日本香粧品学会誌　Vol. 46, No. 1, pp. 30–36（2022）

〈シンポジウム〉

第46回日本香粧品学会（2021）・シンポジウム「グローバル環境から見た医薬部外品（添加物）開発の将来」

医薬部外品承認申請における動物実験代替法の利用と留意点

小島肇夫[1, 2, *]

Guidance of Alternative Methods for Animal Experiment for Approval of Quasi-Drug Additives

Hajime KOJIMA[1, 2, *]

Abstract

Animal tests of cosmetic ingredients and products have been banned in the EU since 2013. However, in Japan, the application of new quasi-drugs requires the animal data regarding several toxicity tests.

To resolve this concern, we have been coordinating guidance on the use of alternative test methods for the safety assessment of cosmetics and quasi-drugs since 2012. Dermatologists and representatives of cosmetic companies as well as specialists from both the Pharmaceuticals and Medical Devices Agency (PMDA) and the National Institute of Health Sciences (NIHS) have drafted guidance documents for a number of alternative test methods based on the OECD (Organisation for Economic Co-operation and Development) test guidelines and Japanese Center for the Validation of Alternative Methods (JaCVAM) evaluation documents. The development of new ones without animal testing are progressing the step-by-step process in Japan.

By next year, it is promising to gain approval of guidance document for additives to quasi-drug products and cosmetic ingredients without data from animal testing for regulatory acceptance.

Key words: quasi-drug, cosmetic ingredient, additives, alternative test methods, regulatory acceptance.