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General Technical Guidelines on Registration and Notification Dossiers of New Cosmetic Ingredients

《化妆品新原料注册备案资料技术通则》

National Institutes for Food and Drug Control

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Translated by ChemLinked

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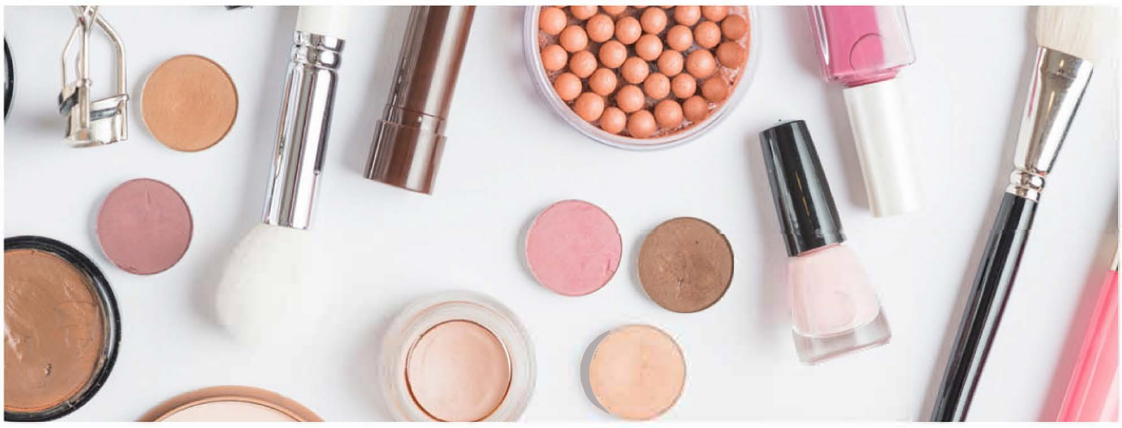

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Attachment

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National Institutes for Food and Drug Control

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I. Overview

In order to clarify the technical requirements for registration and notification dossiers of new cosmetic ingredients, guide and regulate the registration and notification work of new ingredients, the *Guidelines* is hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulation* (CSAR), *Administrative Measures on Cosmetics Registration and Notification*, and *Administrative Provisions on Registration, Notification and Dossier Management of New Cosmetic Ingredients*.

The *Guidelines* is formulated based on existing regulations and standards, and current level of scientific understanding, and the applicability thereof shall follow the principle of specific analysis of specific issues. Adjustments will be made to the *Guidelines* in a timely manner with the update and improvement of regulations and standards, as well as the development of science and technology.

II. Application Scope

The *Guidelines* shall apply to the dossiers submitted by registrants and notifiers of new cosmetic ingredients at the time of applying for registration or notification. If there are other applicable technical guidelines or guiding principles, relevant technical requirements shall also be referred to.

III. General Principles

(I) Basic Requirements

Registrants and notifiers of new cosmetic ingredients shall submit registration or notification dossiers as required, and shall be responsible for the compliance, authenticity, accuracy, completeness, and traceability of the dossiers submitted. Before applying for registration or notification of a new ingredient, the registrant or notifier shall conduct a comprehensive survey on the new ingredient to be registered or notified, and perform necessary test research, fully investigating and confirming the technique, quality, function, safety, and other related aspects of the new ingredient.

Unless otherwise specified by relevant regulations or these rules, registrants and notifiers of new ingredients may conduct relevant research by themselves, or entrust the research work to a third party. If there are qualification, capability, or other requirements for the entrusted third party, such requirements shall be complied with, and relevant qualification certification documents of the party shall be provided together with the test report. Registrants and notifiers of new ingredients shall provide authentic and valid test samples

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+ Cosmetic formula and label compliance review
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+ Cosmetic formula and label compliance review
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+ California Safe Cosmetics Program (CSCP)
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附件

化妆品新原料注册备案

资料技术通则

中国食品药品检定研究院

目 录

一、概述

为明确化妆品新原料注册备案资料技术要求，指导和规范新原料注册备案工作，根据《化妆品监督管理条例》《化妆品注册备案管理办法》《化妆品新原料注册备案及资料管理规定》，制定本通则。

本通则是在现行法规、标准以及当前科学认知水平下制定，应遵循具体问题具体分析原则。随着法规、标准更新完善以及科学技术发展，将适时进行调整。

二、适用范围

化妆品新原料注册人、备案人申请化妆品新原料注册或者进行备案时提交的资料，应当符合本技术通则要求。如同时符合其他技术指南或指导原则适用范围的，还应当同时参考相关技术要求。

三、一般原则

（一）基本要求

化妆品新原料注册人、备案人应当按要求提交化妆品新原料注册备案资料，并对所提交资料的合规性、真实性、准确性、完整性和可追溯性负责。在申请新原料注册或者进行备案前，新原料注册人、备案人应当对拟注册备案新原料进行全面调研，开展必要试验研究，对原料工艺、质量、功能、安全等进行充分研究和确认。

除相关法规或本通则有明确规定外，新原料注册人、备案人可自行开展或者委托第三方开展相关研究。对被委托的第三方有资质、能力或其他要求的，应当符合相关要求，并随试验报告附相关资质证明材料。新原料注册人、备案人应当向被委托机构提供真实有效的检验样品，并采取必要的监督措施，确认其研究的合规性、科学性、规范性；应当对所获得的研究数据进行科学合理的统计分析；提供的试验数据应当完整、清晰、规范，确保能够体现完整试验过程和关键信息。

引用科学文献或其他资料的，应当在注册备案资料相关内容处规范引用，确保有效溯源。应当充分分析所引用文献资料中研究对象与拟注册备案新原料的一致性或相关性，必要时附证明资料或相关说明。新原料功能、安全等相关关键文献资料，应当提供原文及译文。

在各项研究基础上，应当综合全部数据信息，并结合拟注册备案新原料特性进行总结分析，客观、准确描述新原料各项信息，充分说明新原料使用目的、使用范围、使用量等条件下用于化妆品的安全性和风险可控性，形成规范、完整的注册备案资料。

（二）资料形式要求

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