



Measures for the Supervision and Administration of Production and Distribution of Cosmetics¹

Authority: **State Administration for Market Regulation**

Document Number: Order No. 46 of the State Administration for Market Regulation

Promulgation Date: August 2, 2021

Effective Date: January 1, 2022

Chapter I: General Provisions

Article 1

These Measures are formulated in accordance with the *Regulations on the Supervision and Administration of Cosmetics* for the purpose of regulating cosmetic production and business activities, strengthening the supervision and administration of cosmetics, and ensuring the quality and safety of cosmetics.

Article 2

These Measures shall be observed in the territory of the People's Republic of China when engaging in cosmetic production and business activities as well as the supervision and administration thereof.

Article 3

The National Medical Products Administration (NMPA) is responsible for the supervision and administration of cosmetics nationwide.

Departments responsible for drug supervision and administration under the local people's governments at the county level or above are responsible for the supervision and administration of cosmetics within their respective administrative regions.

Article 4

Cosmetic registrants and filers shall, in accordance with the law, establish a cosmetic production quality management system, fulfill obligations such as adverse reaction monitoring, risk control,

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





and product recall, and be responsible for the quality, safety, and efficacy claims of cosmetics. Cosmetic producers and operators shall engage in production and business activities in accordance with laws, regulations, rules, mandatory national standards, and technical specifications, strengthen internal management, uphold integrity and self-discipline, and ensure the quality and safety of cosmetics.

Article 5

The state implements a licensing system for cosmetic production. Anyone engaging in cosmetic production activities shall obtain a cosmetic production license in accordance with the law.

Article 6

Cosmetic producers and operators shall, in accordance with the law, establish systems such as incoming goods inspection records and product sales records to ensure product traceability.

Producers and operators are encouraged to adopt information technology to collect and preserve production and operation information and to establish a cosmetic quality and safety traceability system.

Article 7

The National Medical Products Administration shall strengthen the construction of information technology systems to facilitate public access to cosmetic-related information. Departments responsible for drug supervision and administration shall, in accordance with the law, promptly disclose information such as cosmetic production licenses, supervision and inspection, and administrative penalties.

Article 8

Departments responsible for drug supervision and administration shall give full play to the roles of industry associations, consumer associations and other consumer organizations, and news media, to promote the construction of an integrity system and to advance co-governance of cosmetic safety by society.

Chapter II: Production Licensing

Article 9

To apply for a cosmetic production license, the following conditions must be met:

1-It is an enterprise lawfully established;

2-It has production premises appropriate for the types, quantities, and licensed items of cosmetics to be produced, and the premises are kept at the required distance from toxic, hazardous locations, and other pollution sources;



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP

3-It has production facilities and equipment appropriate for the types, quantities, and licensed items of cosmetics to be produced, with a reasonable layout, and facilities and equipment for air purification, water treatment, etc., that meet specified requirements;

4-It has technical personnel appropriate for the types, quantities, and licensed items of cosmetics to be produced;

5-It has inspection personnel and equipment capable of inspecting the cosmetics produced and appropriate for the types and quantities of cosmetics;

6-It has a management system to ensure the quality and safety of cosmetics.

Article 10

Applicants for a cosmetic production license shall submit an application to the drug supervision and administration department of the province, autonomous region, or municipality directly under the central government where they are located, and provide documentary evidence that they meet the conditions specified in Article 9 of these Measures. Applicants shall be responsible for the authenticity of the submitted materials.

Article 11

The drug supervision and administration department of a province, autonomous region, or municipality directly under the central government shall handle cosmetic production license applications submitted by applicants as follows:

1-If the application does not legally require a license, it shall decide not to accept it and issue a notice of non-acceptance;

2-If the application is not within the jurisdiction of the drug supervision and administration department, it shall decide not to accept it and issue a notice of non-acceptance, and inform the applicant to apply to the relevant administrative authority;

3-If there are errors in the application materials that can be corrected on the spot, the applicant shall be allowed to correct them immediately and sign or stamp the correction with the correction date;

4-If the application materials are incomplete or do not conform to legal form, the applicant shall be informed all at once, either immediately or within 5 working days, of all the required supplementary materials and the time limit for submission. If not notified within the time limit, the application shall be deemed accepted from the date of receipt;

5-If the application materials are complete and conform to the legal form, or the applicant submits all supplementary materials as required, the application shall be accepted.

The drug supervision and administration department shall issue a notice of acceptance or non-acceptance. If the application is not accepted, the reasons shall be stated, and the applicant informed of their right to apply for administrative reconsideration or initiate administrative litigation in accordance with the law.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Article 12

The provincial-level drug supervision and administration department shall review the submitted materials, conduct an on-site inspection of the applicant's production premises, and decide within 30 working days from the date of acceptance whether to approve the application.

Article 13

Based on the results of the document review and on-site inspection, the provincial-level drug supervision and administration department shall make a decision: If the applicant meets the conditions, it shall approve the license and issue a Cosmetic Production License within 5 working days from the decision date; If the conditions are not met, a written decision of denial shall be made with reasons, and the applicant informed of their rights to administrative reconsideration or litigation.

The issue date of the license shall be the date on which the decision is made, and the license shall be valid for 5 years.

Article 14

The cosmetic production license includes a main copy and a duplicate copy, both of which have the same legal effect. The National Medical Products Administration is responsible for determining the format of the license. Provincial-level drug supervision and administration departments are responsible for the printing, issuance, and management of the licenses. Electronically issued licenses have the same legal validity as printed licenses.

Article 15

The Cosmetic Production License shall indicate: license number, name of the production enterprise, address and production site, unified social credit code, legal representative or person in charge, licensed production items, validity period, issuing authority, date of issuance
The duplicate copy shall also indicate any changes made to the license.

Article 16

Licensing items shall be categorized according to production processes, product forms, and uses into units such as general liquid, cream/emulsion, powder, aerosol and organic solvent, wax-based, toothpaste, soap-based and others.

The NMPA may adjust these categories based on the actual needs of cosmetic quality and safety supervision. If the enterprise meets conditions for producing children's skincare or eye care cosmetics, this must be specially noted in the license.

Article 17



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



If there are changes in the conditions of the license holder or in the information stated on the license during its validity period, the enterprise shall apply for a change with the original licensing authority.

Article 18

Where there is a change in the scope of production licensing items, changes in production facilities or equipment that may affect product quality and safety, or the construction, renovation, or expansion of workshops at the original site of the cosmetics production premises, the cosmetics manufacturer shall apply for a modification of the license with the original licensing drug regulatory authority before commencing production. Relevant materials pertaining to the change shall be submitted in accordance with the provisions of Article 10 of these Measures. The original licensing drug regulatory authority shall review the application and, within 30 working days from the date of accepting the modification application, decide whether to approve the modification and record the change in the annex of the cosmetics production license. If an on-site inspection is required, it shall be conducted in accordance with the provisions of Article 12 of these Measures.

If a comprehensive on-site inspection is required due to changes in production licensing items, and the inspection by the provincial, autonomous region, or municipal drug regulatory department confirms compliance with the requirements, a new cosmetics production license shall be issued. The license number shall remain unchanged, and the validity period shall be recalculated from the date of issuance.

Where a cosmetics manufacturer applies to add a production address within the same province, autonomous region, or municipality, the modification may be handled in accordance with the provisions of these Measures.

Article 19

If the enterprise's name, address, or legal representative/person in charge changes, it shall apply for a license change within 30 working days from the date of change. The authority must process the change within 3 working days from the date of acceptance. If the person is responsible for product safety or contact information changes, this must be reported within 10 working days.

Article 20

Where the validity period of a cosmetics production license expires and renewal is needed, the applicant shall apply for renewal to the drug regulatory authority of the province, autonomous region, or municipality directly under the central government where it is located, between 90 and 30 working days prior to the expiration date. The applicant shall undertake that it complies with the conditions for cosmetics production licensing as stipulated in these Measures and shall be responsible for the authenticity and legality of the submitted materials and undertakings. Applications for renewal submitted after the deadline shall not be accepted.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP

Article 21

The drug regulatory department of the province, autonomous region, or municipality directly under the central government shall, within 5 working days from receiving the renewal application, conduct a formal review of the submitted materials. If the materials meet the requirements, the application shall be accepted, and a new cosmetics production license shall be issued within 10 working days from the date of acceptance. The validity period of the new license shall be recalculated starting from the day after the original license expires.

Article 22

The drug regulatory authority of the province, autonomous region, or municipality directly under the central government shall supervise the application materials and undertakings submitted by enterprises whose licenses have been renewed. If the enterprise is found not to meet the licensing conditions stipulated in Article 9 of these Measures, the cosmetics production license shall be revoked in accordance with the law.

Article 23

Where a cosmetics production enterprise meets any of the following circumstances, the original licensing drug regulatory authority shall cancel its cosmetics production license in accordance with the law and publish the cancellation on a government website:

- 1-The enterprise voluntarily applies for cancellation;
- 2-The enterprise's legal entity is lawfully terminated;
- 3-The cosmetics production license expires and no application for renewal has been submitted;
- 4-The production license is lawfully withdrawn, revoked, or the license is legally revoked;
- 5-Other circumstances requiring cancellation under laws and regulations.

If, during the enterprise's application for license cancellation, the licensing authority determines that cancellation may affect the handling of pending cases, it may suspend the cancellation process.

Chapter III: Cosmetics Production

Article 24

The National Medical Products Administration (NMPA) shall formulate Good Manufacturing Practices (GMP) for cosmetics production, clarifying requirements for quality management departments and personnel, quality assurance and control, premises and equipment management, material and product management, production process management, and product sales management. Cosmetics registrants, filing entities, and contract manufacturers shall organize production in accordance with GMP requirements, establish a cosmetics production quality management system, and ensure its continuous and effective operation.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Workshops and other production premises shall not store or manufacture products that adversely affect the quality of cosmetics.

Article 25

Cosmetics registrants, filing entities, and contract manufacturers shall establish and implement management systems to ensure the quality and safety of cosmetics, including supplier qualification, raw material acceptance, production process and quality control, equipment management, product testing, and sample retention.

Article 26

Where a cosmetics registrant or filing entity entrusts production of cosmetics, they shall engage a production enterprise that has obtained the appropriate cosmetics production license. The registrant or filing entity shall supervise the entire production process and is responsible for the quality and safety of the commissioned cosmetics. The contract manufacturer must possess appropriate production conditions and organize production in accordance with laws, regulations, mandatory national standards, technical specifications, and contractual agreements. It shall be responsible for its production activities and accept the supervision of the entrusting party.

Article 27

Cosmetics registrants, filing entities, and contract manufacturers shall establish a quality and safety responsibility system and implement the primary responsibility for cosmetics quality and safety. The legal representative and principal person in charge of cosmetics registrants, filing entities, and contract manufacturers shall bear overall responsibility for quality and safety of cosmetics.

Article 28

The quality and safety responsible person shall assist the legal representative and principal person in charge of cosmetics registrants, filing entities, and contract manufacturers in assuming the following responsibilities for product quality and release management, in accordance with the cosmetics quality and safety responsibility system:

- 1-Establish and organize the implementation of the enterprise's quality management system, and enforce quality and safety responsibilities;
- 2-Review and manage product formulations, production processes, and material suppliers;
- 3-Manage material and product release;
- 4-Manage adverse reaction monitoring for cosmetics;
- 5-Supervise the production activities of contract manufacturers.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



The person responsible for quality and safety shall possess professional knowledge and legal understanding in fields related to cosmetics quality and safety, such as cosmetics, chemistry, chemical engineering, biology, medicine, pharmacy, food, public health, or law. They shall be familiar with relevant laws, regulations, rules, mandatory national standards, and technical specifications, and shall have at least five years of experience in cosmetics production or quality management.

Article 29

Cosmetics registrants, filing entities, and contract manufacturers shall establish and implement a health management system for employees and maintain health records for personnel. Health records shall be kept for no less than three years. Personnel directly engaged in cosmetics production shall undergo an annual health check-up. Those diagnosed with diseases that could adversely affect cosmetics quality and safety, as determined by the administrative health department under the State Council, shall not be allowed to directly participate in cosmetics production.

Article 30

Cosmetics registrants, filing entities, and contract manufacturers shall formulate annual training plans for employees, conduct training on cosmetics laws, regulations, rules, mandatory national standards, and technical specifications, and establish training records. Personnel in production and testing positions shall possess relevant knowledge and practical skills.

Article 30

Cosmetic registrants, filers, and entrusted production enterprises shall establish annual training plans for their personnel, and conduct training on cosmetics-related laws, regulations, rules, mandatory national standards, and technical specifications. They shall also establish training records. Production operators and inspection personnel shall possess the corresponding knowledge and practical operational skills.

Article 31

Cosmetics may only be marketed and sold after passing factory inspection.

Cosmetic registrants and filers shall retain samples of factory-released cosmetics and keep records in accordance with regulations. Retained samples shall be kept in their original sales packaging and in quantities sufficient for product quality testing. The retention period of samples shall not be less than 6 months after the expiration of the product's shelf life.

For entrusted production of cosmetics, the entrusted production enterprise shall also retain samples and keep records in accordance with the preceding paragraph.

Article 32



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Cosmetic registrants, filers, and entrusted production enterprises shall establish and implement a system for recording the inspection of incoming raw materials and packaging materials that directly contact cosmetics, as well as a product sales recording system. The records of incoming inspections and product sales shall be true, complete, and traceable, and shall be retained for no less than 1 year after the expiration of the product's shelf life. If the product shelf life is less than 1 year, the records shall be retained for no less than 2 years.

For entrusted production of cosmetics, the entrusted production enterprise may keep the records of incoming raw material inspections and packaging materials as stipulated above.

Article 33

Cosmetic registrants, filers, and entrusted production enterprises shall conduct an annual self-inspection of the implementation of Good Manufacturing Practices (GMP) for cosmetics. The self-inspection report shall include identified issues, product quality and safety assessments, corrective measures, and shall be retained for no less than 2 years.

If the self-inspection reveals that production conditions have changed and no longer comply with the requirements of cosmetic GMP, the cosmetic registrant, filer, or entrusted production enterprise shall immediately take corrective measures. If a potential impact on cosmetic quality and safety is identified, production shall be immediately suspended, and a report shall be submitted to the drug regulatory department of the province, autonomous region, or municipality where the enterprise is located. Production may only be resumed once risk factors affecting quality and safety have been eliminated. The provincial drug regulatory authority may organize on-site inspections as needed.

Article 34

If cosmetic registrants, filers, or entrusted production enterprises suspend production for more than one year, they must conduct a comprehensive self-inspection before resuming production. Production may only resume once compliance has been confirmed. The results of the self-inspection and corrective actions shall be reported to the provincial-level drug regulatory department within 10 working days from the date of resumption.

Article 35

The smallest sales unit of a cosmetic product shall bear a Chinese label. The label content shall be consistent with the sample label submitted during product registration or filing.

The name, ingredients, efficacy claims, and other labeling information must be truthful and legal. The label shall not explicitly or implicitly claim medical effects, nor may it contain false, misleading, or socially inappropriate content that violates laws or regulations. If the product name includes a trademark, it must also comply with relevant national trademark laws and regulations.

Article 36



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Cosmetic products intended for use by children must comply with laws, regulations, mandatory national standards, technical specifications, and Good Manufacturing Practices relating to children's cosmetic quality and safety. They must also be labeled in accordance with the requirements of the National Medical Products Administration.

Article 37

Where a cosmetic label contains minor defects that do not affect product quality or safety and are unlikely to mislead consumers, such cases may be determined as label flaws under Article 61, Paragraph 2 of the Cosmetics Supervision and Administration Regulation. Such defects include:

- 1-Non-standard font sizes, symbols, or numbers, or typographical errors such as extra, missing, or incorrect characters, or use of non-standard Chinese characters;
- 2-Non-standard formats or methods for indicating shelf life or net content;
- 3-Unclear labels that are difficult to recognize or read, or partial print loss, or labels that are poorly affixed;
- 4-Non-standard cosmetic ingredient names or ingredient listings not in descending order by concentration;
- 5-Other labeling violations that do not impact product quality or safety and are unlikely to mislead consumers.

Article 38

Cosmetic registrants, filers, and entrusted production enterprises shall take measures to avoid confusion between the physical characteristics or appearance of cosmetics and products such as food or medicine, in order to prevent accidental ingestion or misuse.

For the production or sale of toys, utensils, or other products intended for minors, legal warning statements must be included, and measures must be taken to prevent such products from being mistaken for children's cosmetics.

General cosmetics shall not claim efficacy related to special cosmetics.

Chapter IV: Cosmetics Business

Article 39

Cosmetics operators shall establish and implement a system for inspecting and recording incoming goods, verify the market entity registration certificates of direct suppliers, registration certificates for special cosmetics or filing information for ordinary cosmetics, and certificates of product quality inspection, and keep related documents. They shall truthfully record the cosmetics' names, registration certificate numbers for special cosmetics or filing numbers for ordinary cosmetics, expiration dates, net contents, purchase quantities, supplier names, addresses, contact information, purchase dates, and other relevant details.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Article 40

Cosmetics operators implementing unified distribution may have the headquarters uniformly establish and execute the incoming goods inspection and recording system, and carry out inspections and keep related documents in accordance with these measures. The headquarters shall ensure that its affiliated branches can provide relevant records and certificates for the cosmetics they operate.

Article 41

Beauty and hairdressing institutions, hotels, and the like that use cosmetics in their business services or provide cosmetics to consumers shall lawfully perform the obligations of cosmetics operators as stipulated in the Cosmetics Supervision and Administration Regulations and these measures.

Cosmetics used by beauty and hairdressing institutions in their operations and cosmetics provided to consumers by hotels and others shall comply with the requirements for the minimum sales unit label. Beauty and hairdressing institutions shall prominently display the sales packaging of the cosmetics they operate and use at their service locations to facilitate consumers' review of the full information on the cosmetics labels, and shall correctly use or guide consumers to correctly use cosmetics according to the cosmetics labels or instructions.

Article 42

The initiator of a centralized cosmetics trading market and the holder of an exhibition shall establish a management system that ensures the quality and safety of cosmetics and effectively implement it, assume the management responsibilities of cosmetics distributors that enter the market, urge the cosmetics distributors that enter the market to perform their obligations in accordance with the law, and organize one training on cosmetics quality and safety knowledge at a minimum every year or during the exhibition.

The initiator of a centralized cosmetics trading market and the holder of an exhibition shall create files of cosmetics distributors that enter the market, examine the market participant registration certificates of cosmetics distributors that enter the market, and truthfully record the name, contact information, domicile and other information on the distributors. The file information of the cosmetics distributors entering the market shall be verified and updated in a timely manner to ensure that it is authentic, accurate and complete, and the retention period shall not be less than two years after the distributors stop business operation in the market.

A holder of a cosmetics exhibition shall report the time, location, and other basic information on the fair to the medical products administrative administration at the county level at the place where it is located before the exhibition is held.

Article 43

Centralized cosmetics trading market operators and exhibition organizers shall establish inspection systems for cosmetics, conduct inspections of operators' operating conditions and



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



cosmetics quality and safety status. If they discover that cosmetics operators violate the Cosmetics Supervision and Administration Regulations or these measures, they shall promptly stop such violations, handle the matter according to market management regulations or agreements signed with operators, and report to the county-level drug supervision department.

It is encouraged that centralized cosmetics trading market operators and exhibition organizers establish systems for cosmetics sampling inspections and unified sales voucher formats.

Article 44

Cosmetics operators on e-commerce platforms and those operating cosmetics through self-built websites or other online services shall fully, truthfully, and accurately disclose information consistent with cosmetics registration or filing data on the main page of their business activities.

Article 45

E-commerce platform operators of cosmetics shall conduct real-name registration for cosmetics operators applying to enter the platform, require submission of true identity, address, and contact information, verify and record these details, establish registration archives, and verify and update such information at least every six months. The platform operators shall retain the identity information of cosmetics operators on the platform for no less than three years after they exit the platform.

Article 46

Cosmetics e-commerce platform operators shall set up cosmetics quality management institutions or assign full-time or part-time managers, establish and effectively implement systems for daily inspections, prevention and reporting of illegal acts, complaint handling, and other cosmetics quality and safety management measures on the platform, and strengthen the publicity of relevant laws and regulations among cosmetics operators on the platform. Sampling inspections are encouraged.

E-commerce platform operators shall lawfully undertake management responsibilities for cosmetics operators on the platform, conduct daily inspections of their business conduct, urge them to fulfill obligations stipulated in the Cosmetics Supervision and Administration Regulations and these measures. Upon discovering illegal cosmetics business activities, they shall take necessary measures such as deletion, blocking, or disconnecting links in a timely manner according to law or platform service agreements and trading rules, and report to the provincial, autonomous region, or municipality drug supervision department.

Article 47

When e-commerce platform operators receive information about adverse reactions, complaints, or reports related to cosmetics, they shall record and promptly transfer the information to the cosmetics operators on the platform for handling; if the information involves major product quality and safety issues, they shall promptly report to the provincial, autonomous region, or



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



municipality drug supervision department. Drug supervision departments, due to supervision, inspection, or case investigation needs, may require e-commerce platform operators to lawfully provide relevant information, and the platform operators shall cooperate and assist.

Article 48

If cosmetics e-commerce platform operators discover any of the following serious illegal acts, they shall immediately stop providing e-commerce platform services to the cosmetics operators on the platform:

- 1-Being sentenced to criminal punishment by a people's court for crimes related to cosmetics quality and safety;
- 2-Being detained by public security organs or subjected to other public security administrative penalties for cosmetics quality and safety violations;
- 3- Having their licenses revoked or being ordered to suspend production or business by drug supervision authorities;
- 4- Other serious illegal acts.

If there is evidence showing possible harm to human health in a case of investigation or prosecution for suspected cosmetics quality and safety crimes, platform operators may suspend services to the cosmetics operators according to law or platform service agreements and trading rules.

If platform operators know or should know that cosmetics operators on the platform are legally prohibited from engaging in cosmetics production or business, they shall not provide e-commerce platform services to them.

Article 49

Providing cosmetics to consumers in the form of free trials, gifts, exchanges, and other methods shall comply with the obligations of cosmetics operators stipulated in the Cosmetics Supervision and Administration Regulations and these measures.

Chapter V: Supervision and Administration

Article 50

Departments responsible for drug supervision and administration shall determine the key product types, key stages, inspection methods, and inspection frequencies for supervision and inspection based on the principle of risk management, and shall strengthen supervision and inspection of cosmetic manufacturers and operators. When necessary, departments responsible for drug supervision and administration may conduct extended inspections of suppliers and manufacturers of cosmetic raw materials and packaging materials that directly contact cosmetics.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Article 51

The National Medical Products Administration (NMPA) shall, in accordance with laws, regulations, rules, mandatory national standards, and technical specifications, formulate national key points for inspection under the Good Manufacturing Practices (GMP) for cosmetics, clarifying key and general inspection items and the principles for inspection determination. Drug supervision and administration departments at the provincial, autonomous region, and directly-administered municipality levels may refine and supplement the key points of cosmetic supervision and inspection within their administrative regions based on actual circumstances.

Article 52

The NMPA shall organize national sampling inspections of cosmetics. Drug supervision and administration departments at the provincial, autonomous region, and directly-administered municipality levels shall organize sampling inspections of cosmetics within their respective jurisdictions.

Municipal and county-level governments responsible for drug supervision may organize local sampling inspections based on work needs.

For cosmetics with frequent issues found in reports or daily inspections, or those identified as possibly having quality and safety risks through adverse reaction monitoring or risk evaluation, the drug supervision and administration departments may carry out targeted sampling inspections. Inspection results of cosmetic sampling must be published in a timely manner according to regulations.

Article 53

If a cosmetic product fails sampling inspection, the cosmetic registrant or filer shall, in accordance with Article 44 of the Cosmetics Supervision and Administration Regulation, immediately cease production, recall the products that have been marketed, notify relevant operators and consumers to stop sales and use, conduct a self-inspection per Article 33, paragraph 2, of this Regulation, and implement corrective measures.

Article 54

If there is any objection to the conclusion of a sampling inspection, the applicant may request reinspection and shall prepay the reinspection fee to the designated reinspection institution. If the reinspection result is consistent with the original, the fee is borne by the applicant. If inconsistent, the fee is borne by the drug supervision and administration department that conducted the sampling inspection.

Article 55



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Reports of adverse cosmetic reactions shall follow the principle of “report if suspected.” The NMPA shall establish and improve a cosmetic adverse reaction monitoring system and information system.

Article 56

Without the consent of the cosmetic manufacturer or operator, departments responsible for drug supervision, professional technical institutions, and their personnel shall not disclose any trade secrets learned during inspections, except as otherwise provided by law or where national security or significant public interest is involved.

Chapter VI: Legal Liabilities

Article 57

For illegal activities in the production or operation of cosmetics that are already stipulated in the Cosmetics Supervision and Administration Regulation and other laws and regulations, those provisions shall apply.

Article 58

If a cosmetic manufacturer's licensing conditions change or it needs to modify licensed information but fails to apply for changes as required—violating Articles 17, 18 (first paragraph), or 19 (first paragraph)—the original drug regulatory department that issued the license shall order rectification, issue a warning, and impose a fine between 10,000 and 30,000 yuan.

If the person responsible for quality and safety or the reserved contact information changes and the change is not reported in accordance with Article 19 (second paragraph), the original licensing authority shall order rectification. If there is refusal to rectify, a warning shall be issued, and a fine of up to 5,000 yuan shall be imposed. If a cosmetic manufacturer produces cosmetics not covered by its production license category, relocates without approval, or fails to renew its license before the expiration date, it shall be deemed to be producing cosmetics without a license.

Article 59

If supervision and inspection reveal that a registrant, filer, or contract manufacturer has violated the key inspection points under the national GMP for cosmetics and has failed to organize production in accordance with GMP requirements, they shall be punished in accordance with Item 3 of Article 60 of the Cosmetics Supervision and Administration Regulation. If the violations pertain only to general inspection items, are minor, are corrected in a timely manner, and have not caused harmful consequences, no administrative penalties shall be imposed.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



Article 60

Whoever violates Article 42, Paragraph 3 of these Measures, whereby the organizer of a trade fair fails to report the basic information of the trade fair to the local drug supervision and administration department as required, shall be ordered to make corrections by the competent drug supervision and administration department and given a warning; if refusal to make corrections, a fine between 5,000 yuan and 30,000 yuan shall be imposed.

Article 61

Any of the following circumstances shall be deemed as “serious circumstances” as stipulated in the Cosmetics Supervision and Administration Regulations:

- 1-Using raw materials prohibited for use in cosmetics production, using new raw materials that should be registered but are not registered to produce children's cosmetics, or illegally adding substances that may harm human health into children's cosmetics;
- 2-Intentionally providing false information or concealing the truth;
- 3-Refusing or evading supervision and inspection;
- 4-Committing the same nature of illegal act within one year after receiving administrative punishment for cosmetics-related violations, or committing cosmetics quality and safety violations again after being criminally punished for such violations;
- 5-Other serious circumstances.

When imposing fines for serious violations, the punishment shall be severe and strict according to the law.

Article 62

If cosmetics producers or operators violate laws, regulations, rules, mandatory national standards, or technical specifications, and the violation is a first-time offense, causes only minor consequences, and is promptly corrected, no administrative penalty may be imposed. If the concerned party can provide evidence proving that there was no subjective fault, no administrative penalty shall be imposed. Where laws or administrative regulations provide otherwise, such provisions shall prevail.

Chapter VII: Supplementary Provisions

Article 63



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP



To prepare, fill, or package the contents of cosmetics, a cosmetics production license must be obtained. The labeling procedure of production must be completed within the cosmetics manufacturing enterprise that performs the final production step that comes into contact with the contents of the cosmetics.

Article 64

The “technical requirements specified in the registration and filing materials for cosmetics” referred to in Article 60, item 2 of the Cosmetics Supervision and Administration Regulations, refer to technical requirements that have a substantial impact on the quality and safety of cosmetics.

Article 65

The layout of the cosmetics production license number is: X Zhuang XXXXXXXX, where, the first X represents the abbreviation of the province, autonomous region, or municipality directly under the Central Government where the licensing department is located, the second to the fifth X represents the 4-digit licensing year, and the sixth to the ninth X represents the 4-digit serial number of license.

Article 66

These Measures shall be implemented starting from January 1, 2022.



HEALTH LAW ASIA

Shanghai - Bologna - Milan - Rome

Copyright © 2025, All rights reserved.

ZUNARELLI GROUP