



SEP 05 2003

Kenneth Olden, Ph.D.
Director
National Institute of
Environmental Health Sciences
P.O. Box 12233, B1-02
Research Triangle Park, North Carolina 27709

Dear Dr. Olden:

Thank you for your March 21 letter forwarding the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) test recommendations, sent on behalf of the Secretary of the Department of Health and Human Services. Pursuant to Sections 4(a) and 4(d) of the ICCVAM Authorization Act (P.L. 106-545), I am responding on behalf of the National Institutes of Health (NIH), with the exception of the National Library of Medicine (NLM), National Cancer Institute (NCI), and National Institute of Environmental Health Sciences (NIEHS). I understand that NLM, NCI, and NIEHS will respond directly to your letter regarding the applicability of ICCVAM Test recommendations in their respective programs.

Section 5(a) of the ICCVAM Authorization Act 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 humans or animals." Since the mission of the NIH is biomedical research related to the causes, diagnosis, treatment control or prevention of physical or mental diseases or impairments of humans, the ICCVAM recommendations do not apply ordinarily to the research activities conducted by the Institutes and Centers of the NIH.

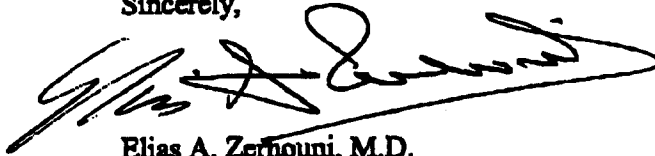
The NIH does support researchers or contractors conducting toxicological evaluations needed for safety assessment and preclinical development of experimental therapeutics or biological compounds (e.g., imaging agents). These researchers conduct preliminary dose-range finding toxicity studies by a variety of methods. These methods are selected on a case-by-case basis based on chemical structure, availability of previous data (e.g., animal efficacy data), and other information. Wherever scientifically appropriate, ICCVAM-recommended methods are recognized as valuable in predicting dose levels before moving into full toxicology assays required by the Food and Drug Administration.

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Consideration of the applicable ICCVAM recommendations in all animal-related activities conducted or supported by NIH 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).

In closing, I want to acknowledge the contributions of NIH staff and NIH-supported researchers and contractors to ICCVAM's efforts. Numerous members of the NIH community participated in the development and validation of these first ICCVAM recommendations. NIH remains committed to animal welfare efforts consistent with sound research design.

Sincerely,

A handwritten signature in black ink, appearing to read 'Elias A. Zernouni', written over a horizontal line.

Elias A. Zernouni, M.D.
Director