



Guidelines for Submission of Cosmetics Safety Assessment Dossiers (Draft for Comments)

化妆品安全评估资料提交指南 (征求意见稿)

National Institutes for Food and Drug Control

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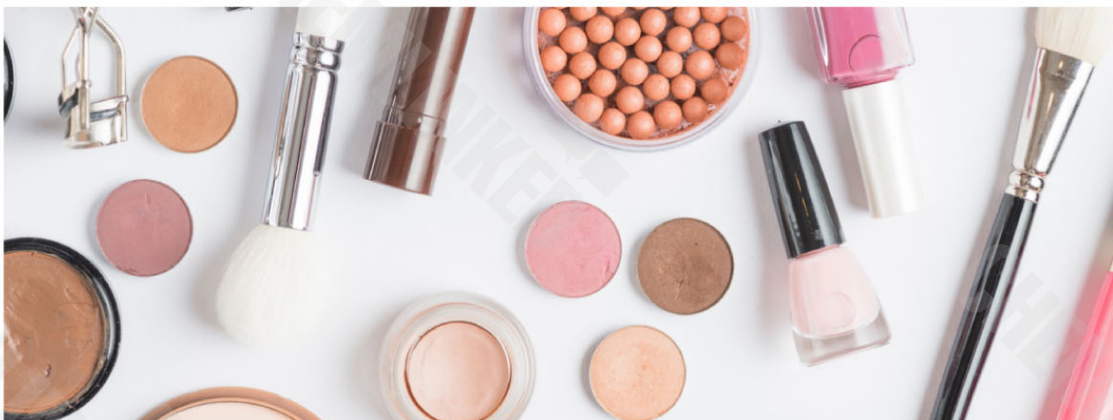
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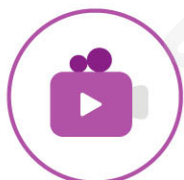


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(Draft for Comments)

Draft for Comments

National Institutes for Food and Drug Control

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I. Overview

According to the *Cosmetic Supervision and Administration Regulations (CSAR)*, cosmetic registrants/notifiers shall conduct safety assessments by themselves or through entrusting a professional institution before applying for registration or handling notification, and shall submit safety assessment dossiers when applying for registration or handling notification. According to the requirements of the National Medical Products Administration (NMPA) for optimizing the management of cosmetic safety assessments, in order to promote the orderly implementation of the cosmetic safety assessment system, and fully carry out the primary responsibility of enterprises, the submissions of cosmetic safety assessment dossiers are classified based on the principles of risk management, and self-inspection points for cosmetic safety assessment reports are established to guide enterprises for product safety assessments, improving the standardization, completeness, and scientificity of product safety assessment reports.

The *Guidelines for Submission of Cosmetic Safety Assessment Dossiers (Draft for Comments)* (hereinafter referred to as the "*Guidelines for Submission (Draft for Comments)*") are hereby formulated according to the requirements of the CSAR, *Administrative Measures on Cosmetic Registration and Notification, Technical Guidelines for Cosmetic Safety Assessment (2021)*, and other relevant laws and regulations, national standards, and technical specifications.

The *Guidelines for Submission (Draft for Comments)* are based on current regulations, standards, and levels of understanding, taking into account the actual situation of the industry. With the constant improvement of regulations and standards, as well as the continuous development of science, technology, and industry, relevant content will be adjusted in a timely manner.

II. Scope of Application

The *Guidelines for Submission (Draft for Comments)* is applicable to the determination of submissions of safety assessment dossiers content by cosmetic registrants/notifiers when applying for registration or handling notification, and the self-inspections of safety



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