



U.S. CONSUMER PRODUCT SAFETY COMMISSION

4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814-4408

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Acting Chairman Nancy A. Nord
 Commissioner Thomas H. Moore

ITEM:

Staff Recommendation on Response to ICCVAM on the use of *In Vitro* Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing
(Briefing package dated August 21, 2008)

DECISION:

The Commission voted unanimously (2-0) to accept the Interagency Coordinating Committee on the Validation of Alternative Methods ("ICCVAM") recommendations on the use of *in vitro* basal cytotoxicity test methods for estimating starting doses for acute oral systemic toxicity testing and instruct the staff to so inform ICCVAM by letter.

For the Commission:

A handwritten signature in black ink, appearing to read "Todd A. Stevenson".

Todd A. Stevenson
Secretary

* Ballot vote due August 28, 2008



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Todd Stevenson
Secretary
Office of the Secretary

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August 28, 2008

Rear Admiral William S. Stokes
Executive Director
Interagency Coordinating Committee
on the Validation of Alternative Methods
National Institute of Environmental Health Sciences
P.O. Box 12233, Mail Code EC-17
Research Triangle Park, N.C. 27709

Dear Admiral Stokes:

We are pleased to inform you, as required by the ICCVAM Authorization Act, that the U.S. Consumer Product Safety Commission (Commission) voted unanimously on August 28, 2008 to approve the recommendations of ICCVAM that *in vitro* basal cytotoxicity test methods should be considered and used where appropriate as part of a weight-of-evidence approach to estimate the starting dose for acute oral *in vivo* toxicity testing. Although this approach can be used to estimate the starting doses for acute oral *in vivo* toxicity tests, it may not be used as a replacement for testing in animals or to predict acute oral toxicity for the purpose of regulatory hazard classification. The use of this approach can possibly reduce the number of animals required for the acute oral toxicity tests and is consistent with the Commission's policy to reduce, refine, or replace the use of animals in testing. Consequently, the Commission supports the use of *in vitro* basal cytotoxicity test methods to estimate the starting doses for acute oral *in vivo* toxicity tests that will be used for the purpose of classification and labeling under the Federal Hazardous Substances Act "FHSA" 15 U.S.C. §1261-1278. The briefing package sent to the Commission can be found on the Commission website (www.cpsc.gov) in the Library (FOIA) section at <http://www.cpsc.gov/library/foia/foia08/brief/invitr11.pdf>.

Sincerely,

A handwritten signature in black ink, appearing to read "Todd Stevenson", is written over a horizontal line.

Todd Stevenson