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Guidelines for Submitting Information on the Cosmetic Ingredient Safety Information Submission Platform (Draft for Comments)

化妆品原料安全信息登记平台填报指南（征求意见稿）

National Institutes for Food and Drug Control

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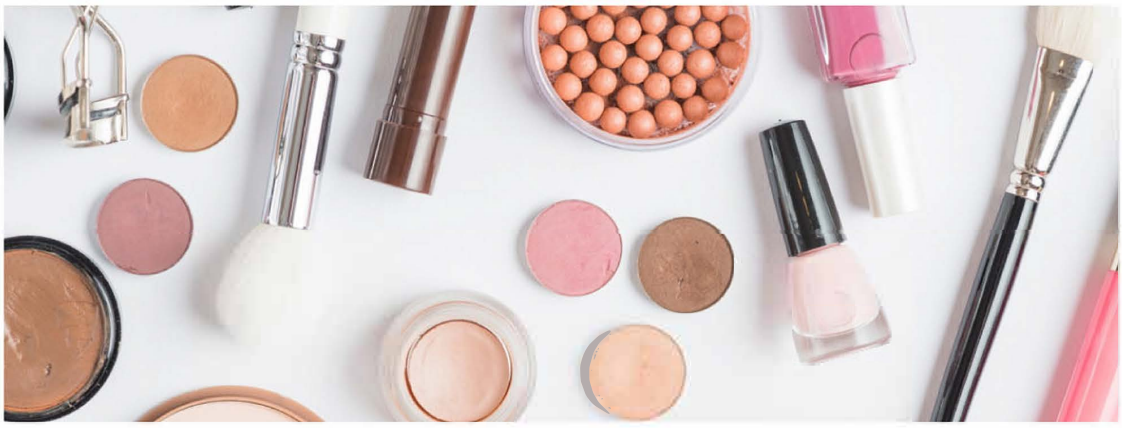

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Attachment 2

Drafting Instruction of *Guidelines for Submitting Information through the Cosmetic Ingredient Safety Information Submission Platform* (Draft for Comments)

To standardize and guide the information submission through the Cosmetic Ingredient Safety Information Submission Platform (hereinafter referred to as the "Ingredient Platform"), the Department of Cosmetics Regulation under the National Medical Products Administration (NMPA) organized the National Institutes for Food and Drug Control (NIFDC) to draft up the *Guidelines for Submitting Information through the Cosmetic Ingredient Safety Information Submission Platform (Draft for Comments)* (hereinafter referred to as the *Submission Guidelines (Draft for Comments)*) in accordance with the *Cosmetic Supervision and Administration Regulations* (*CSAR*), *Administrative Measures on Cosmetic Registration and Notification* (hereinafter referred to as the *Measures*), *Provisions for Management of Cosmetic Registration and Notification Dossiers* (hereinafter referred to as the *Provisions*) and the *NMPA Announcement on Further Optimizing Measures for Cosmetic Ingredient Safety Information Administration (No. 34 of 2023)* (hereinafter referred to as the *Announcement*) and other relevant regulations. The drafting information is explained as follows:

I. Necessity

As an important basis for product safety assessment, cosmetic ingredient safety information mainly includes ingredient quality specification, safety risk substance control, ingredient safety risk assessment conclusion, and other information related to ingredient safety.

To facilitate enterprises in submitting cosmetic safety information, the NMPA has established a Cosmetic Ingredient Safety Information Submission Platform (hereinafter referred to as the "Ingredient Platform"), mainly used for the unified registration of safety information related to existing cosmetic ingredients included in the *Inventory of Existing Cosmetic Ingredients in China 2021* (hereinafter referred to as the *IECIC*). To guide

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+ Preparation of Product Information File (PIF)

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+ California Safe Cosmetics Program (CSCP)
+ Toxicological Risk Assessment (TRA)
+ INCI application

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附件 2

《化妆品原料安全信息登记平台填报指南（征求意见稿）》起草说明

为规范和指导化妆品原料安全信息登记平台（以下简称原料平台）的填报，根据《化妆品监督管理条例》（以下简称《条例》）、《化妆品注册备案管理办法》（以下简称《办法》）、《化妆品注册备案资料管理规定》（以下简称《规定》）和《国家药监局关于进一步优化化妆品原料安全信息管理措施有关事宜的公告（2023 年第 34 号）》（以下简称《公告》）等相关规定，国家药监局化妆品监管司组织中国食品药品检定研究院（以下称中检院）起草了《化妆品原料安全信息登记平台填报指南（征求意见稿）》（以下称《填报指南（征求意见稿）》）。现将起草的有关情况说明如下：

一、必要性

作为产品安全性评价的重要依据，化妆品原料安全信息主要包括原料质量规格、安全性风险物质控制、原料安全风险评估结论等与原料安全相关的信息。

为便利企业填报化妆品安全信息资料，国家药监局搭建了化妆品原料安全信息登记平台（以下简称原料平台），主要用于《已使用化妆品原料目录》（以下简称《目录》）收录的原料相关安全信息的统一登记。为指导原料生产商正确使用原料平台，规范报送化妆品原料安全信息，有必要制定《填报指南》。

二、制定原则

（一）依法依规原则。《填报指南（征求意见稿）》遵循依法依规原则，贯彻《条例》精神，落实《办法》《规定》《公告》等关于化妆品原料安全信息的要求，编制了该指南，以指导原料生产商规范填报。

（二）公开透明原则。《填报指南（征求意见稿）》起草过程中，坚持“公开透明、广泛参与”原则，积极征求监管部门、专家、行业协会、企业意见，同时根据意见反馈情况及时修改完善。

三、主要内容

《填报指南（征求意见稿）》正文共包括十二条，包括填报依据、填报目的、适用范围、填报主体、填报内容、报送码生成及应用等。

四、需要说明的问题

（一）关于适用范围

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