Regulation on the Supervision and Administration of Cosmetics[1]

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Chapter I: General Provisions

Article 1

This Regulation is formulated in order to regulate cosmetic production and business activities, strengthen cosmetic supervision and administration, ensure the quality and safety of cosmetics, protect consumers' health, and promote the healthy development of the cosmetics industry.

Article 2

Those engaging in cosmetic production and business activities as well as their supervision and administration within the territory of the People's Republic of China shall comply with this Regulation.

Article 3

The cosmetics referred to in this Regulation are daily chemical industrial products that are applied to the surface of the human body (such as skin, hair, nails, lips, etc.) by means of smearing, spraying, or other similar methods, for the purposes of cleaning, protecting, beautifying, or modifying.

Article 4

The State implements classified management of cosmetics and cosmetic raw materials based on the degree of risk.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

Cosmetics are divided into special cosmetics and ordinary cosmetics. The State implements registration management for special cosmetics and filing (recordation) management for ordinary cosmetics.

Cosmetic raw materials are divided into new raw materials and used raw materials. The State implements registration management for new raw materials with relatively high risk and filing management for other new cosmetic raw materials.

Article 5

The drug supervision and administration department under the State Council is responsible for the national supervision and administration of cosmetics. Relevant departments under the State Council are responsible for supervision and administration of cosmetics within the scope of their respective duties. Departments responsible for drug supervision and administration under the people's governments at or above the county level are responsible for the supervision and administration of cosmetics within their respective administrative areas. Relevant departments under the people's governments at or above the county level are responsible for supervision and administration of cosmetics within the scope of their respective duties.

Article 6

Cosmetic registrants and filers are responsible for the quality, safety, and efficacy claims of cosmetics. Cosmetic producers and operators shall conduct production and business activities in accordance with laws, regulations, mandatory national standards, and technical specifications, strengthen management, uphold integrity and self-discipline, and ensure the quality and safety of cosmetics.

Article 7

Cosmetic industry associations shall strengthen industry self-discipline, urge and guide cosmetic producers and operators to conduct production and business activities in accordance with the law, and promote the construction of industry integrity.

Article 8

Consumer associations and other consumer organizations shall supervise, in accordance with the law, acts that violate the provisions of this Regulation and harm the lawful rights and interests of consumers.

Article 9

The State encourages and supports research and innovation in cosmetics to meet consumer demand, promotes brand building in cosmetics, and gives full play to the leading role of brands. The State protects the lawful rights and interests of entities and individuals engaged in research and innovation in cosmetics. The State encourages and supports cosmetic producers and operators to adopt advanced technologies and advanced management practices to improve the quality and safety of cosmetics. It also encourages and supports the application of modern scientific and technological achievements, in combination with China's traditional advantageous programs and characteristic plant resources, in the research and development of cosmetics.

Article 10

The State strengthens the informatization construction of cosmetic supervision and administration, improves the level of online government services, facilitates the processing of administrative licenses and filings related to cosmetics, and promotes the sharing of supervision and administration information.

Chapter II: Raw Materials and Products

Article 11

Raw materials that are used for the first time in cosmetics within the territory of China, whether natural or synthetic, are deemed new cosmetic raw materials. New cosmetic raw materials with functions such as preservation, sun protection, coloring, hair dyeing, freckle removal and whitening may be used only after being registered with the drug supervision and administration department under the State Council. Other new cosmetic raw materials shall be filed before use with the drug supervision and administration department under the State Council. The drug supervision and administration department under the State Council may adjust the scope of new cosmetic raw materials subject to registration management based on scientific research and shall implement it after approval by the State Council.

Article 12

Applicants for registration or filing of new cosmetic raw materials shall submit the following materials:

1-The name, address, and contact information of the registrant or filer;

2- A research report on the new raw material;

3- Research materials such as preparation processes, stability, and quality control standards of the new raw material;

4-Safety assessment materials for the new raw material. Registrants and filers shall be responsible for the authenticity and scientific validity of the materials submitted.

Article 13

The drug supervision and administration department under the State Council shall, within 3 working days from the date of acceptance of the application for registration of new cosmetic raw materials, forward the application materials to the technical review institution. The technical review institution shall complete the technical review within 90 working days from the date of receipt of the application materials and submit a review opinion to the drug supervision and administration department under the State Council. The department shall make a decision within 20 working days from the date of receipt of the review opinion. If the application meets the requirements, registration shall be approved and a registration certificate issued. If the application does not meet the requirements, registration shall be denied and reasons shall be provided in writing.

Filers of new cosmetic raw materials shall complete the filing by submitting the required materials via the online government service platform of the drug supervision and administration department under the State Council.

The department shall, within 5 working days from the date of approval of the registration or submission of the filing materials, disclose relevant registration or filing information to the public.

Article 14

Within three years after the registered or filed new cosmetic raw material is put into use, the registrant or filer shall report annually to the drug supervision and administration department under the State Council on its usage and safety status. If safety problems exist, the department shall cancel the registration or filing. If no safety problems occur within three years, the raw material will be included in the catalogue of used cosmetic raw materials formulated by the drug supervision and administration department under the State Council.

Before inclusion into the catalogue, such raw materials will continue to be managed as new raw materials.

Article 15

The list of prohibited raw materials for cosmetics shall be formulated and published by the drug supervision and administration department under the State Council.

Article 16

Cosmetics used for hair dyeing, perming, freckle removal and whitening, sun protection, hair loss prevention, and those claiming new functions are special cosmetics. Cosmetics other than special cosmetics are ordinary cosmetics. The drug supervision and administration department under the State Council shall formulate and publish classification rules and a classification catalogue for cosmetics based on factors such as the claimed efficacy, site of application, product form, and intended user group.

Article 17

Special cosmetics may only be produced or imported after being registered with the drug supervision and administration department under the State Council. Domestic ordinary cosmetics shall be filed with the drug supervision and administration department of the province, autonomous region, or municipality directly under the central government where the filer is located before being marketed. Imported ordinary cosmetics shall be filed with the drug supervision and administration department under the State Council before import.

Article 18

Cosmetic registration applicants and filers shall meet the following conditions:

1-Be legally established enterprises or other organizations;

2-Have a quality management system suitable for the products subject to registration or filing;

3-Have the capability to monitor and evaluate adverse reactions of cosmetics.

Article 19

To apply for registration of special cosmetics or file ordinary cosmetics, the following materials shall be submitted:

1-Name, address, and contact information of the applicant/filer;

2-Name, address, and contact information of the manufacturer;

3- Product name;

4- Product formula or full ingredient list;

5- Standards applied to the product;

6- Sample of product label;

7-Product test report;

8-Product safety assessment materials.

For first-time applications or filings, proof of compliance with Article 18 of this Regulation must be submitted. For imported cosmetics, documents proving that the product has been marketed in the country/region of production and that the overseas manufacturer complies with cosmetic production quality standards must be submitted. If the product is manufactured exclusively for export to China and cannot provide such proof, it must submit research and test materials

targeted at Chinese consumers. Applicants and filers shall be responsible for the authenticity and scientific validity of submitted materials.

Article 20

The drug supervision and administration department under the State Council shall review special cosmetic registration applications according to the registration review procedures in Article 13. If the application meets requirements, registration shall be approved and a certificate for special cosmetics issued; if not, registration shall be denied with written explanation. If there are substantial changes in production process or efficacy claims of a registered special cosmetic, the registrant shall apply for change of registration with the original registration department. Filing of ordinary cosmetics is completed upon submission of the required materials via the online government service platform. Drug supervision and administration departments at or above the provincial level shall publicly announce registration and filing information within 5 working days from the date of registration approval or filing submission.

Article 21

Prior to the registration or filing of new raw materials and cosmetics, the applicant shall independently or entrust a professional institution to conduct safety assessment. Personnel engaged in safety assessment shall have relevant professional knowledge related to cosmetic quality and safety and at least five years of relevant work experience.

Article 22

Cosmetic efficacy claims must have sufficient scientific evidence. Registrants and filers shall publish abstracts of the literature, research data, or product efficacy evaluation supporting the claims on the designated website of the drug supervision and administration department under the State Council, and accept public supervision.

Article 23

Foreign cosmetic registrants and filers shall designate an enterprise legal person within China to handle registration or filing and assist with adverse reaction monitoring and product recall.

Article 24

The validity period of a special cosmetic registration certificate is five years. To renew it, an application shall be submitted at least 30 working days before expiration. Except for circumstances in the second paragraph of this Article, the department shall decide before the certificate expires. If no decision is made within the time limit, it shall be deemed as approval for renewal.

Renewal shall not be approved in the following cases:

1-The registrant fails to submit the application within the prescribed time;

2-Mandatory national standards or technical specifications have been revised, and the product fails to meet the new standards/specifications.

Article 25

The drug supervision and administration department under the State Council is responsible for proposing, organizing, drafting, soliciting opinions, and conducting technical review of mandatory national standards for cosmetics. The national standardization administrative department under the State Council is responsible for the project approval, coding, and external notification of mandatory national standards for cosmetics.

Texts of national cosmetic standards shall be open to the public free of charge. Cosmetics shall comply with mandatory national standards.

Enterprises are encouraged to formulate corporate standards stricter than the national mandatory standards.

Chapter III: Production and Operation

Article 26

Entities engaging in cosmetic production activities shall meet the following conditions:

1-Be a legally established enterprise;

2-Possess production premises, environmental conditions, and facilities suitable for the cosmetics being produced;

3-Employ technical personnel appropriate for the production of such cosmetics;

4-Have inspection personnel and equipment capable of testing the produced cosmetics;

5-Establish quality and safety management systems to ensure cosmetic product safety.

Article 27

Entities intending to produce cosmetics shall apply to the drug regulatory department of the provincial, autonomous region, or municipal government where they are located. They must submit documentation proving compliance with the requirements set forth in Article 26 and bear responsibility for the authenticity of the submitted materials.

The provincial-level drug regulatory authority shall review the application materials and conduct on-site inspections. Within 30 working days of accepting the application, they must decide

whether to approve the license. If the conditions are met, a Cosmetics Production License shall be granted; otherwise, the applicant will be notified in writing with reasons for denial.

The Cosmetics Production License is valid for five years. Renewal shall be handled in accordance with the Administrative Licensing Law of the People's Republic of China.

Article 28

Cosmetics registrants or filers may manufacture cosmetics themselves or contract production to other enterprises. When contracting production, the registrant or filer shall entrust an enterprise that holds a valid cosmetics production license. They must supervise the manufacturing activities of the entrusted manufacturer (hereafter referred to as the "contract manufacturer") to ensure compliance with legal requirements. The contract manufacturer must operate in accordance with laws, regulations, mandatory national standards, technical specifications, and contractual obligations. They are responsible for production activities and shall cooperate with oversight by the registrant or filer.

Article 29

Cosmetics registrants, filers, and contract manufacturers shall comply with the Cosmetics Good Manufacturing Practice (GMP) as established by the national drug regulatory department. They shall implement a quality management system covering: supplier evaluation, raw material acceptance, production and quality control, equipment management, product testing and retention sample management.

They must manufacture in accordance with the technical requirements specified in the product registration or filing documentation.

Article 30

Cosmetic ingredients and packaging materials that come into direct contact with cosmetics shall meet mandatory national standards and technical specifications. It is prohibited to use expired, discarded, or recycled cosmetics or cosmetic ingredients for production.

Article 31

Cosmetic registrants, recordation entities, and entrusted manufacturers shall establish and implement the recording system for checking purchased cosmetic raw materials and packaging materials that directly contact cosmetics and the product sales recording system. The checking records on purchased goods and product sales records shall be true, complete and traceable, and be preserved for not less than one year after the expiration of the product shelf life; if the product shelf life is less than one year, the records shall be kept for not less than two years. Cosmetics may not be marketed until they have passed the ex-factory inspections.

Article 32

Cosmetics registrants, filers, and contract manufacturers must appoint a person responsible for quality and safety who oversees product release and quality assurance. This person shall have relevant professional knowledge and at least 5 years of experience in cosmetics production or quality management.

Article 33

These entities must establish and enforce health management systems for personnel. Individuals with diseases identified by the national health authority as affecting cosmetic safety are prohibited from directly engaging in cosmetic production.

Article 34

Cosmetic registrants, filers, and entrusted manufacturers shall conduct regular self-inspections regarding their compliance with the Good Manufacturing Practice (GMP) requirements for cosmetics. If any changes in production conditions result in non-compliance with GMP requirements, immediate corrective actions shall be taken. Where such changes may affect the safety or quality of cosmetics, production shall be immediately suspended, and the situation shall be reported to the drug regulatory department of the provincial, autonomous region, or municipal government where the enterprise is located.

Article 35

Cosmetic products must carry a label on the smallest sales unit. Labels shall comply with laws, administrative regulations, and mandatory national standards. The content must be truthful, complete, and accurate. Imported cosmetics may use a direct Chinese label or an affixed Chinese label, but affixed labels must match the original label content exactly.

Article 36

Cosmetic labels must indicate the following:

1-Product name, registration certificate number for special cosmetics;

2-Name and address of the registrant, filer, and contract manufacturer;

3-Production license number;

4-Standard implementation number;

5-Full ingredient list;

6-Net content;

7-Expiration date, usage instructions, and necessary safety warnings;

8-Other information required by laws, regulations, or standards.

Article 37

The following are prohibited on cosmetic labels:

1-Claims (explicit or implicit) of medical efficacy;

2-False or misleading information;

3-Content violating public order and decency;

4-Any other content prohibited by laws or regulations.

Article 38

Cosmetics distributors must establish and implement purchase inspection and record systems. They shall verify the supplier's business license, product registration or filing status, and certificate of product quality, and retain the records.

The retention period shall comply with Article 31. Distributors are not allowed to formulate or mix cosmetics themselves.

Article 39

Cosmetic producers and distributors shall store and transport cosmetics according to relevant laws, regulations, and labeling instructions. They must regularly inspect products and promptly handle any that are deteriorated or expired.

Article 40

Operators of centralized trading markets for cosmetics and organizers of exhibition and sales fairs shall review the business entity registration certificates of cosmetic operators entering such venues and assume responsibility for their management. They shall conduct regular inspections of these operators. Upon discovering any violations of this Regulation, they shall take immediate corrective actions and report such violations to the drug regulatory authority at the county level where the venue is located.

Article 41

Operators of e-commerce platforms shall implement real-name registration for cosmetic operators on their platforms and assume responsibility for their management. Upon discovering any violations of this Regulation by platform-based cosmetic operators, they shall take timely action to stop such violations and report them to the drug regulatory authority of the province, autonomous region, or centrally administered municipality where the e-commerce platform operator is located. If any serious violations are found, the platform operator shall immediately cease providing e-commerce services to the violating cosmetic operator.

Cosmetic operators on the platform shall disclose complete, truthful, accurate, and timely information regarding the cosmetics they operate.

Article 42

Institutions such as beauty salons and hotels that use cosmetics in their operations or provide them to consumers shall fulfill the obligations imposed on cosmetic operators under this Regulation.

Article 43

Cosmetic advertisements shall be truthful and lawful.

Cosmetic advertisements shall not explicitly or implicitly claim that the product possesses medical efficacy. They must not contain false or misleading content, nor may they deceive or mislead consumers.

Article 44

Where a cosmetic registrant or filer discovers that a cosmetic product has a quality defect or other issue that may pose a threat to human health, they shall immediately cease production, recall products that have already been marketed, and notify relevant operators and consumers to stop distribution and use. They shall document the recall and notification process. The registrant or filer shall take remedial actions for the recalled products, including harmless disposal or destruction, and report the recall and disposal details to the drug regulatory authority of the relevant province, autonomous region, or centrally administered municipality.

Entrusted manufacturers or cosmetic operators who discover that the cosmetics they produce or operate are subject to the circumstances described in the preceding paragraph shall immediately stop production or distribution and notify the relevant registrants or filers. The registrants or filers shall promptly carry out the recall.

Where the drug regulatory authority discovers, during supervision and inspection, that a cosmetic product meets the conditions stated in the first paragraph, it shall notify the registrant or filer to implement a recall and inform the entrusted manufacturer and cosmetic operator to cease production or distribution.

When a recall is initiated by the registrant or filer, entrusted manufacturers and cosmetic operators shall provide their full cooperation.

If the registrant, filer, entrusted manufacturer, or operator fails to implement the recall or cease production or distribution as required under this Article, the drug regulatory authority shall order them to do so.

Article 45

Entry-exit inspection and quarantine agencies shall conduct inspections on imported cosmetics in accordance with the *Law of the People's Republic of China on Import and Export Commodity Inspection*. Products that fail inspection shall not be allowed entry.

Importers shall verify whether the cosmetics intended for importation have been duly registered or filed and whether they comply with this Regulation and the mandatory national standards and technical specifications. Products failing such verification shall not be imported.

Importers shall maintain truthful records of information related to imported cosmetics. The retention period for such records shall comply with the provisions in the first paragraph of Article 31 of this Regulation.

Exported cosmetics shall comply with the standards or contractual requirements of the importing country (or region).

Chapter IV: Supervision and Administration

Article 46

Departments responsible for drug supervision and administration shall have the authority to take the following measures when conducting supervision and inspection of cosmetics production and operation:

1-Enter production and business premises for on-site inspections;

2-Conduct sampling and testing of cosmetics being produced or marketed;

3-Review and copy relevant contracts, invoices, account books, and other related materials;

4-Seal or seize cosmetics and their raw materials, as well as packaging materials that come into direct contact with cosmetics, which do not conform to mandatory national standards or technical specifications, or are suspected to pose a risk to human health, and tools or equipment suspected of being used in illegal production or operation;

5-Seal sites where illegal production or operation activities are being conducted.

Article 47

When conducting supervision and inspection of cosmetics production and operation, there shall be no fewer than two supervisory and inspection personnel, who must present their law enforcement credentials. Supervisory and inspection personnel shall maintain confidentiality regarding any trade secrets of the inspected entities that they learn during the inspection. Inspected entities shall cooperate with the supervision and inspection and must not conceal any relevant information.

Departments responsible for drug supervision and administration shall record the supervision and inspection process and outcomes, which must be signed by the supervisory personnel and the person in charge of the inspected entity. If the person in charge refuses to sign, such refusal shall be noted.

Article 48

Drug supervision and administration departments at or above the provincial level shall organize sampling and testing of cosmetics. For cosmetics that are frequently reported or found to have issues during routine inspections, the responsible departments may conduct special sampling and testing. Sampling and testing shall be conducted at the expense of the supervising authorities, with such costs included in the corresponding level of government's budget. Results of sampling and testing shall be made public in accordance with regulations.

Article 49

Cosmetics testing institutions must obtain accreditation in accordance with national certification and accreditation regulations before conducting testing activities. Accreditation requirements for cosmetics testing institutions shall be formulated by the State drug regulatory authority and the State market regulatory authority. Testing protocols and standards for cosmetics, as well as the management of reference standards, shall be formulated by the State drug regulatory authority.

Article 50

For cosmetics suspected of adulteration or containing prohibited raw materials, where inspection cannot be conducted using national standard testing items and methods, the State drug regulatory authority may formulate supplementary testing items and methods. Such supplementary methods may be used for sampling inspection, investigation of quality and safety incidents, and handling of adverse reactions related to cosmetics.

Article 51

Where a cosmetics producer or operator disagrees with the inspection conclusion obtained under these Regulations, it may, within 7 working days from receipt of the inspection conclusion, apply for reinspection to the department that conducted the sampling or its superior drug regulatory authority. The department receiving the application shall randomly select a

reinspection institution from the published list to conduct the reinspection. The reinspection result issued by the reinspection institution shall be the final inspection conclusion. The reinspection institution must not be the same as the initial inspection institution. The list of reinspection institutions shall be published by the State drug regulatory authority.

Article 52

The State shall establish a cosmetics adverse reaction monitoring system. Cosmetics registrants and filers shall monitor adverse reactions of marketed cosmetics, conduct timely evaluations, and report such reactions to the adverse reaction monitoring institutions in accordance with the regulations of the State drug regulatory authority. Contract manufacturers, cosmetics operators, and medical institutions that discover suspected adverse reactions related to cosmetics shall report them. Other organizations and individuals are encouraged to report suspected adverse reactions to the adverse reaction monitoring institutions or the drug regulatory departments.

Adverse reaction monitoring institutions are responsible for collecting, analyzing, and evaluating adverse reaction data, and shall submit recommendations to drug regulatory authorities.

Cosmetics producers and operators shall cooperate with adverse reaction monitoring institutions and drug regulatory departments in investigations. "Adverse reaction" refers to pathological changes of the skin or its appendages, or damage to other parts or the entire human body, caused by normal use of cosmetics.

Article 53

The State shall establish a cosmetics safety risk monitoring and assessment system to monitor and assess risk factors that affect cosmetics quality and safety, providing a scientific basis for the formulation of control measures, standards, and for conducting sampling inspections.

The national risk monitoring plan shall be developed, published, and organized by the State drug regulatory authority. The plan shall specify key product types, indicators, and geographic regions to be monitored.

The State drug regulatory authority shall establish a risk information exchange mechanism, and organize communication among producers, testing institutions, industry associations, consumer associations, and media outlets on cosmetics safety risks.

Article 54

For cosmetics that cause harm to human health or are suspected of posing such risks, the responsible drug regulatory departments may order an immediate suspension of production or operation and issue safety warnings. In the case of imported cosmetics, the national entry-exit inspection and quarantine department may suspend imports.

Article 55

When scientific research developments lead to a reassessment of the safety of cosmetics or cosmetic raw materials, or when evidence suggests possible defects, drug regulatory departments at or above the provincial level may require registrants or filers to conduct a safety re-evaluation, or may organize such re-evaluation directly. If re-evaluation results indicate that safety cannot be ensured, the original registration shall be revoked, or the filing shall be canceled.

The State drug regulatory authority shall include such raw materials in the list of substances prohibited for use in cosmetics production and announce them publicly.

Article 56

Departments responsible for drug supervision shall promptly disclose information regarding administrative licensing, filings, routine inspections, and investigations into violations, in accordance with the law. When disclosing information, they must protect trade secrets. Such departments shall establish credit records for cosmetics producers and operators. Entities with poor credit records shall be subject to more frequent inspections; those with seriously bad credit shall be subject to joint disciplinary actions according to relevant regulations.

Article 57

Where there are safety hazards in cosmetics production or operation and no timely corrective measures are taken, the responsible drug regulatory departments may conduct accountability interviews with the legal representative or principal responsible person of the entity. The entity must immediately take corrective action to eliminate the hazard. The interview and corrective action shall be included in the entity's credit file.

Article 58

Drug regulatory departments shall publish their website addresses, email addresses, and telephone numbers to receive inquiries, complaints, and reports, and respond or handle them in a timely manner. Whistleblowers whose reports are verified shall be rewarded in accordance with relevant national regulations.

Chapter V: Legal Liability

Article 59

Under any of the following circumstances, the department responsible for drug supervision and administration shall confiscate the illegal gains, illegally produced or operated cosmetics, and

raw materials, packaging materials, tools, equipment, and other items specially used for the illegal production or operation; If the value of the illegally produced or operated cosmetics is less than 10,000 yuan, a fine of not less than 50,000 yuan and not more than 150,000 yuan shall be imposed; If the value is 10,000 yuan or more, a fine of not less than 15 times and not more than 30 times the value shall be imposed; If the circumstances are serious, order suspension of production and operation, cancel the filing by the filing department, or revoke the cosmetics permit by the original licensing department; No cosmetics filing or administrative licensing application submitted by the violator shall be accepted within 10 years; The legal representative or principal responsible person, directly responsible supervisors, and other directly responsible personnel of the violating entity shall be fined not less than 3 times and not more than 5 times of the income obtained from the entity in the previous year; They shall be permanently prohibited from engaging in cosmetics production and operation activities; If a crime is constituted, criminal responsibility shall be investigated in accordance with the law:

1-Engaging in cosmetics production activities without permission, or a cosmetics registrant or filer entrusting an enterprise that has not obtained the corresponding cosmetics production license to produce cosmetics;

2-Producing, operating, or importing special cosmetics that have not been registered;

3-Using raw materials prohibited for use in cosmetics, or using new raw materials that should be registered but have not been registered to produce cosmetics, illegally adding substances that may endanger human health to cosmetics, or using expired, discarded, or recycled cosmetics or raw materials to produce cosmetics.

Article 60

Under any of the following circumstances, the department responsible for drug supervision and administration shall confiscate the illegal gains, illegally produced or operated cosmetics, and raw materials, packaging materials, tools, equipment, and other items specially used for illegal production or operation; If the value of the illegally produced or operated cosmetics is less than 10,000 yuan, a fine of not less than 10,000 yuan and not more than 50,000 yuan shall be imposed; If the value is 10,000 yuan or more, a fine of not less than 5 times and not more than 20 times the value shall be imposed; If the circumstances are serious, order suspension of production and operation, cancel the filing by the filing department, or revoke the cosmetics permit by the original licensing department; The legal representative or principal responsible person, directly responsible supervisors, and other directly responsible personnel of the violating entity shall be fined not less than 1 time and not more than 3 times of the income obtained from the entity in the previous year; They shall be prohibited from engaging in cosmetics production and operation activities for 10 years; If a crime is constituted, criminal responsibility shall be investigated in accordance with the law:

1-Using raw materials or direct-contact packaging materials that do not comply with mandatory national standards or technical specifications to produce cosmetics, or using new raw materials that should be filed but have not been filed, or not using raw materials in accordance with mandatory national standards or technical specifications;

2-Producing or operating cosmetics that do not comply with mandatory national standards, technical specifications, or the technical requirements stated in the registration or filing documents;

3-Failing to organize production in accordance with the requirements of cosmetics Good Manufacturing Practice;

4-Altering the use period of cosmetics;

5-Cosmetics operators privately preparing cosmetics, or operating deteriorated or expired cosmetics;

6-Refusing to recall cosmetics after being ordered by the department responsible for drug supervision and administration or refusing to stop or suspend production or operation after being ordered by the said department.

Article 61

Under any of the following circumstances, the department responsible for drug supervision and administration shall confiscate the illegal gains, illegally produced or operated cosmetics, and may confiscate the raw materials, packaging materials, tools, equipment, and other items specially used for illegal production or operation; If the value of the illegally produced or operated cosmetics is less than 10,000 yuan, a fine of not less than 10,000 yuan and not more than 30,000 yuan shall be imposed; If the value is 10,000 yuan or more, a fine of not less than 3 times and not more than 10 times the value shall be imposed; If the circumstances are serious, order suspension of production and operation, cancel the filing by the filing department, or revoke the cosmetics permit by the original licensing department; The legal representative or principal responsible person, directly responsible supervisors, and other directly responsible personnel of the violating entity shall be fined not less than 1 time and not more than 2 times of the income obtained from the entity in the previous year; They shall be prohibited from engaging in cosmetics production and operation activities for 5 years:

1-Placing on the market, selling, or importing general cosmetics that have not been filed;

2-Failing to appoint a person responsible for quality and safety as required by these Regulations;

3-A cosmetics registrant or filer failing to supervise the production activities of the entrusted production enterprise;

4-Failing to establish and implement an employee health management system in accordance with these Regulations;

5-Producing or operating cosmetics with labels that do not comply with these Regulations.

If the labeling of the produced or operated cosmetics has defects that do not affect quality and safety and will not mislead consumers, the department responsible for drug supervision and administration shall order rectification; Refusal to rectify shall result in a fine of less than 2,000 yuan.

Article 62

Where an entity falls under any of the following circumstances, the department in charge of medical products administration shall order it to take corrective action, give it a warning, and impose a fine of not less than 10,000 yuan nor more than 30,000 yuan; and if the circumstances are serious, it shall be ordered to suspend production and business, and be fined not less than 30,000 yuan nor more than 50,000 yuan, and its legal representative or primary person in charge, directly responsible persons in charge and other directly liable persons shall be fined not less than 10,000 yuan nor more than 30,000 yuan:

1-It fails to publish a summary of the basis for cosmetic efficacy claims in accordance with this Regulation.

2-It fails to establish and implement the recording system for checking the purchased goods and the product sales recording system in accordance with this Regulation.

3- It fails to conduct self-examination of the implementation of the Good Manufacturing Practices for Cosmetics in accordance with this Regulation.

4-It fails to store and transport cosmetics in accordance with this Regulation.

5-It fails to monitor and report adverse cosmetic reactions in accordance with this Regulation, or fail to support the investigations of adverse cosmetic reactions conducted by adverse cosmetic reaction monitoring institution and the department in charge of medical products administration.

Importers that fail to record and save information on imported cosmetics in accordance with this Regulation shall be punished by the entry-exit inspection and quarantine institutions in accordance with the provisions of the preceding paragraph.

Article 63

If a registrant or recordation entity of new cosmetic raw materials fails to report information on the use and safety of such materials in accordance with this Regulation, the medical products administration under the State Council shall order rectification and impose a fine ranging from 50,000 yuan to 200,000 yuan. Where the circumstances are serious, the registration certificate for the new cosmetic raw material shall be revoked or the recordation canceled, and a fine between 200,000 yuan and 500,000 yuan shall be imposed.

Article 64

Where an entity provides false materials or engages in other fraudulent practices when applying for a cosmetics administrative license, the application shall be rejected. If the license has already

been granted, the issuing authority shall revoke it. The entity shall be barred from submitting cosmetic license applications for five years, and any illegal income and cosmetics that have been produced or imported shall be confiscated. Where the value of the cosmetics involved is less than 10,000 yuan, a fine between 50,000 yuan and 150,000 yuan shall be imposed. Where the value is 10,000 yuan or more, a fine of 15 to 30 times the value of the goods shall be imposed. The legal representative, primary person in charge, directly responsible persons, and other individuals directly liable shall be subject to a fine of three to five times their income from the entity in the previous year and be prohibited from engaging in cosmetics production and distribution for life.

Where a cosmetics license is forged, altered, leased, lent, or transferred, the relevant medical products authority or the original issuing department shall revoke the license and confiscate any illegal income. If the illegal income is less than 10,000 yuan, a fine between 50,000 yuan and 100,000 yuan shall be imposed. If the illegal income is 10,000 yuan or more, a fine of 10 to 20 times the illegal income shall be imposed. Where the act constitutes a violation of public security administration, the public security organs shall impose administrative penalties in accordance with the law. Where the act constitutes a criminal offense, criminal liability shall be pursued in accordance with the law.

Article 65

Where an entity submits false materials during the recordation process, the recordation authority shall cancel the recordation, refuse to accept further recordation applications from the entity for three years, and confiscate any illegal income and cosmetics that have been produced or imported. If the value of the cosmetics is less than 10,000 yuan, a fine between 10,000 yuan and 30,000 yuan shall be imposed. If the value is 10,000 yuan or more, a fine of three to ten times the value of the goods shall be imposed. Where the violation is serious, the entity may be ordered to suspend production or business operations, and its cosmetic production license may be revoked by the original issuing authority. The legal representative, primary person in charge, directly responsible persons, and other individuals directly liable shall be fined not less than one time and not more than two times their income from the entity in the previous year, and shall be prohibited from engaging in cosmetics production and distribution for a period of five years.

Where the recordation materials fail to meet the relevant requirements, the recordation department shall order the entity to take corrective action within a specified time limit. If the materials relate to the safety of cosmetics or new raw materials and still fail to meet the requirements, the department may also order the suspension of their sale and use. If corrective action is not taken within the specified time, the recordation shall be canceled.

If, after the cancellation of recordation, the entity continues to produce cosmetics with the new raw materials or continues to market or import general cosmetics, penalties shall be imposed in accordance with Articles 60 and 61 of this Regulation.

Article 66

Where the organizers of centralized cosmetic trading markets or trade fairs fail to fulfill their administrative responsibilities, including inspection, supervision, and reporting, in accordance with this Regulation, the medical products administration shall impose a fine between 20,000 yuan and 100,000 yuan. Where the circumstances are serious, the organizer shall be ordered to suspend operations, and a fine between 100,000 yuan and 500,000 yuan shall be imposed.

Article 67

Where an e-commerce platform operator fails to fulfill regulatory obligations such as real-name registration, enforcement, reporting, or the suspension of services as required by this Regulation, the medical products administrative department at the provincial, autonomous region, or municipal level shall impose penalties in accordance with the provisions of the E-Commerce Law of the People's Republic of China.

Article 68

Where a cosmetics business operator has fulfilled the obligations stipulated in these Regulations, such as inspection and record-keeping of purchased goods, and there is evidence proving that it was unaware that the purchased cosmetics did not comply with mandatory national standards, technical specifications, or the technical requirements specified in the cosmetics registration or recordation documents, the cosmetics in question shall be confiscated, but administrative penalties may be waived.

Article 69

Where cosmetics advertising violates the provisions of these Regulations, penalties shall be imposed in accordance with the *Advertising Law of the People's Republic of China*. Where false or misleading publicity is conducted through other means, penalties shall be imposed in accordance with relevant laws. Where a criminal offense is constituted, criminal liability shall be pursued in accordance with the law.

Article 70

Where the designated domestic enterprise legal person of an overseas cosmetics registrant or record-filer fails to assist in adverse reaction monitoring or in product recall, the drug regulatory department of the people's government at the provincial, autonomous region, or municipal level shall order it to make corrections, issue a warning, and impose a fine ranging from 20,000 yuan to 100,000 yuan; where circumstances are serious, a fine ranging from 100,000 yuan to

500,000 yuan shall be imposed, and the legal representative, principal responsible person, persons directly in charge, and other directly liable persons shall be prohibited from engaging in cosmetics production or operation for five years.

Where an overseas cosmetics registrant or record-filer refuses to implement an administrative penalty decision made in accordance with these Regulations, the import of its cosmetics shall be prohibited for ten years.

Article 71

Where a cosmetics testing institution issues a false test report, the certification and accreditation authority shall revoke its qualification certificate, deny any qualification application for ten years, confiscate the testing fees received, and impose a fine ranging from 50,000 yuan to 100,000 yuan. The legal representative, principal responsible person, directly responsible supervisors, and other directly liable persons shall be fined not less than one time and not more than three times the income obtained from the institution in the previous year, and may be subject to disciplinary actions such as demotion, dismissal, or expulsion according to law. People expelled shall be prohibited from engaging in cosmetics testing work for ten years. Where a criminal offense is constituted, criminal liability shall be pursued in accordance with the law.

Article 72

Where technical evaluation institutions for cosmetics, cosmetics adverse reaction monitoring institutions, or institutions responsible for cosmetics safety risk monitoring fail to perform their duties in accordance with these Regulations, resulting in major errors in technical review, adverse reaction monitoring, or safety risk monitoring, the drug regulatory department shall order corrections, issue a warning, and circulate a notice of criticism. Where serious consequences are caused, the legal representative, principal responsible person, directly responsible supervisors, and other directly liable persons shall be subject to disciplinary actions such as demotion, dismissal, or expulsion according to law.

Article 73

Where cosmetics manufacturers, operators, or testing institutions employ individuals who are legally prohibited from engaging in cosmetics production, operation, or testing, the drug regulatory department or other relevant departments shall order rectification and issue a warning. Where rectification is refused, the relevant entities shall be ordered to suspend production or operation, and their cosmetics licenses or qualification certificates shall be revoked.

Article 74

Under any of the following circumstances, where a violation of public security administration is constituted, the public security authority shall impose administrative penalties in accordance with the law. Where a criminal offense is constituted, criminal liability shall be pursued in accordance with the law:

1-Obstructing staff of drug regulatory departments from lawfully performing their duties;

2-Forging, destroying, concealing evidence, or hiding, transferring, selling, or damaging sealed or seized items.

Article 75

Where personnel of drug regulatory departments violate these Regulations by abusing their power, dereliction their duties, or engaging in favoritism or malpractice, disciplinary actions such as warnings, demerits, or serious demerits shall be imposed in accordance with the law. Where serious consequences are caused, demotion, dismissal, or expulsion shall be imposed in accordance with the law. Where a criminal offense is constituted, criminal liability shall be pursued in accordance with the law.

Article 76

Where violations of these Regulations cause personal injury, property damage, or other harm, liability for compensation shall be borne in accordance with the law.

Chapter VI: Supplementary Provisions

Article 77

Toothpaste shall be managed with reference to the provisions of these Regulations concerning ordinary cosmetics. After toothpaste record-filers conduct efficacy evaluation in accordance with national standards and industry standards, they may claim that toothpaste has effects such as anti-caries, inhibition of dental plaque, anti-dentin hypersensitivity, and alleviation of gum problems. The specific management measures for toothpaste shall be formulated by the drug regulatory department of the State Council and submitted to the market supervision department of the State Council for review and promulgation.

Soap is not subject to these Regulations; however, soap that claims special cosmetic efficacy shall be subject to these Regulations.

Article 78

For cosmetics registered before the implementation of these Regulations that are used for hair growth, hair removal, breast enhancement, body shaping, and deodorization, a transitional period of five years is set from the date of implementation of these Regulations. During the transitional period, such cosmetics may continue to be produced, imported, and sold. After the expiration of the transitional period, such cosmetics shall no longer be produced, imported, or sold.

Article 79

The technical specifications referred to in these Regulations mean supplementary technical requirements for the quality and safety of cosmetics formulated by the drug regulatory department of the State Council based on supervisory needs when mandatory national standards have not yet been established.

Article 80

These Regulations shall come into force on January 1, 2021. The "Regulations on Hygiene Supervision of Cosmetics" shall be repealed simultaneously.