

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

Workshop Goals and Objectives

The primary objective of this workshop is to assist participants in gaining a practical understanding of the theory and application of available alternative methods for evaluating the potential for chemically induced eye injuries that can also minimize animal use and avoid pain and distress.

The specific goals of the workshop are to:

- 1) Provide an overview of the available methods, including the applications, strengths and weaknesses of each method.
- 2) Provide information on the procedures for conducting and interpreting data in accordance with regulatory testing requirements and guidelines.
- 3) Allow an opportunity to become familiar with data generated by each test method.
- 4) Provide a forum for scientists to share information on the appropriate use of results in regulatory safety testing.
- 5) Discuss challenges of incorporating alternative test methods into regulatory safety testing guidelines.
- 6) Identify and discuss new methods in the development and validation pipeline for each safety testing area, and ways to increase the availability of high quality data necessary for validating new methods.

Background

Each year, approximately 2 million eye injuries occur in the U.S., of which more than 40,000 result in permanent visual impairment. Data on consumer product-related eye injuries indicate that the products causing the most eye injuries in children under the age of 10 are household cleaners and other chemical products. To protect workers and consumers, regulatory agencies require testing to determine if chemicals and products may cause eye injuries, and these tests represent one of the four most commonly conducted product safety tests. Testing results are used to classify the ocular hazard and determine appropriate labeling to warn consumers and workers of the potential hazard for temporary or permanent eye injuries from chemicals and products.

The U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals and the U.S. Department of Agriculture's Animal Welfare Act Regulations¹ require that alternatives to procedures that can cause more than slight or momentary pain or distress be considered and used where available. This workshop will create awareness of available alternatives that should be considered prior to using animals, and provide information about the usefulness and limitations of these test methods that can be used to determine when their

¹ 7 U.S.C. Sections 2131-2159

use is appropriate. Use of these methods is expected to reduce the number of animals required to identify substances with the potential to cause chemically induced eye injuries. In those instances where it is necessary to conduct *in vivo* testing, this workshop will highlight the pain management procedures that the safety community may use to minimize or eliminate pain and distress in those animals required for such testing.

The development, validation, and application of new safety testing methods for ocular hazard identification and risk assessment remains an important priority for stakeholders that produce products requiring such data and for regulators that are responsible for protecting public health. Substantial progress has been made in recent years towards the development, validation, and regulatory acceptance of alternative test methods that reduce, refine (decrease or eliminate pain and distress), and replace the use of animals for ocular safety assessments.

While toxicologists recognize the utility and strengths of these new approaches, many are unfamiliar with the specific techniques. Before a new test method is implemented, the safety community must understand the method, as well as the manner in which agencies expect the method to be conducted and data interpreted. Users and regulatory agency staff need to become familiar with the technical procedures required to conduct the new method, and to understand the method's usefulness and limitations. Consequently, there is a need for in-depth training of individuals in the safety and regulatory community on the appropriate use of new tools for hazard, safety, and risk assessments.

This workshop brings together scientific experts representing relevant stakeholder organizations to discuss available alternative test methods and strategies for ocular safety assessments. Participants will learn the strengths and weaknesses of available alternatives, become familiar with the types of data they provide, and learn how to use these data in hazard, safety, and risk assessments.

Who Should Attend

Scientists from industry, government, and academia that have an interest in learning more about the available alternative test methods for assessing chemically induced eye injuries are encouraged to participate. Topics discussed during this workshop will be of particular interest to involved in conducting ocular safety tests (such as toxicologists and study directors), those responsible for reviewing study protocols prior to testing (such as chairpersons and members of Institutional Animal Care and Use Committees [IACUCs]), and regulators who will review data generated by the tests.

Workshop Program

The workshop will be convened January 19, 2010, from 8:30 a.m. to 5:00 p.m. U.S. requirements for the consideration of available alternatives, current regulatory requirements for ocular safety testing, and acceptance status of alternative methods will be presented. Background information on the scientific development of the test method and discussion of the validation status of the test method will then be provided followed by detail presentations to provide practical instruction on application of the test method including standard protocols and data interpretation. Workshop participants will also have an opportunity to apply knowledge gained from the program using case studies in breakout group discussion sessions. A poster session will highlight new methods and technologies applicable to ocular safety assessment.