

# Provisions on the Administration of Cosmetic Registration and Filing Dossiers of the PRC

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## Chapter I — General Provisions

Article 1 — These Provisions are formulated in accordance with the Regulations on the Supervision and Administration of Cosmetics and other relevant laws and regulations, for the purpose of regulating the administration of cosmetic registration and filing dossiers and ensuring the quality and safety of cosmetics.

Article 2 — These Provisions apply to the registration and filing of cosmetic products within the territory of the People's Republic of China, and to the supervision and administration of registration and filing dossiers.

Article 3 — The registrant or record-filing person of cosmetics shall be responsible for the authenticity and completeness of the materials submitted for registration or filing, and shall bear legal liability for the quality and safety of the cosmetics.

## Chapter II — Registration Management

Article 4 — Special cosmetics shall be subject to registration management. The registrant applying for registration of special cosmetics shall submit the following materials to the drug regulatory authority under the State Council:

- (1) the registration application form for special cosmetics;
- (2) the product formula, including all raw materials and their amounts;
- (3) the manufacturing process description for the product;
- (4) the product quality and safety control requirements;
- (5) the product packaging and labeling design drafts;
- (6) the product inspection report; and
- (7) the safety assessment report for the product.

Article 5 — Where a registrant applies for the renewal of registration of special cosmetics, the application shall be submitted within 90 days before the expiration of the validity period of the registration certificate. The validity period of the registration certificate for special cosmetics is five years.

Article 6 — Where there is a change to the registered items of special cosmetics, the registrant shall apply for registration of the change to the drug regulatory authority. No entity or individual may change the formula or other registered items of registered cosmetics without authorization.

### **Chapter III — Filing Management**

Article 7 — General cosmetics shall be subject to filing management. The record-filing person of general cosmetics shall submit the following materials for filing before the product is placed on the market:

- (1) the record-filing form for general cosmetics;
- (2) the product formula;
- (3) the manufacturing process description;
- (4) the product quality and safety control requirements;
- (5) the product packaging and labeling design drafts;
- (6) the product inspection report; and
- (7) the safety assessment report for the product.

Article 8 — After a general cosmetic product has been filed, the record-filing person shall submit the product listing information to the drug regulatory authority within three months. The product listing information includes the date of first listing and the product traceability information.

Article 9 — Where there is a change to the filed items of general cosmetics, the record-filing person shall update the filing information. A material change involving the product safety shall be re-evaluated for safety.

### **Chapter IV — Administration of Dossiers**

Article 10 — The registrant or record-filing person of cosmetics shall keep the registration or filing dossier properly for a period of not less than the shelf life of the product plus two years after the last product is placed on the market.

Article 11 — The drug regulatory authority shall review, supervise, and inspect the registration and filing dossiers. During the review of dossiers, the authority may conduct on-site verification of the content of the dossiers depending on the situation.

Article 12 — The drug regulatory authority shall establish a credit file for cosmetic registrants and record-filing persons, and shall make registration and filing information publicly available, except for information involving trade secrets.

## **Chapter V — Legal Liability**

Article 13 — Where a registrant or record-filing person submits false materials for registration or filing, or conceals relevant information, the drug regulatory authority shall not grant the registration or filing. Where a registration certificate has been issued, it shall be revoked. Where a filing has been completed, it shall be canceled. A fine shall be imposed, and the relevant responsible persons shall be prohibited from engaging in cosmetics production and business activities for a specified period.

Article 14 — Where a registrant or record-filing person fails to keep the dossiers as required, or the dossiers are incomplete, the drug regulatory authority shall order it to rectify the situation and impose a warning and a fine.

Article 15 — Where drug regulatory authorities and their staff members abuse their power, neglect their duties, or engage in malpractices for personal gain in the administration of registration and filing dossiers, they shall be subject to sanctions in accordance with the law. Where a crime is constituted, criminal liability shall be pursued in accordance with the law.

## **Chapter VI — Supplementary Provisions**

Article 16 — The formats of the registration application form and the record-filing form shall be prescribed by the drug regulatory authority under the State Council.

Article 17 — Where existing cosmetic products need to be transitioned to comply with these Provisions, transitional measures shall be separately formulated by the drug regulatory authority under the State Council.

Article 18 — These Provisions shall come into effect on May 1, 2021.

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