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化妆品监督管理条例

Regulations on the Supervision and Administration of Cosmetics

中华人民共和国国务院令 第727号

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《化妆品监督管理条例》已经2020年1月3日国务院第77次常务会议通过，现予公布，自2021年1月1日起施行。

The Regulations on the Supervision and Administration of Cosmetics, which were adopted at the 77th executive meeting of the State Council on January 3, 2020, are hereby promulgated for implementation as of January 1, 2021.

总 理 李 克 强

Li Keqiang, Premier

化妆品监督管理条例

Regulations on the Supervision and Administration of Cosmetics

第一章 总 则

Chapter I General Provisions

第一条 为了规范化妆品生产经营活动，加强化妆品监督管理，保证化妆品质量安全，保障消费者健康，促进化妆品产业健康发展，制定本条例。

Article 1 The Regulations are formulated to standardize the production and operation activities of cosmetics, strengthen the supervision and administration of cosmetics, ensure the quality safety of cosmetics, safeguard consumer health, and promote the sound development of the cosmetics industry.

第二条 在中华人民共和国境内从事化妆品生产经营活动及其监督管理，应当遵守本条例。

Article 2 Those engaged in the production and operation of cosmetics and the supervision and administration of such activities within the territory of the People's Republic of China shall abide by the Regulations.

第三条 本条例所称化妆品，是指以涂擦、喷洒或者其他类似方法，施用于皮肤、毛发、指甲、口唇等人体表面，以清洁、保护、美化、修饰为目的的日用化学工业产品。

Article 3 For the purpose of the Regulations, cosmetics refer to those daily chemical products applied on the surface of the human body such as skin, hair, nails and lips by way of smearing, spraying or other similar methods for cleaning, protection, beautification and modification purposes.

第四条 国家按照风险程度对化妆品、化妆品原料实行分类管理。

Article 4 The State implements classified management of cosmetics and raw materials of cosmetics according to the degree of risk.

化妆品分为特殊化妆品和普通化妆品。国家对特殊化妆品实行注册管理，对普通化妆品实行备案管理。

Cosmetics are divided into special cosmetics and general cosmetics. The State implements registration-based management of special cosmetics and filing-based management of general cosmetics.

化妆品原料分为新原料和已使用的原料。国家对风险程度较高的化妆品新原料实行注册管理，对其他化妆品新原料实行备案管理。

Raw materials of cosmetics are divided into new raw materials and used raw materials. The State implements registration-based management of new raw materials of cosmetics with a high degree of risk, and filing-based management of new raw materials of other cosmetics.

第五条 国务院药品监督管理部门负责全国化妆品监督管理工作。国务院有关部门在各自职责范围内负责与化妆品有关的监督管理工作。

Article 5 The medical products administration of the State Council is responsible for the nationwide supervision and administration of cosmetics. The relevant departments of the State Council are responsible for the supervision and administration of cosmetics within their respective duties.

县级以上地方人民政府负责药品监督管理的部门负责本行政区域的化妆品监督管理工作。县级以上地方人民政府有关部门在各自职责范围内负责与化妆品有关的监督管理工作。

The department in charge of supervision and administration of medical products of the local people's government at or above the county level is responsible for the supervision and administration of cosmetics in its administrative area. The relevant departments of the local people's governments at or above the county level are responsible for the supervision and administration work relating to cosmetics within their respective duties.

第六条 化妆品注册人、备案人对化妆品的质量安全和功效宣称负责。

Article 6 The cosmetics registrants and record-filing applicants are responsible for the quality safety and efficacy description of cosmetics.

化妆品生产经营者应当依照法律、法规、强制性国家标准、技术规范从事生产经营活动，加强管理，诚信自律，保证化妆品质量安全。

Cosmetics producers and operators shall engage in production and operation activities in accordance with laws, regulations, mandatory national standards and technical specifications, strengthen management and exert integrity and self-discipline, to ensure the quality safety of cosmetics.

第七条 化妆品行业协会应当加强行业自律，督促引导化妆品生产经营者

Article 7 Cosmetics industry associations shall strengthen industry self-discipline, urge and instruct cosmetics producers and operators to engage in

依法从事生产经营活动，推动行业诚信建设。

第八条 消费者协会和其他消费者组织对违反本条例规定损害消费者合法权益的行为，依法进行社会监督。

第九条 国家鼓励和支持开展化妆品研究、创新，满足消费者需求，推进化妆品品牌建设，发挥品牌引领作用。国家保护单位和个人开展化妆品研究、创新的合法权益。

国家鼓励和支持化妆品生产经营者采用先进技术和先进管理规范，提高化妆品质量安全水平；鼓励和支持运用现代科学技术，结合我国传统优势项目和特色植物资源研究开发化妆品。

第十条 国家加强化妆品监督管理信息化建设，提高在线政务服务水平，为办理化妆品行政许可、备案提供便利，推进监督管理信息共享。

第二章 原料与产品

第十一条 在我国境内首次使用于化妆品的天然或者人工原料为化妆品新原料。具有防腐、防晒、着色、染发、祛斑美白功能的化妆品新原料，经国务院药品监督管理部门注册后方可使用；其他化妆品新原料应当在使用前向国务院药品监督管理部门备案。国务院药品监督管理部门可以根据科学研究的发展，调整实行注册管理的化妆品新原料的范围，经国务院批准后实施。

第十二条 申请化妆品新原料注册或者进行化妆品新原料备案，应当提交下列资料：

- (一) 注册申请人、备案人的名称、地址、联系方式；
 - (二) 新原料研制报告；
 - (三) 新原料的制备工艺、稳定性及其质量控制标准等研究资料；
 - (四) 新原料安全评估资料。
- 注册申请人、备案人应当对所提交资料的真实性、科学性负责。

第十三条 国务院药品监督管理部门应当自受理化妆品新原料注册申请之日起3个工作日内将申请材料转交技术审评机构。技术审评机构应当自收到申请材料之日起90个工作日内完成技术审评，向国务院药品监督管理部门提交审评意见。国务院药品监督管理部门应当自收到审评意见之日起20个工作日内作出决定。对符合要求的，准予注册并颁发给化妆品新原料注册证；对不符合要求的，不予注册并书面说明理由。

化妆品新原料备案人通过国务院药品监督管理部门在线政务服务平台提交本条例规定的备案资料后即完成备案。

国务院药品监督管理部门应当自化妆品新原料准予注册之日起、备案人提交备案资料之日起5个工作日内向社会公布注册、备案有关信息。

第十四条 经注册、备案的化妆品新原料投入使用后3年内，新原料注册

production and operation activities in accordance with the law, and promote the construction of integrity in the industry.

Article 8 Consumer associations and other consumer organizations conduct social supervision in accordance with the law for violations of the Regulations that damage the legitimate rights and interests of consumers.

Article 9 The State encourages and supports the development of cosmetics research and innovation to meet consumer demand, promotes the brand building of cosmetics, and gives play to the leading role of brands. The State protects the legitimate rights and interests of entities and individuals carrying out cosmetics research and innovation.

The State encourages and supports cosmetics producers and operators to improve the quality safety of cosmetics by adopting advanced technology and practices; and encourages and supports the development of cosmetics by adopting modern science and technology and in combination with our country's traditional superior projects and characteristic plant resources.

Article 10 The State is strengthening the construction of information technology in the supervision and administration of cosmetics, improving online government services, facilitating the handling of administrative licensing and filing for cosmetics, and promotes the sharing of supervision and administration information.

Chapter II Raw Materials and Products

Article 11 Natural or artificial raw materials used in cosmetics for the first time in China are new raw materials of cosmetics. New raw materials of cosmetics with functions of anti-corrosion, anti-suntan, coloring, hair coloring, freckle removal and whitening cannot be used until registered with the medical products administration of the State Council; other new raw materials of cosmetics shall be filed with the medical products administration of the State Council before use. The medical products administration of the State Council may adjust the scope of new raw materials of cosmetics subject to registration-based management according to the development of scientific research, which will be implemented with the approval of the State Council.

Article 12 To apply for registration or record-filing of new raw materials of cosmetics, the following materials shall be submitted:

1. the name, address and contact information of the registration or record-filing applicant;
2. a research report on new raw materials;
3. research materials such as the preparation process, stability and quality control standards of new raw materials; and
4. safety assessment data of new raw materials.

The applicant for registration or record-filing shall be responsible for the authenticity and scientificity of the materials submitted.

Article 13 The medical products administration of the State Council shall forward the application materials to the technical evaluation institution within three working days of acceptance of the application for the registration of new raw materials of cosmetics. The technical evaluation institution shall complete the technical evaluation within 90 working days of receipt of the application materials, and submit evaluation opinions to the medical products administration of the State Council. The medical products administration of the State Council shall make a decision within 20 working days of receipt of the evaluation opinions. For those applicants which meet the requirements, registration is approved with a registration certificate of new raw materials of cosmetics issued; for those which do not meet the requirements, registration is disapproved, with reasons stated in writing.

Record-filing is completed after a record-filing applicant of new raw materials of cosmetics submits the record-filing materials specified in the Regulations through the online government service platform of the medical products administration of the State Council.

The medical products administration of the State Council shall announce the registration and record-filing information to the public within five working days of approval of the registration of new raw materials of cosmetics or of submission of the record-filing materials by the record-filing applicant.

Article 14 Within three years after the new raw materials of cosmetics registered or filed are put into use, the registrant or record-filing applicant of new

人、备案人应当每年向国务院药品监督管理部门报告新原料的使用和安全情况。对存在安全问题的化妆品新原料，由国务院药品监督管理部门撤销注册或者取消备案。3年期满未发生安全问题的化妆品新原料，纳入国务院药品监督管理部门制定的已使用的化妆品原料目录。

经注册、备案的化妆品新原料纳入已使用的化妆品原料目录前，仍然按照化妆品新原料进行管理。

第十五条 禁止用于化妆品生产的原料目录由国务院药品监督管理部门制定、公布。

第十六条 用于染发、烫发、祛斑美白、防晒、防脱发的化妆品以及宣称新功效的化妆品为特殊化妆品。特殊化妆品以外的化妆品为普通化妆品。

国务院药品监督管理部门根据化妆品的功效宣称、作用部位、产品剂型、使用人群等因素，制定、公布化妆品分类规则和分类目录。

第十七条 特殊化妆品经国务院药品监督管理部门注册后方可生产、进口。国产普通化妆品应当在上市销售前向备案人所在地省、自治区、直辖市人民政府药品监督管理部门备案。进口普通化妆品应当在进口前向国务院药品监督管理部门备案。

第十八条 化妆品注册申请人、备案人应当具备下列条件：

- (一) 是依法设立的企业或者其他组织；
- (二) 有与申请注册、进行备案的产品相适应的质量管理体系；
- (三) 有化妆品不良反应监测与评价能力。

第十九条 申请特殊化妆品注册或者进行普通化妆品备案，应当提交下列资料：

- (一) 注册申请人、备案人的名称、地址、联系方式；
- (二) 生产企业的名称、地址、联系方式；
- (三) 产品名称；
- (四) 产品配方或者产品全成分；
- (五) 产品执行的标准；
- (六) 产品标签样稿；
- (七) 产品检验报告；
- (八) 产品安全评估资料。

注册申请人首次申请特殊化妆品注册或者备案人首次进行普通化妆品备案的，应当提交其符合本条例第十八条规定条件的证明资料。申请进口特殊化妆品注册或者进行进口普通化妆品备案的，应当同时提交产品在生产国（地区）已经上市销售的证明文件以及境外生产企业符合化妆品生产质量管理规范的证明资料；专为向我国出口生产、无法提交产品在生产国（地区）已经上市销售的证明文件的，应当提交面向我国消费者开展的相关研究和试验的资料。

注册申请人、备案人应当对所提交资料的真实性、科学性负责。

第二十条 国务院药品监督管理部

raw materials shall report the use and safety of the new raw materials to the medical products administration of the State Council every year. The medical products administration of the State Council will revoke the registration, or cancel the record-filing, of new raw materials of cosmetics with safety problems. New raw materials of cosmetics that do not have safety problems upon expiration of the three-year period are included in the catalog of used raw materials of cosmetics formulated by the medical products administration of the State Council.

Before being included in the catalog of used raw materials of cosmetics, new raw materials of cosmetics registered or filed are still managed as per new raw materials of cosmetics.

Article 15 The catalog of raw materials prohibited for use in the production of cosmetics shall be formulated and published by the medical products administration of the State Council.

Article 16 Cosmetics used for hair coloring, hair perming, freckle removal and whitening, anti-suntan and anti-hair loss and cosmetics that claim new effects are special cosmetics. Cosmetics other than special cosmetics are ordinary cosmetics.

The medical products administration of the State Council shall formulate and publish classification rules and catalogs of cosmetics based on factors such as the efficacy description, application parts, dosage forms and user groups of cosmetics.

Article 17 Special cosmetics can only be produced and imported after being registered with the medical products administration of the State Council. Domestic ordinary cosmetics shall be filed with the medical products administration of the people's government of the province, autonomous region or municipality directly under the Central Government of the place where the record-filing applicant is located for the record before being launched for sales. Imported ordinary cosmetics shall be filed with the medical products administration of the State Council for the record before being imported.

Article 18 An applicant for registration or record-filing of cosmetics shall meet the following conditions:

1. it is an enterprise or any other organization established in accordance with the law;
2. there is a quality management system appropriate for the products under the application for registration or the record-filing; and
3. it has the ability to monitor and evaluate the adverse effects of cosmetics.

Article 19 When applying for the registration of special cosmetics or the record-filing of ordinary cosmetics, an applicant shall submit the following materials:

1. the name, address and contact information of the registration or record-filing applicant;
2. the name, address and contact information of the producer;
3. product name;
4. the product formula or the entire product ingredients;
5. standards for product implementation;
6. sample text of product label;
7. product inspection report; and
8. product safety assessment materials.

When applying for the registration of special cosmetics or the record-filing of ordinary cosmetics for the first time, an applicant shall submit proof of compliance with the conditions specified in Article 18 of the Regulations. When applying for the registration of imported special cosmetics or the record-filing of imported ordinary cosmetics, an applicant shall submit the documents proving that the products have been put on sale in the country (region) of production and the proof of the overseas producer's compliance with the production practices of cosmetics; if it is impossible to submit the documents proving that the products have been put on sale in the country (region) of production for the products especially exported to China, materials for the relevant research and test designated for consumers in China shall be submitted.

The applicant for registration or record-filing shall be responsible for the authenticity and scientificity of the materials submitted.

Article 20 The medical products administration of the State Council shall

门依照本条例第十三条第一款规定的化妆品新原料注册审查程序对特殊化妆品注册申请进行审查。对符合要求的，准予注册并颁发特殊化妆品注册证；对不符合要求的，不予注册并书面说明理由。已经注册的特殊化妆品在生产工艺、功效宣称等方面发生实质性变化的，注册人应当向原注册部门申请变更注册。

普通化妆品备案人通过国务院药品监督管理部门在线政务服务平台提交本条例规定的备案资料后即完成备案。

省级以上人民政府药品监督管理部门应当自特殊化妆品准予注册之日起、普通化妆品备案人提交备案资料之日起5个工作日内向社会公布注册、备案有关信息。

第二十一条 化妆品新原料和化妆品注册、备案前，注册申请人、备案人应当自行或者委托专业机构开展安全评估。

从事安全评估的人员应当具备化妆品质量安全相关专业知识和5年以上相关专业从业经历。

第二十二条 化妆品的功效宣称应当有充分的科学依据。化妆品注册人、备案人应当在国务院药品监督管理部门规定的专门网站公布功效宣称所依据的文献资料、研究数据或者产品功效评价资料的摘要，接受社会监督。

第二十三条 境外化妆品注册人、备案人应当指定我国境内的企业法人办理化妆品注册、备案，协助开展化妆品不良反应监测、实施产品召回。

第二十四条 特殊化妆品注册证有效期为5年。有效期届满需要延续注册的，应当在有效期届满30个工作日前提出延续注册的申请。除有本条第二款规定情形外，国务院药品监督管理部门应当在特殊化妆品注册证有效期届满前作出准予延续的决定；逾期未作决定的，视为准予延续。

有下列情形之一的，不予延续注册：

(一) 注册人未在规定期限内提出延续注册申请；

(二) 强制性国家标准、技术规范已经修订，申请延续注册的化妆品不能达到修订后标准、技术规范的要求。

第二十五条 国务院药品监督管理部门负责化妆品强制性国家标准的项目提出、组织起草、征求意见和技术审查。国务院标准化行政主管部门负责化妆品强制性国家标准的立项、编号和对外通报。

化妆品国家标准文本应当免费向社会公开。

化妆品应当符合强制性国家标准。鼓励企业制定严于强制性国家标准的企业标准。

第三章 生产经营

第二十六条 从事化妆品生产活动，应当具备下列条件：

examine the applications for the registration of special cosmetics according to the procedures for examining the registration of new raw materials of cosmetics in accordance with Paragraph 1 of Article 13 of the Regulations. For those which meet the requirements, registration is approved with a registration certificate of special cosmetics issued; for those which do not meet the requirements, registration is disapproved with reasons stated in writing. If the registered special cosmetics have undergone substantial changes in the production process, efficacy description and other aspects, the registrant shall apply to the original registration department for registration of the changes.

Record-filing is completed when a record-filing applicant of ordinary cosmetics submits the record-filing materials specified in the Regulations through the online government service platform of the medical products administration of the State Council.

The medical products administrations of people's governments at or above the provincial level shall announce the registration and record-filing information to the public within five working days of the date on which the registration of special cosmetics is approved or the date when the record-filing applicants of ordinary cosmetics submit record-filing materials.

Article 21 Before the registration or record-filing of new raw materials of cosmetics and cosmetics, the registration or record-filing applicant shall carry out a safety assessment itself or by appointing a professional institution.

The personnel engaged in safety assessment shall possess professional knowledge related to quality safety of cosmetics, and have over five years of relevant professional experience.

Article 22 The efficacy description of cosmetics shall have sufficient scientific basis. Registrants and record-filing applicants of cosmetics shall publish on the special website prescribed by the medical products administration of the State Council a summary of the literature, research data or evaluation materials for product efficacy on which the efficacy description is based for social supervision.

Article 23 Overseas registrants and record-filing applicants of cosmetics shall designate corporate legal persons in China to handle registration and record-filing of cosmetics, assist in the monitoring of adverse reactions of cosmetics, and implement product recalls.

Article 24 The registration certificate of special cosmetics is valid for five years. If registration needs to be renewed upon expiration of the validity period, an application for renewal shall be filed 30 working days before the expiration of such validity period. Except for the circumstances specified in Paragraph 2 of this article, the medical products administration of the State Council shall make a decision to approve renewal before the expiration of the validity period of the registration certificate of special cosmetics.

Under either of the following circumstances, registration will not be renewed:

1. the registrant fails to file an application for renewal of registration within the prescribed time limit; and

2. the mandatory national standards and technical specifications have been revised, and cosmetics under the application for renewal of registration cannot meet the requirements of the revised standards and technical specifications.

Article 25 The medical products administration of the State Council is responsible for project proposal, organization of drafting, solicitation of opinions and technical review of mandatory national standards for cosmetics. The administrative department of standardization of the State Council is responsible for the establishment of projects for, numbering and notification of mandatory national standards for cosmetics.

The text of the national standard for cosmetics shall be disclosed to the public free of charge.

Cosmetics shall meet mandatory national standards. Enterprises are encouraged to formulate enterprise standards that are stricter than the mandatory national standards.

Chapter III Production and Operation

Article 26 An enterprise shall meet the following conditions in order to engage in cosmetics production activities:

(一) 是依法设立的企业；
(二) 有与生产的化妆品相适应的生产场地、环境条件、生产设施设备；
(三) 有与生产的化妆品相适应的技术人员；
(四) 有能对生产的化妆品进行检验的检验人员和检验设备；
(五) 有保证化妆品质量安全的管理制度。

1. it is an enterprise established in accordance with the law;
2. it has a production site, environmental conditions, and production facilities and equipment suitable for the cosmetics produced;
3. it has technical personnel suitable for the cosmetics produced;
4. it has inspectors and inspection equipment capable of inspecting the cosmetics produced; and
5. it has a management system that ensures the quality safety of cosmetics.

第二十七条 从事化妆品生产活动，应当向所在地省、自治区、直辖市人民政府药品监督管理部门提出申请，提交其符合本条例第二十六条规定条件的证明资料，并对资料的真实性负责。

Article 27 To engage in cosmetics production activities, an applicant shall file an application with the medical products administration of the people's government of the province, autonomous region or municipality directly under the Central Government where it is located, with proof of compliance with the conditions specified in Article 26 of the Regulations provided, and shall be responsible for the authenticity of such proof.

省、自治区、直辖市人民政府药品监督管理部门应当对申请资料进行审核，对申请人的生产场所进行现场核查，并自受理化妆品生产许可申请之日起30个工作日内作出决定。对符合规定条件的，准予许可并颁发化妆品生产许可证；对不符合规定条件的，不予许可并书面说明理由。

The medical products administration of the people's government of the province, autonomous region or municipality directly under the Central Government shall examine the application materials, conduct on-site verification of the applicant's production site, and make a decision within 30 working days of acceptance of the application for production licensing for cosmetics. For those which meet the prescribed conditions, licensing will be granted with a production license of cosmetics issued; for those which do not meet the prescribed conditions, licensing will not be granted with the reasons stated in writing.

化妆品生产许可证有效期为5年。有效期届满需要延续的，依照《中华人民共和国行政许可法》的规定办理。

The production license of cosmetics is valid for five years. If the license needs to be renewed upon expiration of its validity period, it shall be handled in accordance with the Administrative Licensing Law of the People's Republic of China.

第二十八条 化妆品注册人、备案人可以自行生产化妆品，也可以委托其他企业生产化妆品。

Article 28 A registrant or record-filing applicant of cosmetics may produce cosmetics itself or by appointing other enterprises.

委托生产化妆品的，化妆品注册人、备案人应当委托取得相应化妆品生产许可的企业，并对受委托企业（以下称受托生产企业）的生产活动进行监督，保证其按照法定要求进行生产。受托生产企业应当依照法律、法规、强制性国家标准、技术规范以及合同约定进行生产，对生产活动负责，并接受化妆品注册人、备案人的监督。

In the case of appointing other enterprises to produce cosmetics, the registrant or record-filing applicant of cosmetics shall appoint an enterprise that has obtained the corresponding production license of cosmetics, and supervise the production activities of the appointed enterprise (the "appointed producer") to ensure that it produces cosmetics according to the legal requirements. The appointed producer shall carry out production in accordance with laws, regulations, mandatory national standards, technical specifications and contractual agreements, be responsible for production activities, and accept the supervision by the registrant or record-filing applicant of cosmetics.

第二十九条 化妆品注册人、备案人、受托生产企业应当按照国务院药品监督管理部门制定的化妆品生产质量管理规范的要求组织生产化妆品，建立化妆品生产质量管理体系，建立并执行供应商遴选、原料验收、生产过程及质量控制、设备管理、产品检验及留样等管理制度。

Article 29 Registrants and record-filing applicants of cosmetics and appointed producers shall organize the production of cosmetics, establish a system of production practices of cosmetics and establish and implement management systems such as supplier selection, acceptance of raw materials, production process and quality control, equipment management, product inspection and sample retention in accordance with the requirements of the production practices of cosmetics formulated by the medical products administration of the State Council.

化妆品注册人、备案人、受托生产企业应当按照化妆品注册或者备案资料载明的技术要求生产化妆品。

Registrants and record-filing applicants of cosmetics and appointed producers shall produce cosmetics in accordance with the technical requirements stated in the registration materials and record-filing of cosmetics.

第三十条 化妆品原料、直接接触化妆品的包装材料应当符合强制性国家标准、技术规范。

Article 30 The raw materials of cosmetics and the packing materials in direct contact with cosmetics shall comply with the mandatory national standards and technical specifications.

不得使用超过使用期限、废弃、回收的化妆品或者化妆品原料生产化妆品。

It is not permitted to use cosmetics or raw materials of cosmetics whose shelf life has expired or which are discarded or recycled to produce cosmetics.

第三十一条 化妆品注册人、备案人、受托生产企业应当建立并执行原料以及直接接触化妆品的包装材料进货查验记录制度、产品销售记录制度。进货查验记录和产品销售记录应当真实、完整，保证可追溯，保存期限不得少于产品使用期限届满后1年；产品使用期限不足1年的，记录保存期限不得少于2年。

Article 31 Registrants and record-filing applicants of cosmetics and appointed producers shall establish and implement a purchase inspection records system and a product sales records system for raw materials and packing materials in direct contact with cosmetics. Purchase inspection records and product sales records shall be authentic and complete, with traceability guaranteed. The retention period shall not be less than one year after the expiration of products' shelf life. If products' shelf life is less than one year, the records retention period shall not be less than two years.

化妆品经出厂检验合格后方可上市

Cosmetics can only be launched to the market after passing the exfactory inspection.

销售。

第三十二条 化妆品注册人、备案人、受托生产企业应当设质量安全负责人，承担相应的产品质量安全管理和产品放行职责。

质量安全负责人应当具备化妆品质量安全相关专业知识和具有5年以上化妆品生产或者质量安全管理经验。

第三十三条 化妆品注册人、备案人、受托生产企业应当建立并执行从业人员健康管理制度。患有国务院卫生主管部门规定的有碍化妆品质量安全疾病的人员不得直接从事化妆品生产活动。

第三十四条 化妆品注册人、备案人、受托生产企业应当定期对化妆品生产质量管理规范的执行情况进行自查；生产条件发生变化，不再符合化妆品生产质量管理规范要求的，应当立即采取整改措施；可能影响化妆品质量安全的，应当立即停止生产并向所在地省、自治区、直辖市药品监督管理部门报告。

第三十五条 化妆品的最小销售单元应当有标签。标签应当符合相关法律、行政法规、强制性国家标准，内容真实、完整、准确。

进口化妆品可以直接使用中文标签，也可以加贴中文标签；加贴中文标签的，中文标签内容应当与原标签内容一致。

第三十六条 化妆品标签应当标注下列内容：

- (一) 产品名称、特殊化妆品注册证编号；
- (二) 注册人、备案人、受托生产企业的名称、地址；
- (三) 化妆品生产许可证编号；
- (四) 产品执行的标准编号；
- (五) 全成分；
- (六) 净含量；
- (七) 使用期限、使用方法以及必要的安全警示；
- (八) 法律、行政法规和强制性国家标准规定应当标注的其他内容。

第三十七条 化妆品标签禁止标注下列内容：

- (一) 明示或者暗示具有医疗作用的内容；
- (二) 虚假或者引人误解的内容；
- (三) 违反社会公序良俗的内容；
- (四) 法律、行政法规禁止标注的其他内容。

第三十八条 化妆品经营者应当建立并执行进货查验记录制度，查验供货者的市场主体登记证明、化妆品注册或者备案情况、产品出厂检验合格证明，如实记录并保存相关凭证。记录和凭证保存期限应当符合本条例第三十一条第一款的规定。

化妆品经营者不得自行配制化妆品。

第三十九条 化妆品生产经营者应当依照有关法律、法规的规定和化妆品标签标示的要求贮存、运输化妆品，定

Article 32 Registrants and record-filing applicants of cosmetics and appointed producers shall have persons in charge of quality safety responsible for the corresponding product quality safety management and product release.

The persons in charge of quality safety shall have professional knowledge related to the quality safety of cosmetics and over five years of experience in cosmetic production or quality safety management.

Article 33 Registrants and record-filing applicants of cosmetics and appointed producers shall establish and implement a health management system for practitioners. Persons suffering from diseases that impede the quality safety of cosmetics as prescribed by the competent department of health of the State Council may not directly engage in the cosmetics production activities.

Article 34 Registrants and record-filing applicants of cosmetics and appointed producers shall regularly conduct self-examination of the implementation of production practices of cosmetics; if production conditions change and no longer meet the requirements of the production practices of cosmetics, rectification shall be effected immediately; if the quality safety of cosmetics may be affected, production shall be stopped immediately and be reported to the medical products administrations of the local people's governments of the provinces, autonomous regions and municipalities directly under the Central Government.

Article 35 The smallest sales unit of cosmetics shall have a label. The label shall comply with the relevant laws, administrative regulations and mandatory national standards, and the content therein shall be authentic, complete and accurate.

Imported cosmetics can use Chinese labels directly or have Chinese labels affixed; if Chinese labels are affixed, the content of the Chinese labels shall be consistent with that of the original labels.

Article 36 A label of cosmetics shall specify the following content:

1. the product name and the number of registration certificate of special cosmetics;
2. the name and address of the registrant, the record-filing applicant and the appointed producer;
3. the number of the production license of cosmetics;
4. the number of the standard to which the products are subject;
5. full ingredients;
6. net content;
7. shelf life, method of use, and necessary safety warnings; and
8. other content that should be marked in accordance with laws, administrative regulations and mandatory national standards.

Article 37 It is forbidden to mark the following content on a label of cosmetics:

1. content expressing or implying medical efficacy;
2. false or misleading content;
3. content that violates social order and good customs; and
4. other content prohibited to be marked by laws and administrative regulations.

Article 38 A cosmetics operator shall establish and implement a purchase inspection records system, check the suppliers' market player registration certificate, cosmetics registration or record-filing status and the products' certificate of passing exfactory inspection, and truthfully record and save the relevant vouchers. The retention period of records and vouchers shall comply with Paragraph 1 of Article 31 of the Regulations.

Cosmetics operators shall not prepare cosmetics themselves.

Article 39 Cosmetics producers and operators shall store and transport cosmetics in accordance with the relevant laws and regulations and the requirements for the labeling of cosmetics, and regularly inspect and promptly

期检查并及时处理变质或者超过使用期限的化妆品。

第四十条 化妆品集中交易市场开办者、展销会举办者应当审查入场化妆品经营者的市场主体登记证明,承担入场化妆品经营者管理责任,定期对入场化妆品经营者进行检查;发现入场化妆品经营者有违反本条例规定行为的,应当及时制止并报告所在地县级人民政府负责药品监督管理的部门。

第四十一条 电子商务平台经营者应当对平台内化妆品经营者进行实名登记,承担平台内化妆品经营者管理责任,发现平台内化妆品经营者有违反本条例规定行为的,应当及时制止并报告电子商务平台经营者所在地省、自治区、直辖市人民政府药品监督管理部门;发现严重违法行为的,应当立即停止向违法的化妆品经营者提供电子商务平台服务。

平台内化妆品经营者应当全面、真实、准确、及时披露所经营化妆品的信息。

第四十二条 美容美发机构、宾馆等在经营中使用化妆品或者为消费者提供化妆品的,应当履行本条例规定的化妆品经营者义务。

第四十三条 化妆品广告的内容应当真实、合法。

化妆品广告不得明示或者暗示产品具有医疗作用,不得含有虚假或者引人误解的内容,不得欺骗、误导消费者。

第四十四条 化妆品注册人、备案人发现化妆品存在质量缺陷或者其他问题,可能危害人体健康的,应当立即停止生产,召回已经上市销售的化妆品,通知相关化妆品经营者和消费者停止经营、使用,并记录召回和通知情况。化妆品注册人、备案人应当对召回的化妆品采取补救、无害化处理、销毁等措施,并将化妆品召回和处理情况向所在地省、自治区、直辖市人民政府药品监督管理部门报告。

受托生产企业、化妆品经营者发现其生产、经营的化妆品有前款规定情形的,应当立即停止生产、经营,通知相关化妆品注册人、备案人。化妆品注册人、备案人应当立即实施召回。

负责药品监督管理的部门在监督检查中发现化妆品有本条第一款规定情形的,应当通知化妆品注册人、备案人实施召回,通知受托生产企业、化妆品经营者停止生产、经营。

化妆品注册人、备案人实施召回的,受托生产企业、化妆品经营者应当予以配合。

化妆品注册人、备案人、受托生产企业、经营者未依照本条规定实施召回或者停止生产、经营的,负责药品监督管理的部门责令其实施召回或者停止生产、经营。

第四十五条 出入境检验检疫机构依照《中华人民共和国进出口商品检验法》的规定对进口的化妆品实施检验;检验不合格的,不得进口。

dispose of cosmetics that have deteriorated or have exceeded their shelf lives.

Article 40 Owners of the centralized cosmetics trading markets and organizers of trade fairs shall examine the registration certificates of market players of entering cosmetics operators, assume the responsibility for the management of entering cosmetics operators, and regularly inspect the entering cosmetics operators; and shall promptly stop cosmetics operators' violations of the Regulations and report the case to the departments in charge of medical products administration of the local people's governments at the county level.

Article 41 Operators of e-commerce platforms shall register the real name of the cosmetics operators on the platforms, assume the responsibility for the management of cosmetics operators on the platforms, and promptly stop violations by cosmetics operators on the platforms of the Regulations and report the case to the medical products administrations of the people's governments of the provinces, autonomous regions, or municipalities directly under the Central Government where the platform operators are located; if serious violations are found, the e-commerce platforms shall immediately stop the provision of e-commerce platform services to the illegal cosmetics operators.

Cosmetics operators on the platforms shall disclose the information of the cosmetics they operate in a full, authentic, accurate and timely manner.

Article 42 Beauty salons, hotels and other operators that use cosmetics or provide cosmetics for consumers in operation shall perform the obligations of cosmetics operators as prescribed in the Regulations.

Article 43 The content of cosmetics advertisements shall be authentic and lawful.

Cosmetic advertisements shall not express or imply that the products have a medical effect, and shall not contain false or misleading content or deceive or mislead consumers.

Article 44 If a registrant or record-filing applicant of cosmetics finds that the cosmetics have quality defects or other problems that may endanger human health, it shall immediately stop production, recall the cosmetics that have been launched to the market, notify the relevant cosmetics operators and consumers to stop the operation and use, and record the recall and notification. The registrant or record-filing applicant of cosmetics shall take measures such as remediation, harmless treatment and destruction of the recalled cosmetics, and report the recall and disposal of cosmetics to the medical products administration of the local people's government of the province, autonomous region, or municipality directly under the Central Government.

If an appointed producer or cosmetics operator finds that the cosmetics it produces or sells fall under the circumstances specified in the preceding paragraph, it shall immediately stop production or operation, and notify the relevant registrant or record-filing applicant of cosmetics. The registrant or record-filing applicant of cosmetics shall immediately implement the recall.

If the department in charge of medical products administration finds that the cosmetics fall under the circumstances specified in Paragraph 1 of this article during the supervision and inspection, it shall notify the registrant or record-filing applicant of cosmetics to implement the recall, and notify the appointed producer or cosmetics operator to stop production or operation.

If a registrant or record-filing applicant of cosmetics implements the recall, the appointed producer or cosmetics operator shall render cooperation.

If a registrant or record-filing applicant of cosmetics, appointed producers or operator fails to implement the recall or stop production or operation in accordance with this article, the department in charge of medical products administration shall order it to implement the recall or stop production or operation.

Article 45 Entry-exit inspection and quarantine institutions shall conduct inspections of imported cosmetics in accordance with the provisions of the Law of the People's Republic of China on Imported and Exported Commodities Inspection; those cosmetics failing to pass the inspection shall not be imported.

进口商应当对拟进口的化妆品是否已经注册或者备案以及是否符合本条例和强制性国家标准、技术规范进行审核；审核不合格的，不得进口。进口商应当如实记录进口化妆品的信息，记录保存期限应当符合本条例第三十一条第一款的规定。

出口的化妆品应当符合进口国（地区）的标准或者合同要求。

第四章 监督管理

第四十六条 负责药品监督管理的部门对化妆品生产经营进行监督检查时，有权采取下列措施：

（一）进入生产经营场所实施现场检查；

（二）对生产经营的化妆品进行抽样检验；

（三）查阅、复制有关合同、票据、账簿以及其他有关资料；

（四）查封、扣押不符合强制性国家标准、技术规范或者有证据证明可能危害人体健康的化妆品及其原料、直接接触化妆品的包装材料，以及有证据证明用于违法生产经营的工具、设备；

（五）查封违法从事生产经营活动的场所。

第四十七条 负责药品监督管理的部门对化妆品生产经营进行监督检查时，监督检查人员不得少于2人，并应当出示执法证件。监督检查人员对监督检查中知悉的被检查单位的商业秘密，应当依法予以保密。被检查单位对监督检查应当予以配合，不得隐瞒有关情况。

负责药品监督管理的部门应当对监督检查情况和处理结果予以记录，由监督检查人员和被检查单位负责人签字；被检查单位负责人拒绝签字的，应当予以注明。

第四十八条 省级以上人民政府药品监督管理部门应当组织对化妆品进行抽样检验；对举报反映或者日常监督检查中发现问题较多的化妆品，负责药品监督管理的部门可以进行专项抽样检验。

进行抽样检验，应当支付抽取样品的费用，所需费用纳入本级政府预算。

负责药品监督管理的部门应当按照规定及时公布化妆品抽样检验结果。

第四十九条 化妆品检验机构按照国家有关认证认可的规定取得资质认定后，方可从事化妆品检验活动。化妆品检验机构的资质认定条件由国务院药品监督管理部门、国务院市场监督管理部门制定。

化妆品检验规范以及化妆品检验相关标准管理规定，由国务院药品监督管理部门制定。

第五十条 对可能掺杂掺假或者使用禁止用于化妆品生产的原料生产的化妆品，按照化妆品国家标准规定的检验项目和检验方法无法检验的，国务院药品监督管理部门可以制定补充检验项目和检验方法，用于对化妆品的抽样检验、化妆品质量安全案件调查处理和

Importers shall examine whether the cosmetics to be imported have been registered or filed for the record and whether they comply with the Regulations and mandatory national standards and technical specifications; those cosmetics failing to pass the examination shall not be imported. Importers shall faithfully record the information of imported cosmetics, and the retention period of records shall comply with Paragraph 1 of Article 31 of the Regulations.

The exported cosmetics shall meet the standards or contractual requirements of the importing country (region).

Chapter IV Supervision and Administration

Article 46 When supervising and inspecting the production or operation of cosmetics, a department in charge of medical products administration has the right to take the following measures:

1. enter the production or operation site to carry out on-site inspection;
2. conduct a sampling inspection of cosmetics produced or operated;
3. check and copy the relevant contracts, bills, account books and other relevant materials;
4. seal up or seize cosmetics and raw materials thereof and packing materials in direct contact with cosmetics that do not comply with the mandatory national standards and technical specifications or that might endanger human health, and tools and equipment that are proved to be used for illegal production or operation; and
5. close down places that illegally engage in production or business activities.

Article 47 When supervising and inspecting the production or operation of cosmetics, a department in charge of medical products administration shall send at least two supervisors or inspectors who shall present their law enforcement certificates. Supervisors or inspectors shall keep the trade secrets of the entities under inspection which come to be known during the supervision or inspection confidential in accordance with the law. The entities under inspection shall cooperate with the supervision or inspection, and shall not conceal the relevant information.

The department in charge of medical products administration shall keep records on the status of supervision or inspection and the results of the treatment, which shall be signed by the supervisors or inspectors and the persons in charge of the entities under inspection; if the person in charge of an entity under inspection refuses to do so, it shall be indicated.

Article 48 The medical products administrations of the people's governments at or above the provincial level shall organize sampling inspections of cosmetics; for cosmetics that are reported to have many problems or are found to be problematic in regard to daily supervision or inspection, the departments in charge of medical products administration may conduct special sampling inspections.

For sampling inspections, the costs of taking samples shall be paid and included in the budget of the government at the corresponding level.

The departments in charge of medical products administration shall promptly publish the results of sampling inspections of cosmetics in accordance with provisions.

Article 49 Cosmetics inspection institutions shall not engage in cosmetics inspection activities until they have obtained the qualification accreditation in accordance with the relevant national certification and accreditation provisions. The qualification accreditation requirements for cosmetics inspection institutions shall be formulated by the medical products administration of the State Council and the administration for market regulation of the State Council.

The cosmetics inspection specifications and the provisions on the management of cosmetics-related standard products shall be formulated by the medical products administration of the State Council.

Article 50 For cosmetics that may be adulterated or produced by use of raw materials prohibited for cosmetics production, and cannot be inspected according to the inspection items and inspection methods stipulated by the national standards for cosmetics, the medical products administration of the State Council may formulate additional inspection items and inspection methods for sampling inspections of cosmetics, investigation and disposal of cases related to quality safety of cosmetics, and investigation and disposal of adverse reactions.

不良反应调查处置。

第五十一条 对依照本条例规定实施的检验结论有异议的，化妆品生产经营者可以自收到检验结论之日起7个工作日内向实施抽样检验的部门或者其上一级负责药品监督管理的部门提出复检申请，由受理复检申请的部门在复检机构名录中随机确定复检机构进行复检。复检机构出具的复检结论为最终检验结论。复检机构与初检机构不得为同一机构。复检机构名录由国务院药品监督管理部门公布。

第五十二条 国家建立化妆品不良反应监测制度。化妆品注册人、备案人应当监测其上市销售化妆品的不良反应，及时开展评价，按照国务院药品监督管理部门的规定向化妆品不良反应监测机构报告。受托生产企业、化妆品经营者和医疗机构发现可能与使用化妆品有关的不良反应的，应当报告化妆品不良反应监测机构。鼓励其他单位和个人向化妆品不良反应监测机构或者负责药品监督管理的部门报告可能与使用化妆品有关的不良反应。

化妆品不良反应监测机构负责化妆品不良反应信息的收集、分析和评价，并向负责药品监督管理的部门提出处理建议。

化妆品生产经营者应当配合化妆品不良反应监测机构、负责药品监督管理的部门开展化妆品不良反应调查。

化妆品不良反应是指正常使用化妆品所引起的皮肤及其附属器官的病变，以及人体局部或者全身性的损害。

第五十三条 国家建立化妆品安全风险监测和评价制度，对影响化妆品质量安全的风险因素进行监测和评价，为制定化妆品质量安全风险控制措施和标准、开展化妆品抽样检验提供科学依据。

国家化妆品安全风险监测计划由国务院药品监督管理部门制定、发布并组织实施。国家化妆品安全风险监测计划应当明确重点监测的品种、项目和地域等。

国务院药品监督管理部门建立化妆品质量安全风险信息交流机制，组织化妆品生产经营者、检验机构、行业协会、消费者协会以及新闻媒体等就化妆品质量安全风险信息进行交流沟通。

第五十四条 对造成人体伤害或者有证据证明可能危害人体健康的化妆品，负责药品监督管理的部门可以采取责令暂停生产、经营的紧急控制措施，并发布安全警示信息；属于进口化妆品的，国家出入境检验检疫部门可以暂停进口。

第五十五条 根据科学研究的发展，对化妆品、化妆品原料的安全性有认识上的改变的，或者有证据表明化妆品、化妆品原料可能存在缺陷的，省级以上人民政府药品监督管理部门可以责令化妆品、化妆品新原料的注册人、备

Article 51 If there is any objection to the conclusion of the inspection carried out in accordance with the Regulations, the cosmetics producer or operator may file an application for re-inspection with the department implementing sampling inspections or the department in charge of medical products administration at the next higher level within seven working days of receipt of the inspection conclusion. The department that accepts the applications for re-inspection shall randomly determine a re-inspection institution in the list of re-inspection institutions for re-inspection. The re-inspection conclusion issued by the re-inspection institution is the final inspection conclusion. The re-inspection institution and the initial inspection institution shall not be the same institution. The list of re-inspection institutions shall be announced by the medical products administration of the State Council.

Article 52 The State has established a monitoring system for adverse reactions of cosmetics. A registrant or record-filing applicant of cosmetics shall monitor the adverse reactions of its cosmetics on the market, carry out timely evaluations, and report the same to the cosmetics adverse reactions monitoring institution in accordance with the provisions of the medical products administration of the State Council. A registrant or record-filing applicant of cosmetics shall monitor the adverse reactions of its cosmetics on the market, carry out timely evaluations, and report the same to the cosmetics adverse reactions monitoring institution in accordance with the provisions of the medical products administration of the State Council. Other entities and individuals are encouraged to report adverse reactions that may be related to the use of cosmetics to the department in charge of medical products administration or the department in charge of medical products administration.

The cosmetic adverse reactions monitoring institution is responsible for the collection, analysis and evaluation of information on adverse reactions of cosmetics, and makes disposal suggestions to the department in charge of medical products administration.

Cosmetics producers and operators shall cooperate with cosmetics adverse reactions monitoring institutions and departments in charge of medical products administration in investigations into adverse reactions of cosmetics.

Adverse reactions of cosmetics refer to lesions of the skin and its accessory organs caused by the normal use of cosmetics, as well as partial or systemic damage to the human body.

Article 53 The State has established a cosmetics safety risk monitoring and evaluation system to monitor and evaluate the risk factors that affect the quality safety of cosmetics, and to provide a scientific basis for formulating cosmetics quality safety risk control measures and standards and conducting sampling inspections of cosmetics.

The national cosmetics safety risk monitoring plan is formulated, promulgated and implemented under the organization by the medical products administration of the State Council. The national cosmetics safety risk monitoring plan shall specify the varieties, items and regions to be monitored.

The medical products administration of the State Council shall establish an information communication mechanism for the quality safety risk of cosmetics, and organize exchange and communication of information on the quality safety risk of cosmetics with cosmetics producers and operators, inspection institutions, industry associations, consumer associations, and news media.

Article 54 For cosmetics that cause human injury or might endanger human health, the departments in charge of medical products administration may take emergency control measures to order the suspension of production or operation, and issue safety warning information; for imported cosmetics, the entry-exit inspection and quarantine department of the State may suspend the import of such cosmetics.

Article 55 If, according to the development of scientific research, there is a change in the understanding of the safety of cosmetics and raw materials thereof, or there is evidence proving that the cosmetics and raw materials thereof may be defective, the medical products administrations of the people's governments at or above the provincial level may order the registrants or record-filing applicants of cosmetics and new raw materials of cosmetics to carry out safety reassessment

案人开展安全再评估或者直接组织开展安全再评估。再评估结果表明化妆品、化妆品原料不能保证安全的，由原注册部门撤销注册、备案部门取消备案，由国务院药品监督管理部门将该化妆品原料纳入禁止用于化妆品生产的原料目录，并向社会公布。

第五十六条 负责药品监督管理的部门应当依法及时公布化妆品行政许可、备案、日常监督检查结果、违法行为查处等监督管理信息。公布监督管理信息时，应当保守当事人的商业秘密。

负责药品监督管理的部门应当建立化妆品生产经营者信用档案。对有不良信用记录的生产经营者，增加监督检查频次；对有严重不良信用记录的生产经营者，按照规定实施联合惩戒。

第五十七条 化妆品生产经营过程中存在安全隐患，未及时采取措施消除的，负责药品监督管理的部门可以对化妆品生产经营者的法定代表人或者主要负责人进行责任约谈。化妆品生产经营者应当立即采取措施，进行整改，消除隐患。责任约谈情况和整改情况应当纳入化妆品生产经营者信用档案。

第五十八条 负责药品监督管理的部门应当公布本部门的网站地址、电子邮件地址或者电话，接受咨询、投诉、举报，并及时答复或者处理。对查证属实的举报，按照国家有关规定给予举报人奖励。

第五章 法律责任

第五十九条 有下列情形之一的，由负责药品监督管理的部门没收违法所得、违法生产经营的化妆品和专门用于违法生产经营的原料、包装材料、工具、设备等物品；违法生产经营的化妆品货值金额不足1万元的，并处5万元以上15万元以下罚款；货值金额1万元以上的，并处货值金额15倍以上30倍以下罚款；情节严重的，责令停产停业、由备案部门取消备案或者由原发证部门吊销化妆品许可证件，10年内不予办理其提出的化妆品备案或者受理其提出的化妆品行政许可申请，对违法单位的法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员处以其上一年度从本单位取得收入的3倍以上5倍以下罚款，终身禁止其从事化妆品生产经营活动；构成犯罪的，依法追究刑事责任：

(一) 未经许可从事化妆品生产活动，或者化妆品注册人、备案人委托未取得相应化妆品生产许可的企业生产化妆品；

(二) 生产经营或者进口未经注册的特殊化妆品；

(三) 使用禁止用于化妆品生产的原料、应当注册但未经注册的新原料生产化妆品，在化妆品中非法添加可能危害人体健康的物质，或者使用超过使用期限、废弃、回收的化妆品或者原料生产化妆品。

第六十条 有下列情形之一的，由负责药品监督管理的部门没收违法所

or directly organize the safety reassessment. If the reassessment results show that the safety of cosmetics and raw materials thereof cannot be guaranteed, the original registration department will cancel the registration and the record-filing department will cancel the record-filing. The medical products administration of the State Council will include the raw materials of cosmetics in the catalog of raw materials prohibited for cosmetics production and make it public.

Article 56 The departments in charge of medical products administration shall promptly publish information on supervision and administration such as administrative licensing, record-filing, daily supervision and inspection results, and investigation and handling of illegal acts related to cosmetics in accordance with the law. When information on supervision and administration is published, the parties' trade secrets shall be kept confidential.

The departments in charge of medical products administration shall establish credit files for cosmetics producers and operators. More supervision and inspections shall be carried out for cosmetics producers and operators with bad credit records; joint punishment shall be imposed on those producers and operators with serious bad credit records in accordance with provisions.

Article 57 If there are safety hazards in the production and operation of cosmetics, and no measures are taken in a timely manner to eliminate them, the departments in charge of medical products administration may conduct duty interviews with the legal representatives or primary principals of cosmetics producers and operators. Cosmetics producers and operators shall take immediate measures to effect rectifications and eliminate hazards. The situation of duty interviews and rectifications shall be included in the credit files of cosmetics producers and operators.

Article 58 The departments in charge of medical products administration shall publish their websites, e-mail addresses or telephone numbers for consultations, complaints and tip-offs, and reply to or deal with them in a timely manner. For tip-offs that are true upon verification, whistleblowers shall be rewarded in accordance with the relevant provisions of the State.

Chapter V Legal Liability

Article 59 Under any of the following circumstances, the department in charge of medical products administration shall confiscate illegal income, cosmetics illegally produced or operated and raw materials, packing materials, tools, equipment and other items specifically used for illegal production or operation; if the value of cosmetics illegally produced or operated is less than CNY10,000, a fine of no less than CNY50,000 but no more than CNY150,000 shall be imposed concurrently; if the value is CNY10,000 or more, a fine of no less than 15 times but no more than 30 times the value shall be imposed concurrently; if the circumstances are serious, the enterprise shall be ordered to suspend production and business with its registration canceled by the record-filing department or license of cosmetics revoked by the original license issuer, and its application for record-filing of cosmetics or for administrative licensing for cosmetics shall not be handled or accepted for ten years, and the legal representative or primary principal or the director directly in charge and other persons directly liable of the enterprise violating the law shall be fined no less than three times but no more than five times the income they obtained from the enterprise in the previous year, and be prohibited from engaging in cosmetics production or operation activities for life; if a crime is constituted, criminal liability shall be investigated in accordance with the law:

1. the enterprise engages in cosmetics production activities without permission, or the registrant or record-filing applicant of cosmetics appoints an enterprise that has not obtained the corresponding production licenses of cosmetics to produce cosmetics;

2. the enterprise produces, operates or imports unregistered special cosmetics; or

3. the enterprise produces cosmetics by using raw materials prohibited for cosmetics production or new raw materials that should be registered but have not been registered, illegally adds substances that may endanger human health, or produces cosmetics by using cosmetics or raw materials that exceed the shelf life or those discarded or recycled.

Article 60 Under any of the following circumstances, the department in charge of medical products administration shall confiscate illegal income,

得、违法生产经营的化妆品和专门用于违法生产经营的原料、包装材料、工具、设备等物品；违法生产经营的化妆品货值金额不足1万元的，并处1万元以上5万元以下罚款；货值金额1万元以上的，并处货值金额5倍以上20倍以下罚款；情节严重的，责令停产停业、由备案部门取消备案或者由原发证部门吊销化妆品许可证件，对违法单位的法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员处以其上一年度从本单位取得收入的1倍以上3倍以下罚款，10年内禁止其从事化妆品生产经营活动；构成犯罪的，依法追究刑事责任：

（一）使用不符合强制性国家标准、技术规范的原料、直接接触化妆品的包装材料，应当备案但未备案的新原料生产化妆品，或者不按照强制性国家标准或者技术规范使用原料；

（二）生产经营不符合强制性国家标准、技术规范或者不符合化妆品注册、备案资料载明的技术要求的化妆品；

（三）未按照化妆品生产质量管理规范的要求组织生产；

（四）更改化妆品使用期限；

（五）化妆品经营者擅自配制化妆品，或者经营变质、超过使用期限的化妆品；

（六）在负责药品监督管理的部门责令其实施召回后拒不召回，或者在负责药品监督管理的部门责令停止或者暂停生产、经营后拒不停止或者暂停生产、经营。

第六十一条 有下列情形之一的，由负责药品监督管理的部门没收违法所得、违法生产经营的化妆品，并可以没收专门用于违法生产经营的原料、包装材料、工具、设备等物品；违法生产经营的化妆品货值金额不足1万元的，并处1万元以上3万元以下罚款；货值金额1万元以上的，并处货值金额3倍以上10倍以下罚款；情节严重的，责令停产停业、由备案部门取消备案或者由原发证部门吊销化妆品许可证件，对违法单位的法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员处以其上一年度从本单位取得收入的1倍以上2倍以下罚款，5年内禁止其从事化妆品生产经营活动：

（一）上市销售、经营或者进口未备案的普通化妆品；

（二）未依照本条例规定设质量安全负责人；

（三）化妆品注册人、备案人未对受托生产企业的生产活动进行监督；

（四）未依照本条例规定建立并执行从业人员健康管理制度；

（五）生产经营标签不符合本条例规定的化妆品。

生产经营的化妆品的标签存在瑕疵但不影响质量安全且不会对消费者造成误导的，由负责药品监督管理的部门责令改正；拒不改正的，处2000元以下罚款。

第六十二条 有下列情形之一的，由负责药品监督管理的部门责令改正，

cosmetics illegally produced or operated and raw materials, packing materials, tools, equipment and other items specifically used for illegal production or operation; if the value of cosmetics illegally produced or operated is less than CNY10,000, a fine of no less than CNY10,000 but no more than CNY50,000 shall be imposed concurrently; if the value is CNY10,000 or more, a fine of no less than five times but no more than 20 times the value shall be imposed concurrently; if the circumstances are serious, the enterprise shall be ordered to suspend production and business and apply for its registration to be canceled by the record-filing department or license of cosmetics to be revoked by the original license issuer, and the legal representative or primary principal or the director directly in charge and other persons directly liable of the enterprise violating the law shall be fined no less than one but no more than three times the income they obtained from the enterprise in the previous year, and be prohibited from engaging in cosmetics production or operation activities for ten years; if a crime is constituted, criminal liability shall be investigated in accordance with the law:

1. the enterprise produces cosmetics by using raw materials that do not meet the mandatory national standards and technical specifications, or packing materials that directly come into contact with cosmetics, or new raw materials that should be filed but have not been filed, or fails to use raw materials in accordance with the mandatory national standards or technical specifications;

2. the enterprise produces or operates cosmetics that do not meet the mandatory national standards and technical specifications or the technical requirements stated in the cosmetics registration or record-filing materials;

3. the enterprise fails to organize production in accordance with the requirements of good cosmetics production practices;

4. the shelf life of cosmetics is changed;

5. the cosmetics operator prepares cosmetics without authorization, or manages cosmetics that have deteriorated or exceeded the shelf life; or

6. the enterprise refuses to recall cosmetics after the department in charge of medical products administration orders it to do so, or refuses to stop or suspend production or operation after the department in charge of medical products administration orders it to do so.

Article 61 Under any of the following circumstances, the department in charge of medical products administration shall confiscate illegal income, cosmetics illegally produced or operated and raw materials, packing materials, tools, equipment and other items specifically used for illegal production or operation; if the value of cosmetics illegally produced or operated is less than CNY10,000, a fine of no less than CNY10,000 but no more than CNY30,000 shall be imposed concurrently; if the value is CNY10,000 or more, a fine of no less than three times but no more than ten times the value shall be imposed concurrently; if the circumstances are serious, the enterprise shall be ordered to suspend production and business and apply for its registration to be canceled by the record-filing department or license of cosmetics to be revoked by the original license issuer, and the legal representative or primary principal or the director directly in charge and other persons directly liable of the enterprise violating the law shall be fined no less than one but no more than two times the income they obtained from the enterprise in the previous year, and be prohibited from engaging in cosmetics production or operation activities for five years:

1. ordinary cosmetics that have not been filed are launched for sale, managed or imported;

2. no person in charge of quality safety is arranged in accordance with the Regulations;

3. the registrant or record-filing applicant in relation to cosmetics does not supervise the production activities of the appointed producer;

4. no health management system for practitioners is established or implemented in accordance with the Regulations; or

5. cosmetics whose labels do not comply with the provisions are produced or managed.

If the labels of the cosmetics produced or operated have defects but do not affect the quality safety and will not mislead consumers, the department in charge of medical products administration shall order the producing or managing entity to make corrections; if it fails to make corrections, it shall be fined no more than CNY2,000.

Article 62 Under any of the following circumstances, the department in charge of medical products administration shall order the enterprise to make

给予警告，并处1万元以上3万元以下罚款；情节严重的，责令停产停业，并处3万元以上5万元以下罚款，对违法单位的法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员处1万元以上3万元以下罚款：

(一) 未依照本条例规定公布化妆品功效宣称依据的摘要；

(二) 未依照本条例规定建立并执行进货查验记录制度、产品销售记录制度；

(三) 未依照本条例规定对化妆品生产质量管理规范的执行情况进行自查；

(四) 未依照本条例规定贮存、运输化妆品；

(五) 未依照本条例规定监测、报告化妆品不良反应，或者对化妆品不良反应监测机构、负责药品监督管理的部门开展的化妆品不良反应调查不予配合。

进口商未依照本条例规定记录、保存进口化妆品信息的，由出入境检验检疫机构依照前款规定给予处罚。

第六十三条 化妆品新原料注册人、备案人未依照本条例规定报告化妆品新原料使用和安全情况的，由国务院药品监督管理部门责令改正，处5万元以上20万元以下罚款；情节严重的，吊销化妆品新原料注册证或者取消化妆品新原料备案，并处20万元以上50万元以下罚款。

第六十四条 在申请化妆品行政许可时提供虚假资料或者采取其他欺骗手段的，不予行政许可，已经取得行政许可的，由作出行政许可决定的部门撤销行政许可，5年内不受理其提出的化妆品相关许可申请，没收违法所得和已经生产、进口的化妆品；已经生产、进口的化妆品货值金额不足1万元的，并处5万元以上15万元以下罚款；货值金额1万元以上的，并处货值金额15倍以上30倍以下罚款；对违法单位的法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员处以其上一年度从本单位取得收入的3倍以上5倍以下罚款，终身禁止其从事化妆品生产经营活动。

伪造、变造、出租、出借或者转让化妆品许可证件的，由负责药品监督管理的部门或者原发证部门予以收缴或者吊销，没收违法所得；违法所得不足1万元的，并处5万元以上10万元以下罚款；违法所得1万元以上的，并处违法所得10倍以上20倍以下罚款；构成违反治安管理行为的，由公安机关依法给予治安管理处罚；构成犯罪的，依法追究刑事责任。

第六十五条 备案时提供虚假资料的，由备案部门取消备案，3年内不予办理其提出的该项备案，没收违法所得和已经生产、进口的化妆品；已经生产、进口的化妆品货值金额不足1万元的，并处1万元以上3万元以下罚款；货值金额1万元以上的，并处货值金额3倍以上10倍以下罚款；情节严重的，责令

corrections, give a warning, and impose a fine of no less than CNY10,000 but no more than CNY30,000 concurrently; if the circumstances are serious, the enterprise shall be ordered to suspend production and business, and fined no less than CNY30,000 but no more than CNY50,000 concurrently, and the legal representative or primary principal or the director directly in charge and other persons directly liable of the enterprise violating the law shall be fined no less than CNY10,000 but no more than CNY30,000:

1. no summary of the basis for the efficacy description of cosmetics is published in accordance with the Regulations;

2. no purchase inspection recording system or product sales recording system is established or implemented in accordance with the Regulations;

3. no self-examination of the implementation of good production practices of cosmetics is conducted in accordance with the Regulations;

4. cosmetics are not stored or transported in accordance with the Regulations; or

5. the enterprise fails to monitor or report the adverse reactions of cosmetics in accordance with the Regulations, or refuses to cooperate in the investigation into the adverse reactions of cosmetics carried out by the cosmetics adverse reactions monitoring institution or the department in charge of medical products administration.

If an importer fails to record or preserve information on the imported cosmetics in accordance with the Regulations, the entry-exit inspection and quarantine institution shall impose a penalty in accordance with the preceding paragraph.

Article 63 If a registrant or record-filing applicant of new raw materials of cosmetics fails to report the use and safety of new raw materials of cosmetics in accordance with the Regulations, it shall be ordered to make corrections by the medical products administration of the State Council and fined no less than CNY50,000 but no more than CNY200,000 concurrently; if the circumstances are serious, its registration certificate or record-filing of new raw materials of cosmetics shall be revoked or canceled, and a fine of no less than CNY200,000 but no more than CNY500,000 shall be imposed concurrently.

Article 64 If any applicant provides false materials or adopts other deceptive means when applying for administrative licensing for cosmetics, no administrative licensing shall be granted; if administrative licensing has already been obtained, the department making an administrative licensing decision shall revoke the administrative licensing, not accept any application related to cosmetics filed by it for five years, and confiscate illegal income and cosmetics that have been produced or imported; if the value of cosmetics that have been produced or imported is less than CNY10,000, a fine of no less than CNY50,000 but no more than CNY150,000 shall be imposed concurrently; if the value is CNY10,000 or more, a fine of no less than 15 times but no more than 30 times the value shall be imposed concurrently; the legal representative or primary principal or the director directly in charge and other persons directly liable of the enterprise violating the law shall be fined no less than three times but no more than five times the income they obtained from the enterprise in the previous year and be prohibited from engaging in cosmetics production or operation activities for life.

If anyone forges, alters, rents, lends or transfers a cosmetics license, such license shall be confiscated or revoked by the department in charge of medical products administration or the original license issuer, and the illegal income shall be confiscated; if the illegal income is less than CNY10,000, a fine of no less than CNY50,000 but no more than CNY100,000 shall be imposed concurrently; if the illegal income is no less than CNY10,000, a fine of no less than ten times but no more than 20 times the illegal income shall be imposed concurrently; if a violation of public security administration is constituted, the public security organ shall impose a public security administration penalty in accordance with the law; if a crime is constituted, criminal liability shall be investigated in accordance with the law.

Article 65 If an applicant provides false materials for record-filing, the record-filing department shall cancel the record-filing, not accept any application related to such record-filing made by it for three years, and confiscate illegal income and cosmetics that have been produced or imported; if the value of cosmetics that have been produced or imported is less than CNY10,000, a fine of no less than CNY10,000 but no more than CNY30,000 shall be imposed concurrently; if the value is CNY10,000 or more, a fine of no less than three times but no more than ten times the value shall be imposed concurrently; if the circumstances are

停产停业直至由原发证部门吊销化妆品生产许可证，对违法单位的法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员处以其上一年度从本单位取得收入的1倍以上2倍以下罚款，5年内禁止其从事化妆品生产经营活动。

已经备案的资料不符合要求的，由备案部门责令限期改正，其中，与化妆品、化妆品新原料安全性有关的备案资料不符合要求的，备案部门可以同时责令暂停销售、使用；逾期不改正的，由备案部门取消备案。

备案部门取消备案后，仍然使用该化妆品新原料生产化妆品或者仍然上市销售、进口该普通化妆品的，分别依照本条例第六十条、第六十一条的规定给予处罚。

第六十六条 化妆品集中交易市场开办者、展销会举办者未依照本条例规定履行审查、检查、制止、报告等管理义务的，由负责药品监督管理的部门处2万元以上10万元以下罚款；情节严重的，责令停业，并处10万元以上50万元以下罚款。

第六十七条 电子商务平台经营者未依照本条例规定履行实名登记、制止、报告、停止提供电子商务平台服务等管理义务的，由省、自治区、直辖市人民政府药品监督管理部门依照《中华人民共和国电子商务法》的规定给予处罚。

第六十八条 化妆品经营者履行了本条例规定的进货查验记录等义务，有证据证明其不知道所采购的化妆品是不符合强制性国家标准、技术规范或者不符合化妆品注册、备案资料载明的技术要求，收缴其经营的不符合强制性国家标准、技术规范或者不符合化妆品注册、备案资料载明的技术要求的化妆品，可以免除行政处罚。

第六十九条 化妆品广告违反本条例规定的，依照《中华人民共和国广告法》的规定给予处罚；采用其他方式对化妆品作虚假或者引人误解的宣传的，依照有关法律的规定给予处罚；构成犯罪的，依法追究刑事责任。

第七十条 境外化妆品注册人、备案人指定的在我国境内的企业法人未协助开展化妆品不良反应监测、实施产品召回的，由省、自治区、直辖市人民政府药品监督管理部门责令改正，给予警告，并处2万元以上10万元以下罚款；情节严重的，处10万元以上50万元以下罚款，5年内禁止其法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员从事化妆品生产经营活动。

境外化妆品注册人、备案人拒不履行依据本条例作出的行政处罚决定的，10年内禁止其化妆品进口。

第七十一条 化妆品检验机构出具虚假检验报告的，由认证认可监督管理部门吊销检验机构资质证书，10年内不受理其资质认定申请，没收所收取的检

serious, it shall be ordered to suspend production and business until the original license issuer revokes the production license for cosmetics, and the legal representative or primary principal or the director directly in charge and other persons directly liable of the enterprise violating the law shall be fined no less than one but no more than two times the income they obtained from the enterprise in the previous year and be prohibited from engaging in cosmetics production or operation activities for five years.

If the filed materials do not meet the requirements, the record-filing department shall order the enterprise to make corrections within a time limit. Specifically, if the filed materials related to the safety of cosmetics and new raw materials of cosmetics do not meet the requirements, the record-filing department may order the enterprise to suspend sale or use; if the enterprise fails to make corrections within the time limit, the record-filing shall be canceled by the record-filing department.

If, after the record-filing department cancels the record-filing, the enterprise still uses the new raw materials of cosmetics to produce cosmetics or still launches such ordinary cosmetics for sale or imports such ordinary cosmetics, it shall be punished in accordance with Article 60 and Article 61 of the Regulations respectively.

Article 66 If the owner of a centralized cosmetics trading market or the organizer of the trade fair fails to perform the management obligations such as review, inspection, suppression, and reporting in accordance with the Regulations, the department in charge of medical products administration shall impose a fine of no less than CNY20,000 but no more than CNY100,000; if the circumstances are serious, it shall be ordered to suspend business and fined no less than CNY100,000 but no more than CNY500,000.

Article 67 If the operator of an e-commerce platform fails to perform the management obligations such as real-name registration, suppression, reporting, and cease of provision of e-commerce platform services in accordance with the Regulations, the medical products administration of the people's government of the province, autonomous region, or municipality directly under the Central Government shall impose a penalty in accordance with the E-commerce Law of the People's Republic of China.

Article 68 Where a cosmetics operator has fulfilled its obligations such as purchase inspection recording as stipulated in the Regulations, and there is evidence to prove that it does not know the cosmetics purchased do not comply with mandatory national standards, technical specifications or the technical requirements stated in the cosmetics registration or record-filing materials, such unqualified cosmetics managed by it shall be confiscated and an administrative penalty may be exempted.

Article 69 Where a cosmetics advertisement violates the Regulations, a penalty shall be imposed in accordance with the Advertising Law of the People's Republic of China; anyone making false or misleading publicity of cosmetics in other ways shall be punished in accordance with the relevant laws; if a crime is constituted, criminal liability shall be investigated in accordance with the law.

Article 70 If an enterprise legal person designated by an overseas registrant or cosmetics record-filing applicant does not assist in the monitoring of adverse reactions of cosmetics and the implementation of product recalls, the medical products administration of the people's government of the province, autonomous region or municipality directly under the Central Government shall order it to make corrections, give a warning and impose a fine of no less than CNY20,000 but no more than CNY100,000 concurrently; if the circumstances are serious, a fine of no less than CNY100,000 but no more than CNY500,000 shall be imposed, and its legal representative or primary principal or the director directly in charge and other persons directly liable shall be prohibited from engaging in cosmetics production or operation activities for five years.

For overseas cosmetics registrants and record-filing applicants who refuse to perform the administrative penalty decisions made in accordance with the Regulations, their cosmetics shall be prohibited from import for ten years.

Article 71 If a cosmetics inspection institution issues a false inspection report, the certification and accreditation administration shall revoke its qualification certificate, and will not accept its qualification accreditation application for ten years, confiscate the inspection fees collected, and impose a fine of no less than

验费用，并处5万元以上10万元以下罚款；对其法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员处以其上一年度从本单位取得收入的1倍以上3倍以下罚款，依法给予或者责令给予降低岗位等级、撤职或者开除的处分，受到开除处分的，10年内禁止其从事化妆品检验工作；构成犯罪的，依法追究刑事责任。

第七十二条 化妆品技术审评机构、化妆品不良反应监测机构和负责化妆品安全风险监测的机构未依照本条例规定履行职责，致使技术审评、不良反应监测、安全风险监测工作出现重大失误的，由负责药品监督管理的部门责令改正，给予警告，通报批评；造成严重后果的，对其法定代表人或者主要负责人、直接负责的主管人员和其他直接责任人员，依法给予或者责令给予降低岗位等级、撤职或者开除的处分。

第七十三条 化妆品生产经营者、检验机构招用、聘用不得从事化妆品生产经营活动的人员或者不得从事化妆品检验工作的人员从事化妆品生产经营活动或者检验的，由负责药品监督管理的部门或者其他有关部门责令改正，给予警告；拒不改正的，责令停产停业直至吊销化妆品许可证件、检验机构资质证书。

第七十四条 有下列情形之一的，构成违反治安管理行为的，由公安机关依法给予治安管理处罚；构成犯罪的，依法追究刑事责任：

(一) 阻碍负责药品监督管理的部门工作人员依法执行职务；

(二) 伪造、销毁、隐匿证据或者隐藏、转移、变卖、损毁依法查封、扣押的物品。

第七十五条 负责药品监督管理的部门工作人员违反本条例规定，滥用职权、玩忽职守、徇私舞弊的，依法给予警告、记过或者记大过的处分；造成严重后果的，依法给予降级、撤职或者开除的处分；构成犯罪的，依法追究刑事责任。

第七十六条 违反本条例规定，造成人身、财产或者其他损害的，依法承担赔偿责任。

第六章 附 则

第七十七条 牙膏参照本条例有关普通化妆品的规定进行管理。牙膏备案人按照国家标准、行业标准进行功效评价后，可以宣称牙膏具有防龋、抑牙菌斑、抗牙本质敏感、减轻牙龈问题等功效。牙膏的具体管理办法由国务院药品监督管理部门拟订，报国务院市场监督管理部门审核、发布。

香皂不适用本条例，但是宣称具有特殊化妆品功效的适用本条例。

第七十八条 对本条例施行前已经注册的用于育发、脱毛、美乳、健美、除臭的化妆品自本条例施行之日起设置5年的过渡期，过渡期内可以继续生

CNY50,000 but no more than CNY100,000; its legal representative or primary principal or director directly in charge and other persons directly liable shall be fined no less than one but no more than three times the income they obtained from the institution in the previous year, and shall be imposed by law or ordered to be imposed a sanction of degrading of posts, removal or expulsion, and those subject to the sanction of expulsion shall be prohibited from conducting cosmetics inspection for ten years; if a crime is constituted, criminal liability shall be investigated in accordance with the law.

Article 72 If a cosmetics technical evaluation institution, cosmetics adverse reactions monitoring institution or institution responsible for monitoring safety risks of cosmetics fails to perform its duties in accordance with the Regulations, resulting in major errors in technical evaluation, adverse reaction monitoring, and safety risk monitoring, the department in charge of medical products administration shall order it to make corrections, give a warning, and circulate a notice of criticism; if serious consequences are caused, its legal representative or primary principal or director directly in charge and other persons directly liable shall be downgraded, removed or expelled in accordance with the law.

Article 73 Where a cosmetics producer or operator or inspection institution recruits or employs a person who is not allowed to engage in cosmetics production and operation activities or inspection of cosmetics to engage in cosmetics production or operation or inspection thereof, the department in charge of medical products administration or other relevant departments shall order it to make corrections and give a warning; if it refuses to make corrections, it shall be ordered to suspend production and business until its license or the inspection institution's qualification certificate is revoked.

Article 74 If anyone falls under either of the following circumstances, which constitutes a violation of public security management, the public security organ shall impose a public security management punishment in accordance with the law; if a crime is constituted, criminal liability shall be investigated in accordance with the law:

1. obstruction of the officials of the department in charge of medical products administration to perform their duties in accordance with the law; or

2. forging, destruction or concealment of evidence or hiding, transfer, resale or damage of the items that are sealed up or seized in accordance with the law.

Article 75 If an official of the department in charge of medical products administration abuses his/her powers, neglects his/her duties, or engages in malpractice for selfish ends, the official shall be given a warning, or a demerit or a serious demerit will be recorded against them; if serious consequences are caused, the official shall be downgraded, removed or expelled in accordance with the law; if a crime is constituted, criminal liability shall be investigated in accordance with the law.

Article 76 Anyone who violates the Regulations, causing personal, property or other damage, shall be liable for compensation in accordance with the law.

Chapter VI Supplementary Provisions

Article 77 The provisions of the Regulations on general cosmetics shall apply mutatis mutandis to the management of toothpaste. After evaluating the efficacy of toothpaste in accordance with national standards and industry standards, a record-filing applicant of toothpaste may claim that toothpaste has the efficacy of preventing caries, inhibiting plaque, resisting dentin sensitivity, and relieving gum problems. The specific administrative measures for toothpaste shall be formulated by the drug administration of the State Council and be reported to the administration for market regulation of the State Council for examination and promulgation.

The Regulations shall not apply to soap, but shall apply to soap that is declared to have special cosmetic effects.

Article 78 For cosmetics registered for hair nourishment, hair removal, breast massaging, fitting and deodorant before the implementation of the Regulations, a transition period of five years shall be set from the date of implementation of the Regulations. During such transition period, the production, import and sale of

产、进口、销售，过渡期满后不得生
产、进口、销售该化妆品。

第七十九条 本条例所称技术规
范，是指尚未制定强制性国家标准、国
务院药品监督管理部门结合监督管理工
作需要制定的化妆品质量安全补充技术
要求。

第八十条 本条例自2021年1月1日
起施行。《化妆品卫生监督条例》同时
废止。

such cosmetics may continue. Upon expiration of such transition period, such
cosmetics shall not be produced, imported or sold.

Article 79 For the purpose of the Regulations, technical specifications refer to
the supplementary technical requirements for the quality safety of cosmetics that
are formulated by the drug administration of the State Council in combination with
the need for supervision and administration when no relevant compulsory national
standards have been formulated.

Article 80 The Regulations shall come into force as of January 1, 2021. The
Regulations on the Hygienic Supervision of Cosmetics shall be repealed
simultaneously.