

Administrative Notice

April 26, 2012

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: Guidance on the use of alternative methods to animal testing for skin-sensitization potency and phototoxicity in the safety assessment of quasi-drug and cosmetic products

As part of its activities during 2011, a Regulatory Science Research program chaired by Dr. Hajime Kojima has prepared guidance on the use of alternative methods to animal testing for skin-sensitization potency and phototoxicity in the safety assessment of quasi-drug and cosmetic products and has made the guidelines available in order to promote the use of alternative methods. We kindly request that you publicize this information to concerned parties operating under your jurisdiction.

The Evaluation and Licensing Division prepares and publishes guidance on the use of these and other alternative methods to animal testing as such information become available.

Attachments

1. Guidelines on the use of local lymph node assays (LLNA) as an alternative to animal testing for skin-sensitization potency in the safety assessment of quasi-drug and cosmetic products
2. Guidelines on the use of in vitro 3T3 neutral red uptake (NRU) tests as an alternative to animal testing for phototoxicity in the safety assessment of quasi-drug and cosmetic products