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Department of Energy
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Rear Admiral William S. Stokes
Director
National Toxicology Program
Interagency Center for the Evaluation of Alternative Toxicological Methods
National Institute of Environmental Health Sciences
P.O. Box 12233, Mail Code K2-16
Research Triangle Park, NC 27709

Dear Admiral Stokes:

This letter is in response to a September 19, 2012, request from Dr. Linda Birnbaum, Director, National Institute of Environmental Health Sciences.

Dr. Birnbaum requested the Department of Energy's review of toxicological test method recommendations from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). These recommendations are contained in a document entitled: *Identifying Chemical Eye Hazards with Fewer Animals* (NIH Publication No. 12-7930). This document presents a review of and makes recommendations concerning the use of fewer animals to evaluate chemical eye hazards. The reports presents the results of analysis showing that 3-animal tests are able to provide eye hazard classification equivalent to that specified in 16 SFR 1500.42. Implementation of the 3-animal test criteria can reduce the number of animals used in eye hazard testing by 50% to 80% while providing the same level of eye hazard classification.

These documents were reviewed by staff in the Department of Energy's Office of Science. Based on this review, the Department of Energy finds that the recommendations are consistent with the ICCVAM efforts to identify test protocols that "more accurately assess the safety and hazards of chemicals and products and that refine, reduce, or replace animal use." The Test Method Evaluation Report has been developed in a thorough, open, and technically defensible manner. The report and its underlying documentation have been reviewed vigorously and made available for general public comment. Both reviewer and public comments were considered and responded to carefully.

The Department of Energy does not promulgate regulations or guidelines regarding the assessment of chemical eye hazards and thus does not have relevant test methods for which the ICCVAM test method recommendations may be added or substituted.

Thank you for the opportunity to review these documents and please accept our appreciation for the time, effort, and expertise that were taken to develop these recommendations and their supporting background review documents.

Sincerely,

/s/

J. Michael Kuperberg, Ph.D.
Office of Biological and Environmental Research