



Administrative Measures on Cosmetic Registration and Notification

化妆品注册备案管理办法

State Administration for Market Regulation

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Administrative Measures on Cosmetic Registration and Notification

(Decree No. 35 of the State Administration for Market Regulation promulgated on January 7, 2021)

Chapter I General Rules

Article 1 For the purpose of regulating the registration and notification of cosmetics and ensuring the quality and safety of cosmetics, these Measures are hereby formulated in accordance with the “Cosmetic Supervision and Administration Regulations” (CSAR).

Article 2 These Measures shall apply to the activities of registration, notification, supervision and administration of cosmetics and new cosmetic ingredients within the territory of the People's Republic of China.

Article 3 The registration of cosmetics and new cosmetic ingredients is the activity where the registration applicant submits an application for registration in accordance with legal procedures and requirements, and then the medical products administration department reviews the safety and quality controllability of the cosmetics and new cosmetic ingredients applied for registration, and makes a decision on approving the registration or not.

The notification of cosmetics and new cosmetic ingredients is the activity where the notifier submits the documents indicating the safety and quality controllability of cosmetics and new cosmetic ingredients in accordance with legal procedures and requirements, and the medical products administration department files the submitted documents for future reference.

Article 4 The state implements registration management for special cosmetics and new cosmetic ingredients with higher risk levels, and notification management for general cosmetics and other new cosmetic ingredients respectively.

Article 5 The National Medical Products Administration (NMPA) shall be responsible for the registration and notification management of special cosmetics, imported general cosmetics and new cosmetic ingredients, and guiding and supervising the cosmetic notification-related work undertaken by the medical products administration departments of provinces, autonomous regions, and municipalities directly under the Central Government. The NMPA may entrust the medical products administration departments of

provinces, autonomous regions, and municipalities directly under the Central Government that have the corresponding capabilities to implement notification management of imported general cosmetics.

The Cosmetics Technical Review Institute of NMPA (hereinafter referred to as “Technical Review Institute”) shall be responsible for the technical review of registration of special cosmetics and new cosmetic ingredients, the technical verification of documents for imported general cosmetics and new cosmetic ingredients after notification, and the assessment on the use and safety reports of new cosmetic ingredients.

The Administrative Affairs Acceptance Service Institute of NMPA (hereinafter referred to as “Acceptance Institute”), review and verification institution, adverse reaction monitoring institution, information management institution and other professional technical institutions shall be responsible for registration acceptance, on-site verification, adverse reaction monitoring, and information construction and management required for registration and notification management of cosmetics.

Article 6 The medical products administration departments of provinces, autonomous regions, and municipalities directly under the Central Government shall be responsible for the notification administration of domestic general cosmetics within their respective administrative regions, implementing the notification administration of imported general cosmetics in the name of NMPA within the scope of entrustment, and assisting in the on-site verification of registration of special cosmetics.

Article 7 Registrants and notifiers of cosmetics and new cosmetic ingredients shall fulfill the obligations of product registration and notification in accordance with the law, and be responsible for the quality and safety of the cosmetics and new cosmetic ingredients.

When applying for registration or handling notification, registrants and notifiers of cosmetics and new cosmetic ingredients shall comply with the requirements of relevant laws, administrative regulations, mandatory national standards and technical specifications, and be responsible for the authenticity and scientificity of the submitted documents.

Article 8 Overseas registrants and notifiers shall designate an enterprise legal person within the territory of China as the domestic responsible person who shall fulfill the following obligations:

(I) Handle registration or notification of cosmetics and new cosmetic ingredients in the name of the registrant or notifier;



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