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August 13, 2008

Dr. Jerry Smrchek  
U.S. National Coordinator for the  
OECD Test Guidelines Program  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Mail Code 7403M  
Washington, DC 20460

Dear Dr. Smrchek,

On behalf of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), we are pleased to provide the enclosed table of comments on the proposed draft OECD Test Guideline (TG): *In Vitro Skin Irritation: Human Skin Model Test*. These comments are in response to the June 6, 2008 notification from OECD requesting comments on the draft TG.

A major concern is the limited hazard classification applicability of this TG. As currently written, it is only applicable for the European Union hazard classification system, which would not seem to justify development as an OECD international test guideline. However, recent discussions with the European Centre for the Validation of Alternative Methods (ECVAM) suggest that at least one of the methods on which the TG is based may have limited applicability for hazard classification according to the United Nations Globally Harmonized System for the Classification and Labeling of Chemicals (GHS). The validation data indicate potential usefulness for identifying GHS Category 2 skin irritants, although such data does not currently support its use for identifying GHS Category 3 skin irritants. Given the international applicability of the GHS, ICCVAM therefore recommends that the test guideline should be revised to describe how human skin cell models can be used to identify GHS Category 2 skin irritants.

We understand that the OECD Secretariat is organizing an Expert Consultation to consider national comments and possible revisions to this draft test guideline. The ICCVAM Dermal Irritation and Corrosivity Working Group and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) have considerable experience with the human skin cell models, and would be pleased to assist with this process in order to expedite consideration and adoption of an in vitro test system for skin irritation assessments. We would be glad to solicit and nominate experts who can assist with

this process.

We appreciate the opportunity for ICCVAM to provide comments on this draft TG. Please feel free to contact us at any time if you have questions or concerns regarding these comments.

Sincerely,

**/s/**

**/s/**

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Enclosure