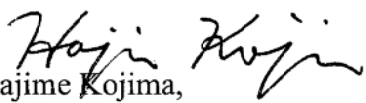



**JaCVAM statement
on the cytotoxicity tests to estimate starting doses
for acute oral systemic toxicity tests**

At the meeting concerning the above method, held on 20 April 2011 at the National Institute of Health Sciences (NIHS), Tokyo, Japan, the members of the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

Following the review of the results of the ICCVAM(Interagency Coordinating Committee on the Validation of Alternative Methods, USA) Background Review Document and Evaluation Report, it is concluded that the cytotoxicity tests can be used to estimate starting doses for acute oral systemic toxicity tests.

The JaCVAM Regulatory Acceptance Board has been regularly kept informed of the progress of the study, and this endorsement is based on an assessment of various documents, including, in particular, the evaluation report prepared by the JaCVAM ad hoc peer review panel.


Hajime Kojima,
Director,
JaCVAM,
National Center for Biological Safety and Research (NCBSR)
NIHS,
Tokyo


Akiyoshi Nishikawa,
Director,
NCBSR,
NIHS,
Tokyo

17, June, 2011

The JaCVAM Regulatory Acceptance Board was established by the JaCVAM Steering Committee, and is composed of nominees from the industry and academia.

This statement was endorsed by the following members of the JaCVAM Regulatory Acceptance Board:

Mr. Akiyoshi Nishikawa (National Institute of Health Sciences: NIHS)
Mr. Noriho Tanaka (Food and Drug Safety Center)
Mr. Takemi Yoshida (Showa Univ.)
Mr. Hiroo Yokozeki (Tokyo Medical and Dental Univ.)
Mr. Isao Yoshimura (Tokyo Univ. of Science)
Mr. Kazuto Watanabe (Japan Pharmaceutical Manufacturers Association)
Ms. Yuko Okamoto (Japan Cosmetic Industry Association)
Mr. Takeyoshi Oshima (Japan Chemical Industry Association)
Mr. Hiroshi Onodera (Pharmaceuticals and Medical Devices Agency)
Mr. Hiromichi Ogasawara (Pharmaceuticals and Medical Devices Agency)
Ms. Midori Yoshida (NIHS)
Mr. Yoshiaki Ikarashi (NIHS)
Mr. Ryuichi Hasegawa (National Institute of Technology and Evaluation)
Mr. Norihide Asano (Former Nitto Denko)

The following members of the JaCVAM Steering Committee were involved as observers in the consultation process, but not in the endorsement process itself.

Mr. Yasuo Ohno (NIHS)
Ms. Yuko Sekino (NIHS)
Mr. Mitsuteru Masuda (JaCVAM)
Mr. Hajime Kojima (JaCVAM)
Mr. Masaharu Akita (Japanese Society for Alternatives to Animal Experiments)
Mr. Masayoshi Shibatsuji (Ministry of Health, Labour and Welfare)
Mr. Shinichi Jitsukuni (Ministry of Economy, Trade and Industry)