

Regulations on the Supervision and Administration of Cosmetics of the PRC

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Chapter I — General Provisions

Article 1 — These Regulations are enacted for the purpose of regulating the production and business operations of cosmetics, strengthening the supervision and administration of cosmetics, ensuring the quality and safety of cosmetics, protecting the health of consumers, and promoting the sound development of the cosmetics industry.

Article 2 — These Regulations apply to the production and business operations of cosmetics and the supervision and administration thereof within the territory of the People's Republic of China. The term "cosmetics" as used in these Regulations refers to chemical industrial products or fine chemical products that are applied to the surface of the human body, such as the skin, hair, nails, lips, and other parts, by means of smearing, spraying, or other similar methods, for the purpose of cleaning, caring for, beautifying, or modifying appearance, or correcting body odor.

Article 3 — Cosmetics are classified into special cosmetics and general cosmetics. Special cosmetics refer to cosmetics used for purposes such as hair dyeing, hair perming, spot removal, sun protection, and cosmetics that claim new functions. Cosmetics other than special cosmetics are general cosmetics.

Article 4 — The state shall implement a classified management system for cosmetics based on risk levels. The drug regulatory authority under the State Council shall be responsible for the supervision and administration of cosmetics nationwide. The drug regulatory authorities of local people's governments at or above the county level shall be responsible for the supervision and administration of cosmetics within their respective administrative areas.

Chapter II — Raw Materials and Products

Article 5 — The state shall implement a categorized management system for cosmetic raw materials. The drug regulatory authority under the State Council shall formulate and publish a catalogue of prohibited raw materials for cosmetics and a catalogue of restricted raw materials for cosmetics. Cosmetic raw materials not listed in the catalogues may be used freely, but shall comply with the mandatory national standards for cosmetics.

Article 6 — New cosmetic raw materials used for the first time in China shall be subject to registration or filing management. New raw materials with higher risks such as preservatives, sunscreens, colorants, hair dyes, and whitening agents shall be subject to registration management. Other new raw materials shall be subject to filing management.

Article 7 — Special cosmetics shall be subject to registration management. The registrant or record-filing person of special cosmetics shall submit an application for registration to the drug regulatory authority under the State Council, together with relevant materials. General cosmetics shall be subject to filing management. The registrant or record-filing person of general cosmetics shall submit the relevant materials for filing to the drug regulatory authority under the State Council.

Article 8 — The registrant or record-filing person of cosmetics shall be responsible for the quality, safety, and efficacy claims of the cosmetics. Cosmetics shall comply with the mandatory national standards, technical specifications, and other relevant regulations.

Chapter III — Production and Operation

Article 9 — A cosmetics production enterprise shall obtain a cosmetics production license. The conditions for applying for a cosmetics production license shall include, among others, having production premises, facilities, and equipment compatible with the cosmetics produced, having management personnel and technical personnel capable of ensuring the quality and safety of cosmetics, and having a quality management system capable of ensuring the quality and safety of cosmetics.

Article 10 — A cosmetics production enterprise shall, in accordance with the requirements of the quality management standards for cosmetics production, organize the production of cosmetics, and establish production quality management systems and records. The quality management standards for cosmetics production shall be formulated by the drug regulatory authority under the State Council.

Article 11 — A cosmetics business operator shall establish and implement a purchase inspection and record system. When purchasing cosmetics, the operator shall verify the supplier's business qualifications, the registration certificate or record-filing certificate of the cosmetics, the inspection report on the quality of the cosmetics, and other relevant information.

Article 12 — The import of cosmetics shall comply with the relevant state regulations on the import of cosmetics. The importer of cosmetics shall be the registrant or record-filing person of the imported cosmetics in China. Imported cosmetics shall have Chinese labels and instructions.

Article 13 — Cosmetics advertisements shall be truthful and lawful, and shall not contain any false or misleading content, or deceive or mislead consumers. The labeling of cosmetics shall comply with the relevant state regulations, and shall truthfully and accurately indicate the required content.

Article 14 — E-commerce platform operators shall verify the identity of cosmetics operators on the platform and register their information. Where an e-commerce platform operator knows or should know that a cosmetics operator on the platform is violating the provisions of these Regulations, it shall take necessary measures such as deletion, blocking, disconnection, or termination of transactions and services, and shall report to the relevant authorities.

Chapter IV — Supervision and Administration

Article 15 — The drug regulatory authority under the State Council shall establish a unified national cosmetics supervision and administration information platform, to promote the sharing of cosmetics supervision and administration information, and to make cosmetics registration and filing information, production license information, sampling inspection results, and other information public.

Article 16 — Drug regulatory authorities shall strengthen supervision and inspection of the production and business operations of cosmetics, and shall have the power to take the following measures:

- (1) entering the production and business operation premises for on-site inspection;
- (2) sampling and inspecting cosmetics produced and operated;
- (3) consulting and duplicating relevant materials such as contracts, invoices, account books, and other relevant materials; and
- (4) sealing up or seizing cosmetics and raw materials that are proved by evidence to be in violation of the relevant regulations.

Article 17 — The drug regulatory authority under the State Council shall organize the monitoring of adverse reactions to cosmetics. Cosmetics registrants and record-filing persons shall monitor any adverse reactions to the cosmetics for which they have registered or filed, and shall report adverse reactions to the monitoring authority in a timely manner.

Chapter V — Legal Liability

Article 18 — Where an entity produces cosmetics without a production license, the drug regulatory authority shall ban the production activities, confiscate the illegally produced cosmetics and raw materials, packaging materials, tools, equipment, and other items used in the illegal production, and impose a fine of not less than five times but not more than fifteen times the value of the illegally produced cosmetics.

Article 19 — Where an entity produces or imports cosmetics that have not been registered or filed, the drug regulatory authority shall confiscate the illegal proceeds and the illegally produced or imported cosmetics, and impose a fine. Where the circumstances are serious, the production license shall be revoked, or the relevant business shall be banned.

Article 20 — Where a cosmetics production enterprise fails to produce cosmetics in accordance with the quality management standards for cosmetics production, the drug regulatory authority shall order it to rectify the situation and shall impose a warning and a fine. Where the circumstances are serious, it shall be ordered to suspend production for rectification, or its production license shall be revoked.

Article 21 — Where a cosmetics business operator fails to establish and implement the purchase inspection and record system, the drug regulatory authority shall order it to rectify the situation and shall impose a warning and a fine. Where the circumstances are serious, it shall be ordered to suspend business for rectification.

Article 22 — Where the labeling of cosmetics does not comply with the provisions, the drug regulatory authority shall order the registrant, record-filing person, or cosmetics business operator to rectify the situation. Where the circumstances are serious, a fine shall be imposed, and the relevant cosmetics shall be ordered to stop being sold.

Article 23 — Where a false or misleading cosmetics advertisement is published, the market regulation authority shall impose penalties in accordance with the Advertising Law and other relevant laws and regulations.

Chapter VI — Supplementary Provisions

Article 24 — The specific measures for the implementation of these Regulations shall be formulated by the drug regulatory authority under the State Council in conjunction with the relevant departments under the State Council.

Article 25 — These Regulations shall come into effect on January 1, 2021. The Regulations on Cosmetics Hygiene Supervision promulgated by the State Council on November 13, 1989 shall be repealed simultaneously.

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