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Newly Approved Ocular Safety Methods Reduce Animal Testing

Federal regulatory agencies have accepted recommendations of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) for two methods that can reduce live animal use for ocular safety testing, the committee announced today. ICCVAM is a permanent interagency committee composed of representatives from 15 federal regulatory and research agencies, including the National Institutes of Health (NIH) that use, generate or disseminate toxicology testing information.

The two alternative test methods, the bovine corneal opacity and permeability (BCOP) assay and the isolated chicken eye (ICE) assay, do not involve the use of live animals. These are the first scientifically valid alternative methods to gain regulatory acceptance for ocular safety testing.

The Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) concurred with the ICCVAM recommendations for the BCOP and ICE tests. CPSC will now accept these tests instead of the conventional ocular toxicity test for the purpose of classification for labeling under the Federal Hazardous Substance Act (15 U.S.C. 1261-1278).

“Based on an extensive database of product test results, the use of these two alternative test methods will likely reduce the use of live animals for eye safety testing by 10 percent or more,” stated William Stokes, D.V.M., the executive director of ICCVAM and director of the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). “More importantly, the use of these tests will eliminate the testing in animals of most substances likely to cause the most severe pain and discomfort.”

If a positive response is obtained using either of the two new approved alternative methods, the product can be labeled as causing irreversible or severe eye damage and no live animal testing will be required. If the response is negative, the product is then tested in an animal to confirm that it does not cause severe or irreversible damage.

The NIH and other federal agencies are committed to the welfare of animals used in research. All animals used in federally funded research are protected by laws, regulations and policies to ensure they are used in the smallest number possible and with the greatest

commitment to their comfort. ICCVAM is working to promote the development and validation of alternative test methods. Alternative test methods are those that accomplish one or more of the 3Rs of reducing the number of animals used in testing, or refining procedures so animals experience less pain and distress, or replacing animals with non-animal systems.

Marilyn Wind, Ph.D., chair of ICCVAM and principal ICCVAM representative for the CPSC said, “The use of these alternative methods will help reduce animal use while ensuring the proper identification and hazard labeling for substances that may cause severe or permanent eye damage.”

Before certain new products such as drugs and pesticides can be marketed in the United States, they must be tested for their potential to adversely affect the health of consumers. Currently, the FDA, the CPSC and the EPA require that these and other products such as cosmetics, shampoos, detergents and household chemical products be labeled with information on hazards for human health. Tests that use animals are among the tests used by these federal agencies to evaluate potential damage to the eye that may result from exposure to these products. ICCVAM conducted a comprehensive scientific review of four alternative test methods and concluded that the BCOP and ICE methods can be useful for identifying products that may cause permanent or severe damage to an exposed eye. ICCVAM’s evaluation report and recommendations were forwarded to federal agencies for their consideration in October 2007.

The ICCVAM Test Method Evaluation Report: *In Vitro* Ocular Toxicity Test Methods for Identifying Severe Irritants and Corrosives (NIH Publication 06-4511) contains the ICCVAM recommendations for these two alternative eye test methods and how results can be used to determine appropriate warning labels and special packaging requirements. The report also includes proposals for new studies that might further increase the usefulness of alternative test methods for detecting products that cause severe eye damage.

ICCVAM’s recommendations were made after consideration of public comments and a report from an independent scientific peer review panel. The full report is available at the ICCVAM-NICEATM Web site (<http://iccvam.niehs.nih.gov>).

To have the greatest impact on reducing animal use, ICCVAM will seek adoption of these test methods internationally by the Organization of Economic Cooperation and Development so they can also be used in the other 29 OECD member countries, which include Japan and most countries in the European Union. There is considerable interest in these methods in Europe due to the impending 2009 ban by the EU on the use of animals for testing cosmetic ingredients and the EU chemicals legislation, REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances), which may require testing of thousands of existing chemicals.

ICCVAM is also evaluating several other non-animal methods that are expected to further reduce animal use for ocular testing including a proposed non-animal testing

strategy for specific types of anti microbial products. The overall goal is an integrated testing strategy using several non-animal tests that can accurately predict whether chemicals or products have the potential to damage the eye.

The National Toxicology Program (NTP) is an interagency program established in 1978. The program was created as a cooperative effort to coordinate toxicology testing programs within the federal government, strengthen the science base in toxicology, develop and validate improved testing methods, and provide information about potentially toxic chemicals to health, regulatory, and research agencies, scientific and medical communities, and the public. The NTP is headquartered at the National Institute of Environmental Health Sciences. For additional information, visit <http://ntp.niehs.nih.gov/>.

The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) administers and provides scientific support for ICCVAM and is a part of the National Toxicology Program at NIEHS. Visit NICEATM at http://iccvam.niehs.nih.gov/about/about_NICEATM.htm.

The primary mission of the National Institute of Environmental Health Sciences, one of 27 Institutes and Centers at the National Institutes of Health, is to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease. For additional information, visit the NIEHS Web site at <http://www.niehs.nih.gov/>.

The National Institutes of Health (NIH) - The Nation's Medical Research Agency - includes 27 Institutes and Centers and is a component of the U. S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments and cures for both common and rare diseases. For more information about NIH and its programs, visit <http://www.nih.gov/>.