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5100 WISCONSIN AVENUE, N.W. • SUITE 400  
WASHINGTON, DC 20016  
T: (202) 686-2210 • F: (202) 686-2216  
PCRM@PCRM.ORG • WWW.PCRM.ORG

November 13, 2001

Dr. Bill Stokes, Director  
NTP Interagency Center for the Evaluation of Alternative  
Toxicological Methods (MD EC-17)  
National Institute of Environmental Health Sciences  
P.O. Box 12233  
Research Triangle Park, NC 27709

***SUBMITTED ELECTRONICALLY TO:*** [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov)

Dear Dr. Stokes:

We are pleased to submit these comments on behalf of the 5,000 physician and 100,000 layperson members of the Physicians Committee for Responsible Medicine, a nonprofit organization dedicated to promoting higher ethical standards in medical and scientific research. We fully support the comments submitted by People for the Ethical Treatment of Animals on November 9, 2001, in response to the National Institute of Environmental Health Sciences' (NIEHS's) *Federal Register* notice dated September 28, 2001. This notice invited public comment on the background review document entitled "EPISKIN™, EpiDerm™ and Rat Skin Transcutaneous Electrical Resistance (TER) Methods: *In Vitro* Test Methods for Assessing the Dermal Corrosivity Potential of Chemicals," as well as the recommendations from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) on the use of these methods.

Specifically, we strongly object to ICCVAM's recommendation that these methods be used in the context of a "weight-of-evidence approach in an integrated testing scheme," whereby "negative *in vitro* corrosivity responses shall be followed by *in vivo* dermal corrosion/irritation testing."

We urge ICCVAM to amend its recommendations to accept the use of any and all of the currently available and validated *in vitro* corrosivity assays (i.e., EPISKIN™, EpiDerm™, the Rat Skin TER assay) as stand-alone tests for the purposes of hazard identification and risk assessment.

Thank you for the opportunity to comment. I can be reached at 202-686-2210, ext. 302, or via e-mail at [ncardello@pcrm.org](mailto:ncardello@pcrm.org). Correspondence should be sent to my attention at PCRM, 5100 Wisconsin Ave., N.W., Suite 400, Washington, DC 20016. I look forward to discussing these important issues with you.

Sincerely,

Nicole Cardello, M.H.S.  
Staff Scientist