

**ICCVAM Workshop Series on
Best Practices for Regulatory Safety Testing:
Assessing the Potential for Chemically Induced Eye Injuries**

January 19, 2011

William H. Natcher Conference Center - Bethesda, Maryland

- 7:30-8:30** **Registration and Poster Setup**
- 8:30-8:50** **Introduction and Public Health Impact of Chemically Induced Eye Injuries**
RADM William Stokes, DVM, U.S. Public Health Service, NICEATM, National Institute of Environmental Health Sciences
- 8:50-9:20** **Review of Alternative Test Methods and Integrated Strategies for Ocular Safety Assessments**
Jill Merrill, PhD, Center for Drug Evaluation and Research, FDA
- 9:20-9:40** **Study Director and IACUC Responsibilities: Consideration of Available Reduction, Refinement, and Replacement Alternative Test Methods (USDA)**
Jodie Kulpa-Eddy, DVM, Animal and Plant Health Inspection Service, USDA
- 9:40-10:00** **Current Guidelines for Ocular Safety Testing**
Deborah McCall, Office of Pesticide Programs, EPA
- 10:00-10:20** **BREAK – Posters available for viewing, rooms C1/C2 and G1/G2**
- 10:20-10:45** **ICCVAM Evaluation and Recommendations on Best Practices for Incorporating Pain Management and Humane Endpoints in Ocular Safety Testing**
RADM William Stokes, DVM, USPHS, NICEATM, NIEHS
- 10:45-11:00** **The Bovine Corneal Opacity and Permeability (BCOP) Test Method: Validation Status**
Elizabeth Lipscomb, PhD, ILS, Inc., Contractor Supporting NICEATM
- 11:00-11:25** **Conducting and Interpreting the BCOP Test Method**
Hans Raabe, Institute for In Vitro Sciences, Inc.
- 11:25-12:00** **The Isolated Chicken Eye Test Method: Validation Status/Conducting and Interpreting the Method**
David Allen, PhD, ILS, Inc., Contractor Supporting NICEATM
- 12:00-1:00** **LUNCH – Posters available for viewing, rooms C1/C2 and G1/G2**

1:00-1:15 The Cytosensor Microphysiometer (CM) Test Method: Validation Status

Elizabeth Lipscomb, PhD, ILS, Inc., Contractor Supporting NICEATM

1:15-1:45 Conducting and Interpreting the CM Test Method

Rodger Curren, PhD, Institute for In Vitro Sciences, Inc.

**1:45-2:30 Roundtable Discussion:
Regulatory Agency Requirements and Acceptable Alternative Test
Methods for Ocular Safety Assessments**

Moderator: RADM William Stokes, DVM, USPHS, NICEATM, NIEHS

- **Environmental Protection Agency**
Jack Fowle, PhD
- **Food and Drug Administration**
Suzanne Fitzpatrick, PhD
- **Consumer Product Safety Commission**
Joanna Matheson, PhD
- **Occupational Safety and Health Administration**
Surender Ahir, PhD

Roundtable Discussion

Question-and-Answer Session for Workshop Participants

2:30-3:00 BREAK – Posters available for viewing, rooms C1/C2 and G1/G2

**3:00-4:00 Alternative Test Methods for Ocular Safety Testing:
Case Studies in Breakout Groups**

Moderators:

Deborah McCall, OPP, EPA

Jill Merrill, PhD, CDER, FDA

John Redden, OPP, EPA

Neil Wilcox, DVM, Center for Food Safety and Nutrition, FDA

4:00-4:25 Case Study Results — Question-and-Answer Session

Moderators:

Jodie Kulpa-Eddy, DVM, APHIS, USDA

Jill Merrill, PhD, CDER, FDA

4:25-4:55 New Models in the Validation Pipeline for Ocular Safety Testing

4:25-4:40 *Jill Merrill, PhD, CDER, FDA*

4:40-4:55 *Hitoshi Sakaguchi, PhD, Kao Corporation*

4:55-5:00 Closing Remarks

5:00 Adjournment