JaCVAM statement

on *in vitro* ocular toxicity test methods for identifying ocular corrosive and severe irritants: Isolated Chicken Eye Test Method

At the meeting concerning the above method, held on 19 December 2009 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 [1] 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 *in vitro* ocular toxicity test methods: Isolated Chicken Eye Test Method can be used for identifying ocular corrosive and severe irritants.

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 report on the results from the study, and also on the evaluation supported by JSAAE of the study prepared for the JaCVAM ad hoc peer review panel.

Hajime Kojima, Director,

JaCVAM,

National Centre for Biological Safety and Research (NCBSR)

NIHS, Tokyo Tohru Inoue,

Director,

NCBSR,

NIHS,

Tokyo

19 December, 2009

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. Tohru Inoue (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. Kazuichi Nakamura (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. Iku Mitta (Pharmaceuticals and Medical Devices Agency)

Ms Midori Yoshida (NIHS)

Mr. Yoshiaki Ikarashi (NIHS)

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)

Mr. Mitsuteru Masuda (JaCVAM)

Mr. Hajime Kojima (JaCVAM)

Mr. Masaharu Akita (JSAAE)