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Guidelines for Research and Determination of Safe Use History of New Cosmetic Ingredients (Trial) (Draft for Comments) and Drafting Explanation

《化妆品新原料安全使用历史研究和判定指南（试行）（征求意见稿）》及起草说明

National Institutes for Food and Drug Control

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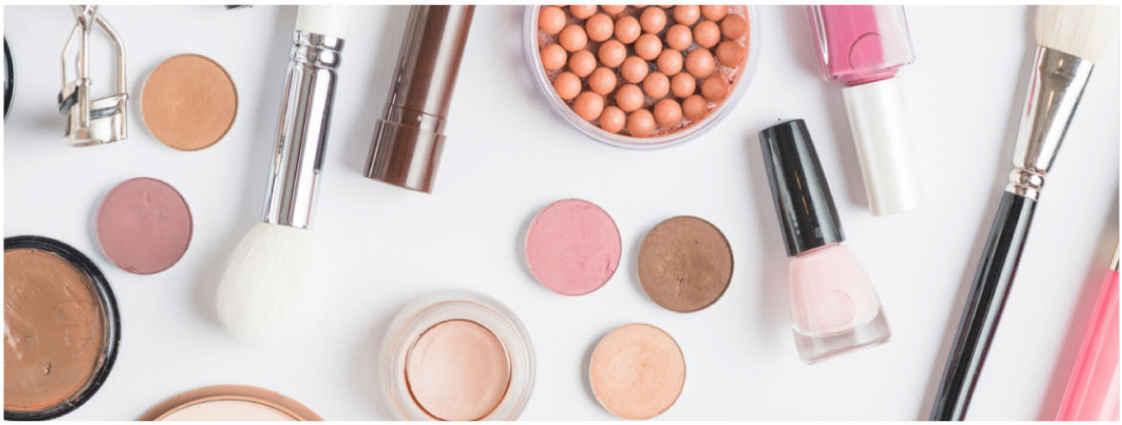

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Attachment 1

Guidelines for Research and Determination of Safe Use History of New Cosmetic Ingredients (Trial)

(Draft for Comments)

National Institutes for Food and Drug Control

ChemLinked Team, REACH24H Consulting Group | http://cosmetic.chemlinked.com
14F, #3 Bldg., Haichuang Technology Center, No. 1288 Wenyi West Road, Hangzhou, China. PC: 311121
Tel: +86 571 8609 4444 | Fax: +86 571 8700 7566 | Email: cosmetic@chemlinked.com

I. Overview

According to the *Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers* (hereinafter referred to as the "*Dossier Provisions*"), new ingredients applied for registration or handled for notification are categorized into six different situations based on their functions, use history, and consumption history, and requirements for corresponding toxicological test items are proposed based on risk management concepts. Situations 3 and 4 are applicable to new ingredients that can be fully proved that they have been safely used in the marketed cosmetics for more than three years. On the premise of sufficient use quantities and an effective adverse reaction monitoring system, the actual use situations of ingredients in the marketed cosmetics can to some extent demonstrate the safety of such ingredients.

This *Guidelines* is developed in accordance with the requirements of the *Cosmetic Supervision and Administration Regulations* (*CSAR*), *Administrative Measures on Cosmetic Registration and Notification*, *Dossier Provisions*, and other relevant regulations for the purpose of standardizing the research and evaluation of new cosmetic ingredients, guiding the collection, determination, and application in safety assessments of safe use history related data and information, and instructing registrants and notifiers to reasonably select the corresponding situations when applying for registration or handling notification of new ingredients.

This *Guidelines* is developed based on current regulations and standards, and level of scientific understanding, and its applicability shall follow the principle of specific analysis of specific issues. Adjustments will be made to this *Guidelines* in a timely manner with the update and improvement of regulations and standards, and development of science and technology.

II. Application Scope

This *Guidelines* shall be applicable to the research and determination of safe use history of new cosmetic ingredients (i.e. Situations 3 and 4 of the *Dossier Provisions*).

Registrants and notifiers of new cosmetic ingredients shall apply this *Guidelines* as per relevant regulations and technical standards. If there are other applicable technical guidelines or guiding principles, relevant technical requirements or suggestions shall also be referred to.

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14th Floor, Building 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China (311121)
Tel: +86 (0)571 8609 4444 / Fax: +86 571 8700 7566 / E-mail: cosmetic@chemlinked.com
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