

Administrative Notice
February 4, 2011

To: All departments involved in supervision of pharmaceuticals at prefectural government agencies responsible for public health

From: Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Re: JaCVAM activities to promote the use of test results obtained from alternatives to animal testing in applications for approval of quasi drugs

In an administrative notification issued on July 19, 2006 and entitled "Questions and answers regarding documentation of requests for revisions to criteria for cosmetic products as well as applications for approval of manufacturing and sales of quasi drugs," the Evaluation and Licensing Division of the Pharmaceutical and Food Safety Bureau indicated that applications for approval of manufacturing and sales of quasi drugs could be based on test results obtained using alternatives to animal testing, provided that the test results were obtained using an alternative method approved by the Organization for Economic Cooperation and Development (OECD) or a suitable variation thereof.

The Japanese Center for the Validation of Alternative Methods (JaCVAM) is party to international initiatives for the development of alternatives to animal testing, such as the International Cooperation on Alternative Test Methods (ICATM). It serves not only as a clearinghouse for information on alternative methods but as a center for the development of new methods and for the evaluation of revisions to existing ones. JaCVAM also undertakes numerous initiatives to promote the results of these and other efforts to expand the use of alternative methods in Japan.

We invite you to make reference to information available on the JaCVAM Website (<http://jacvam.jp/>) in ensuring proper preparation of applications for approval of manufacturing and sales of quasi drugs as well as to requests for revisions to positive lists for cosmetics. We also kindly request that you publicize this information to applicable businesses and other concerned parties operating under your jurisdiction.

The JaCVAM Website is available at <http://jacvam.jp/>.