Regulations on the Administration of Cosmetics Supervision of the PRC

Dan Young Business Consultancy — www.danyoungcpa.com

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Chapter I — General Provisions

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

Article 2 — These Regulations shall apply to the production and operation of cosmetics and the supervision and administration thereof within the territory of the People's Republic of China.

Article 3 — "Cosmetics" as used in these Regulations means chemical industrial products or fine chemical products that are applied to the surface of the human body, such as skin, hair, nails, lips, and other parts, by rubbing, spraying, or other similar methods, for the purposes of cleaning, caring, beautifying, modifying, and changing appearance, or correcting odor and maintaining a good condition.

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Article 4 — The State shall implement classified management of cosmetics based on risk level. Cosmetics shall be divided into special cosmetics and general cosmetics. Special cosmetics refer to cosmetics used for hair dyeing, hair perming, spot removal, sun protection, anti-hair loss, and cosmetics with new functions. Other cosmetics are general cosmetics. The specific scope of special cosmetics shall be determined and published by the pharmaceutical regulatory department under the State Council.

Article 5 — The State shall encourage and support the research and innovation of cosmetics, promote the application of advanced technologies in cosmetics, and improve the quality and safety level of cosmetics.

Article 6 — The pharmaceutical regulatory department under the State Council shall be responsible for the nationwide supervision and administration of cosmetics. Relevant departments under the State Council shall be responsible for the supervision and administration of cosmetics within the scope of their respective responsibilities. Pharmaceutical regulatory departments 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 regions.

Article 7 — Industry associations shall strengthen industry self-regulation, promote the construction of an integrity system, guide and urge cosmetics producers and operators to engage in production and operation activities in accordance with the law, and promote the healthy development of the cosmetics industry.

Chapter II — Cosmetic Ingredients and Products

Article 8 — Cosmetic ingredients shall comply with the mandatory national standards and technical specifications. Cosmetic ingredients shall be safe and shall not cause harm to human health.

Article 9 — The State shall implement classified management of cosmetic ingredients. Cosmetic ingredients shall be divided into new cosmetic ingredients and existing cosmetic ingredients. "New cosmetic ingredients" means cosmetic ingredients that are used within the territory of China for the first time. The State shall implement a registration or filing management system for new cosmetic ingredients.

Article 10 — New cosmetic ingredients with a relatively high risk, such as preservatives, sunscreens, colorants, hair dyes, and whitening agents, shall be subject to registration management. Other new cosmetic ingredients shall be subject to filing management.

Article 11 — A registrant or filer of a new cosmetic ingredient shall conduct safety assessments on the new cosmetic ingredient, entrust a professional institution to conduct toxicological tests, and, after the new cosmetic ingredient is marketed, continue to monitor and evaluate the safety of its use.

Article 12 — The State shall implement a registration or filing management system for cosmetics. Special cosmetics shall be subject to registration management before marketing, and general cosmetics shall be subject to filing management before marketing.

Article 13 — A cosmetic registrant or filer shall have the capability to assume primary responsibility for the quality and safety of cosmetics. Cosmetic registrants and filers shall carry out safety assessments on cosmetics and be responsible for the quality and safety of cosmetics.

Article 14 — A cosmetic registrant or filer applying for registration or filing shall submit the following materials: (1) basic information of the registrant or filer; (2) product name, formula, and implementation standards; (3) product label samples; (4) product inspection report; (5) product safety assessment materials. The product safety assessment materials shall include the safety assessment of the product and the product's technical requirements.

Article 15 — Cosmetic labels shall comply with the provisions of laws, regulations, and mandatory national standards, and the contents shall be truthful, complete, and accurate. Cosmetic labels shall be in the standard Chinese language. Imported cosmetics may be labeled in both Chinese and foreign languages.

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Article 16 — Cosmetic labels shall indicate: (1) product name and special cosmetic registration certificate number or general cosmetic filing number; (2) name, address, and contact information of the registrant, filer, or consignee; (3) name and address of the manufacturer and production license number; (4) implementation standard number of the product; (5) full list of ingredients; (6) net content; (7) usage period or production date and shelf life; (8) necessary safety warnings. The advertising and promotion of cosmetics shall be truthful and lawful and shall not contain false or misleading content.

Chapter III — Production and Operation

Article 17 — Cosmetic manufacturers shall obtain a cosmetics production license. An application for a cosmetics production license shall be filed with the pharmaceutical regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government where the applicant is located. The pharmaceutical regulatory department shall examine and make a decision on whether to grant the license in accordance with the law.

Article 18 — Cosmetic manufacturers shall organize production in accordance with the quality management standards for cosmetics production. Cosmetic manufacturers shall establish production quality management systems and ensure that the entire process of cosmetics production activities meets the statutory requirements.

Article 19 — Cosmetic manufacturers shall not: (1) produce cosmetics using cosmetics ingredients that are prohibited from use, or cosmetics ingredients that have not been registered or filed; (2) produce cosmetics without a cosmetics production license; (3) produce special cosmetics without a registration certificate; (4) produce general cosmetics without filing; (5) produce cosmetics that do not meet the mandatory national standards or technical specifications; (6) produce cosmetics beyond the approved scope of production.

Article 20 — The quality and safety person in charge of a cosmetics manufacturer shall have professional knowledge and relevant experience in the quality and safety of cosmetics and shall be responsible for product quality and safety management.

Article 21 — Cosmetic operators shall establish and implement a purchase inspection and record system, check the relevant certificates for cosmetics purchased, and keep relevant records. The retention period for purchase inspection records shall be no less than two years after the expiration date of the product.

Article 22 — Cosmetic operators shall not: (1) sell cosmetics that have expired, deteriorated, or failed quality tests; (2) alter the content of cosmetic labels; (3) sell cosmetics produced by manufacturers without a cosmetics production license; (4) sell special cosmetics without a registration certificate or general cosmetics without filing; (5) sell cosmetics that have been recalled by the pharmaceutical regulatory department; (6) sell cosmetics by privately packaging them or preparing and repackaging bulk cosmetics.

Article 23 — Cosmetics operators engaged in the centralized trading market of cosmetics or operators of cosmetics e-commerce platforms shall fulfill the obligations of real-name registration, daily inspection, and reporting of illegal activities.

Article 24 — Imported cosmetics shall comply with the laws, regulations, and mandatory national standards of China. Imported special cosmetics shall be subject to registration management, and imported general cosmetics shall be subject to filing management.

Article 25 — Overseas consignees of imported cosmetics shall register with the pharmaceutical regulatory department under the State Council. A consignee shall establish a product traceability system, assume primary responsibility for the quality and safety of imported cosmetics, and ensure that imported cosmetics meet the requirements of Chinese laws and regulations.

Chapter IV — Supervision and Administration

Article 26 — The pharmaceutical regulatory department shall implement classified supervision on cosmetics manufacturers based on risk levels, and determine the frequency of supervision and inspection.

Article 27 — The pharmaceutical regulatory department shall carry out random inspections of cosmetics and promptly publish the inspection results. Where cosmetics fail random inspections, the pharmaceutical regulatory department shall order the manufacturers or operators involved to immediately cease production and sale, recall the relevant products, and take necessary risk control measures.

Article 28 — Where there is evidence that cosmetics may have defects that endanger human health, the cosmetic manufacturer shall promptly recall the cosmetics that have already been marketed. The manufacturer shall report the recall and disposition to the pharmaceutical regulatory department.

Article 29 — The State shall establish a cosmetics adverse reaction monitoring system. Cosmetic registrants and filers shall carry out monitoring of adverse reactions and promptly report adverse reactions.

Article 30 — The pharmaceutical regulatory department shall establish a credit profile for cosmetics producers and operators, and increase the frequency of supervision and inspection for producers and operators with bad credit records.

Chapter V — Legal Liability

Article 31 — Where special cosmetics are produced or imported without registration, or new cosmetic ingredients are produced or imported with relatively high risk without registration, the pharmaceutical regulatory department shall confiscate the illegal gains, and the illegally produced or imported cosmetics, and impose a fine of not less than five times but not more than 20 times the value of the goods. If the circumstances are serious, the production license shall be revoked.

Article 32 — Where cosmetics are produced or imported without filing, the pharmaceutical regulatory department shall order rectification, confiscate illegal gains, and impose a fine of not less than 10,000 yuan but not more than 50,000 yuan. If the circumstances are serious, the production license shall be revoked.

Article 33 — Where cosmetics are produced or operated in violation of these Regulations, causing damage to consumers' health, the producer or operator shall bear civil liability for compensation in accordance with the law. Where the conduct constitutes a crime, criminal liability shall be pursued in accordance with the law.

Article 34 — Where cosmetics labels do not comply with the provisions of these Regulations, the pharmaceutical regulatory department shall order rectification and impose a fine of not less than 10,000 yuan but not more than 50,000 yuan on the producer or operator. If the circumstances are serious, the production license shall be revoked.

Article 35 — Where cosmetics advertising or promotion contains false or misleading content, the market regulatory department shall impose penalties in accordance with the Advertising Law of the People's Republic of China and other relevant laws and regulations.

Chapter VI — Supplementary Provisions

Article 36 — These Regulations shall not apply to toothpaste. The administration of toothpaste shall be governed by relevant provisions to be separately formulated by the pharmaceutical regulatory department under the State Council.

Article 37 — The supervision and administration of soap products shall be governed by the provisions of the Regulations for the Implementation of the Standardization Law of the People's Republic of China and other relevant laws and regulations.

Article 38 — These Regulations shall be subject to interpretation by the State Administration for Market Regulation and the National Medical Products Administration.

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Article 39 — These Regulations shall come into force on January 1, 2021. The Regulations on the Hygiene Supervision of Cosmetics promulgated by the State Council on November 13, 1989, are repealed simultaneously.

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