



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

August 25, 2003

Kenneth Olden, Ph.D.  
Director  
National Institute of Environmental Health Sciences  
P.O. Box 12233  
Research Triangle Park, NC 27709

Dear Dr. Olden:

I am responding on behalf of the National Cancer Institute (NCI) to the test recommendations of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act (P.L. 106-545) Section 5 APPLICATION (a) states that this Act does not apply to "...research related to the causes, diagnosis, treatment, control or prevention of physical or mental diseases or impairments of human or animals." Since the mission of the NCI is biomedical research related to the causes, diagnosis, treatment, control or prevention of cancer, AIDS and other diseases in humans, the ICCVAM recommendations do not apply ordinarily to the research activities.

The NCI rarely performs any lethality studies in animals and does not usually conduct acute oral toxicity studies as defined by ICCVAM. However, in the spirit of ICCVAM, NCI researchers will use the revised Up-and-Down Procedure (UDP) whenever possible if it does not compromise the scientific validity of the research and the in vitro method for estimating starting dose when appropriate. UDP is currently in use by NCI researchers.

Consideration of the applicable ICCVAM recommendations in all animal-related activities conducted or supported by NCI is consistent with the Public Health Service Policy on Humane Care and Use of Laboratory Animals and Section 404c of the NIH Revitalization Act of 1993 (P.L. 103-43).

NCI remains committed to animal welfare efforts consistent with sound research design.

Sincerely,

/Andrew C. von Eschenbach, M.D.  
Director  
National Cancer Institute