DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709
http://www.niehs.nih.gov

September 19, 2012

The Honorable Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Room 2217
Silver Spring, Maryland 20993

Dear Dr. Hamburg:

I am pleased to forward for your consideration toxicological test method recommendations from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) that will identify chemical eye hazards using fewer animals. These test method recommendations are being sent to you for action pursuant to the ICCVAM Authorization Act of 2000 ("the Act," 42 U.S.C. 285*l*-3(e)(4)).

Eye safety testing procedures vary among U.S. agencies. When animal testing is determined necessary, testing can normally be completed using three or fewer animals. However, some current testing procedures (16 CFR 1500.42) require six to eighteen animals, and the procedures do not provide criteria to classify results obtained from a three-animal test. Therefore, the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), in collaboration with ICCVAM, conducted an analysis to determine classification criteria based on results from a three-animal test that would maintain hazard classification equivalent to current testing procedures in 16 CFR 1500.42. Based on this analysis, ICCVAM recommends using a classification criterion of one or more positive animals in a three-animal test to identify chemicals and products that are eye hazards. This test will maintain hazard classification equivalent to that provided by current testing procedures, while using up to 50 percent to 83 percent fewer animals.

Pursuant to the Act (42 USC 285*l*-4), Federal agencies are required to review ICCVAM test method recommendations and notify ICCVAM in writing of the agency's findings no later than 180 days after receipt of the recommendations. In accordance with these requirements, we ask that you please state whether or not your agency will adopt the ICCVAM recommendations, and if your agency will not adopt them, which of the reasons in § 285*l*-4(e) applies.

Please send your agency's response to RADM William S. Stokes, Director, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods[1]. As required, ICCVAM will

[1] Contact information for RADM Stokes: NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709, telephone:

make the final ICCVAM test method recommendations and the responses from the agencies available to the public (§ 285*l*-3(e)(6)) by posting them on the NICEATM-ICCVAM website (http://iccvam.niehs.nih.gov).

I appreciate your agency's participation on ICCVAM. The committee serves an important role in the scientific evaluation and adoption of test methods that will help protect human health and the environment while providing for improved animal welfare whenever possible.

Sincerely,

/s/

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Director
National Institute of Environmental Health Sciences
and National Toxicology Program

Enclosure

cc:
Abby Jacobs, Ph.D., FDA ICCVAM Alternate Agency Representative