current Validation Status of *In Vitro* Test Methods Proposed for Identifying Eye Injury Hazard Potential of Chemicals and Products**"

   FDA does not require the Draize test for regulatory testing of FDA test articles. Although not required, FDA would consider the BCOP assay as an acceptable screen for severe ocular irritation/corrosion for ocular or dermal products.

3. ICCVAM Test Method Evaluation Report: "**Current Validation Status of a Proposed *In Vitro* Testing Strategy for U.S Environmental Protection Agency Ocular Hazard Classification and Labeling of Antimicrobial Cleaning Products**"

   This testing strategy is targeted for use by the Environmental Protection Agency. FDA has no comments on the strategy.

4. ICCVAM Test Method Evaluation Report: "**Recommendation to Discontinue Use of the Low Volume Eye Test for Ocular Safety Testing**"

   Since FDA does not require the Draize test, it does not anticipate seeing the LVET assay for prospective ocular safety testing. FDA has no comment on whether retrospective LVET data could be used in a weight-of-evidence approach to classify ocular hazards provided that the validity of each type of evidence used for such assessments is adequately characterized.

Since, FDA does not require Draize testing for ocular hazard testing, FDA has no plans to modify any of its guidance as a result of these ICCVAM recommendations.

Each of FDA's six product centers regulates products unique to that center. Therefore, each center is responsible for the regulatory requirements for the products it oversees. FDA strongly encourages any sponsor of an FDA-regulated product to meet with FDA if contemplating the use of alternative test methods as part of its regulatory strategy.

If you need further information, please contact Suzanne Fitzpatrick at 301-796-8527.

/s/

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Chief Scientist and Deputy Commissioner for
Science and Public Health