Provisions for the Administration of Cosmetic Registration and Recordation[1]

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Chapter 1: General Provisions

Article 1

In order to standardize the management of cosmetics registration and filing, and to ensure the standardized submission of relevant materials, these management regulations are formulated in accordance with the *Regulations on the Supervision and Administration of Cosmetics*, the *Administrative Measures for the Registration and Filing of Cosmetics*, and other relevant laws and regulations.

Article 2

When applying for cosmetics registration or handling filing procedures within the territory of the People's Republic of China, the materials shall be submitted in accordance with the requirements of these management regulations.

Article 3

Cosmetics registrants and filers shall follow the principles of risk management, base their work on scientific research, and be responsible for the legality, authenticity, accuracy, completeness, and traceability of the submitted registration and filing materials. They shall also bear the corresponding legal responsibilities. Overseas cosmetics registrants and filers shall supervise the registration and filing work of their domestic responsible persons.

Article 4

Cosmetics registration and filing materials shall use standardized Chinese characters published by the state. Except for cases where other languages must be used (e.g., registered trademarks, websites, patent names, names and addresses of overseas enterprises), or for commonly accepted professional terms (such as SPF, PFA, PA, UVA, UVB, vitamin C, etc.), all other foreign

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language content must be fully and properly translated into Chinese, with the original text attached after the corresponding translation.

Article 5

Cosmetics registration and filing materials shall comply with national regulations regarding the use of official seals. The documents shall be fully signed and sealed and possess legal validity. For overseas enterprises and other organizations that do not use official seals, the legal representative or the head of the enterprise (or organization) shall sign the documents. Except for user information-related materials, when the registration and filing materials of a product require signatures or seals from an overseas cosmetics registrant or filer, the legal representative or person-in-charge may authorize a signatory of the registrant, filer, or domestic responsible person to sign on their behalf. If signing under authorization, the original power of attorney and its notarization must be submitted. The power of attorney shall clearly specify the matters and scope of the authorized signature.

Except for original documents issued by government authorities, relevant institutions, registration and filing inspection institutions, and notarization agencies, all other registration and filing documents shall be stamped page by page with the official seal of the domestic registrant, filer, or domestic responsible person.

If an electronic seal with an encrypted certificate is used, it may be directly affixed to the electronic document.

Article 6

Cosmetics registration and filing materials shall use the legal units of measurement of China. If other units are used, they shall be converted into Chinese legal units. References must be accurately cited and include source information to ensure effective traceability. Punctuation marks, charts, and terminology must be used correctly and consistently to ensure the accuracy and standardization of the material.

Article 7

The same content appearing in multiple places within the cosmetics registration and filing materials must remain consistent throughout. If supporting documents are provided, the relevant content must match the contents of those documents.

Article 8

In text documents submitted for cosmetics registration and filing, the main body of the text shall be in black font. The content must be legible, with appropriate line spacing and page margins to ensure that no text is lost during printing or binding.

Article 9

Paper documents submitted for cosmetics registration and filing must use international standard A4-size paper. The content must be complete, clear, and free of alterations. For documents such as unfolded packaging images that require larger paper sizes, other formats may be used, but they must be properly placed within A4-sized documents. The carriers and writing materials used for physical documents must meet durability requirements.

Chapter 2: Requirements for User Information Related Materials

Section 1- Data Items and Requirements

Article 10

When applying for the registration of special cosmetics for the first time or handling the filing of ordinary cosmetics, domestic registrants, filers, and domestic responsible persons shall submit the following user information related materials:

1-Registrant/Filer information form and resume of the person responsible for quality and safety;

2-Overview of the registrant/filer's quality management system;

3-Overview of the registrant/filer's adverse reaction monitoring and evaluation system;

4-Overseas registrants and filers shall submit the domestic responsible person information form ;

5-Original authorization letter of the domestic responsible person and its notarization certificate;

6- If the registrant or filer produces the product themselves or entrusts an overseas manufacturer to produce it, they shall submit the manufacturer information form and information on the person responsible for quality and safety, reporting all existing manufacturers and their information at one time. If the manufacturer is overseas, the original certificate proving compliance with overseas production standards shall be submitted.

Article 11

Enterprises engaged only in entrusted production within China shall submit the manufacturer information form referred to in Article 10, Item (6) for the purpose of confirming the entrusted production relationship.

Article 12

If one party holds multiple identities such as domestic registrant or filer, domestic responsible person, or manufacturer, or if the same domestic responsible person corresponds to multiple overseas registrants or filers, all relevant materials can be submitted at one time to obtain the corresponding user permissions. Existing users can supplement relevant materials as needed to increase user permissions.

Article 13

The resume of the person responsible for quality and safety shall include education background, work experience, and other contents relevant to the requirements.

Article 14

The overview of the quality management system is a summary description of the registrant/filer's ability and processes of quality management and control. It shall truthfully and objectively reflect the actual situation, including management systems such as supplier selection, raw material acceptance, production and quality control, product retention, etc. The language should be concise, highlighting key points of quality control settings and daily execution management requirements. If the registrant or filer has both self-production and entrusted production, they shall submit respective versions of the quality management system overview.

Article 15

The overview of the adverse reaction monitoring and evaluation system is a summary description of the registrant, filer, and domestic responsible person's ability and processes for monitoring and evaluating adverse reactions. It shall truthfully and objectively reflect the actual situation. The language should be concise, reflecting the key points of adverse reaction monitoring, the arrangement of each stage, and daily execution management requirements.

Article 16

The authorization letter of the domestic responsible person shall clearly specify at least the following contents and information: the names of the registrant, filer, and domestic responsible person; the authorization and authorized relationship; the scope and period of authorization. One product shall not be authorized to multiple domestic responsible persons. The domestic person responsible shall conduct registration and filing work within the scope of authorization.

Article 17

Overseas manufacturers shall submit qualification certificates, documents, or other proof materials demonstrating that the manufacturer complies with quality management systems or production quality management standards. The proof materials shall be issued or recognized by the government authority, certification body, or a third party with certification and accreditation qualifications in the country (region) where the manufacturer is located, and shall indicate the manufacturer's name and actual production address. If original proof materials cannot be provided, copies notarized by a Chinese notary or certified by a Chinese embassy or consulate shall be provided.

Section 2- Updates to User Information and Materials

Article 18

When user information or related materials change, they shall be updated in a timely manner to ensure that the user information and related materials on the registration and filing information service platform are true and accurate. The update methods mainly include self-update, general review update, production site update, and other specific regulated review updates. For updates that require review, after review by the drug regulatory department, the relevant information and materials shall be updated.

Article 19

Among user permission related materials, contents that can be self-updated include information of the legal representative, the person responsible for quality and safety, and contact information. When the above information changes, users shall update it by themselves in a timely manner.

Article 20

Among user permission related materials, contents that can undergo general review update include basic information, overview of the quality management system, overview of the adverse reaction monitoring and evaluation system, and the scope and period of authorization of the domestic responsible person. When performing a general review update, a general review update information form shall be submitted, together with the relevant materials that meet requirements. If the name of the overseas registrant or filer changes, an original document proving that the entity has not changed issued by the government authority or relevant organization of the country (region) where it is located shall be provided; if the original cannot be submitted, a notarized copy by a Chinese notary or confirmed by a Chinese embassy (consulate) shall be provided. If the production site address of the overseas manufacturing enterprise changes only in text, an original document proving that the production site has not

changed issued by the government authority or relevant organization of the country (region) where it is located shall be provided; if the original cannot be submitted, a notarized copy by a Chinese notary or confirmed by a Chinese embassy (consulate) shall be provided. If the authorization scope of the domestic responsible person changes, the new authorization scope shall include the original authorization scope.

Article 21

Among user permission related materials, contents that can undergo production site updates are the production site information of the manufacturing enterprise. Specific circumstances include: relocation of the production site, addition of a production site, reduction of a production site, and update of production standard certification documents only. When performing a production site update, a production site update information form shall be submitted. If an overseas manufacturer relocates or adds a production site, or updates the production quality management standard certification documents, they shall provide relevant materials of overseas production quality management standard certification as required.

Article 22

Based on actual production and operation conditions, if it is necessary to add self-production or entrusted overseas manufacturers, relevant materials may be submitted to increase manufacturer information; if necessary, an overview of the corresponding quality management system shall also be supplemented.

Article 23

When updating user information, enterprises shall first check all the information under the username by themselves. If multiple pieces of information change simultaneously, they shall be updated at the same time, submitting relevant materials together.

Article 24

When the authorization period specified in the domestic responsible person's authorization letter expires, a renewed authorization letter shall be resubmitted to extend the authorization period. If it is not resubmitted after expiration, the domestic responsible person will no longer be able to handle new registration or filing matters for the corresponding overseas registrant or filer. Already ongoing registration or filing matters under their name can continue to be processed to completion.

If overseas production quality management standard certification materials have an expiration date, updated certification materials shall be submitted in a timely manner, no later than 90 days after the expiration date; if there is no expiration date, the latest version shall be submitted every five years.

Article 25

Based on actual production and operation conditions, if it is necessary to cancel user permissions, after all related products have completed cancellation or change, the user permission cancellation information form shall be submitted to carry out the cancellation of user permissions.

Chapter 3: Requirements for Registration and Filing Documentation

Article 26

When a registrant or filer handles registration or filing, the following documents shall be submitted:

1-Cosmetics Registration and Filing Information Form and related materials;

2-Product name information;

3-Product formula;

4-Standards implemented for the product;

5-Draft product label;

6-Product test report;

7-Product safety assessment materials.

Article 27

The registrant or filer shall fill in the Cosmetics Registration and Filing Information Form item by item and submit relevant materials:

1- The product name includes the Chinese name and, for imported products, the foreign name. The Chinese name of the product shall comply with relevant regulations on cosmetic labeling.

2- The registrant or filer shall determine the product category and the corresponding product classification code according to the Cosmetics Supervision and Administration Regulations and the rules and directory of cosmetic classification. If the product involves special cosmetics with efficacy claims, it shall be declared as a special cosmetic.

3- For cosmetics commissioned to domestic enterprises for production, the registrant, filer, or domestic responsible person shall select a production enterprise that has already activated user permissions for association. After confirmation by the production enterprise, the registration application or filing shall be submitted. For cosmetics commissioned to overseas enterprises for production, the registrant, filer, or domestic responsible person shall submit a commissioning relationship document. The commissioning document shall at least state the product name, commissioning party, name of the commissioned production enterprise, production address, date of acceptance of the product commission, and signature/seal of the legal representative or authorized person of the commissioned production enterprise. If the registrant or filer and the commissioned production enterprise belong to the same group company, supporting documents showing they belong to the same group and a product quality assurance document issued by the group company may be submitted to confirm the commissioning relationship.

4-For imported products, a certificate of sale issued by the competent government authority or industry association of the country (region) where the registrant, filer, or manufacturer is located shall be provided, except for products commissioned by domestic registrants or filers to overseas manufacturers or whose formula is specially designed for the Chinese market. The certificate of sale shall at least include the name of the registrant, filer, or manufacturer, the product name, the name of the issuing institution, and the date of issuance, and be confirmed by the institution's seal.

For combination-packaged products with both imported and domestic components, only the certificate of sale for the imported part needs to be submitted.

For products with packaging specially designed for the Chinese market, a certificate of sale in the country or region of the registrant, filer, or manufacturer shall be submitted, along with explanatory materials proving that the product formula and production process are consistent with the products in the country or region of the registrant or filer.

5-For imported products with formulas specially designed for the Chinese market (excluding those produced overseas on commission by domestic parties), the following materials shall be submitted:

-Explanatory materials regarding formula design based on Chinese consumers' skin types, consumption needs, etc.

-Consumer testing or human efficacy test data conducted in China using Chinese consumers.

6-The certificate of sale, commissioning documents, or group company proof documents for imported products may list multiple products. When applying for registration or filing, one product may submit the original document, and others may use copies, specifying the product

name that holds the original, as well as the corresponding acceptance number, registration certificate number, or filing number.

Article 28

The registrant or filer shall submit the basis for naming the product. The naming basis shall specify the trademark name, generic name, and attribute name, and explain their specific meanings respectively.

For imported products, explanations of both the foreign name and Chinese name shall be provided, as well as the correspondence between the Chinese and foreign names (except for those designed solely for the Chinese market and without a foreign name). If the trademark name in the Chinese product name contains letters, pinyin, numbers, symbols, etc., a trademark registration certificate shall be provided.

Article 29

The product formula shall be the manufacturing input formula and must comply with the following requirements:

(I) Requirements for the formula table:

The product formula table shall include the following content: raw material serial number, raw material name, percentage content, and purpose of use.

1. Raw material name:

The product formula shall provide the names of all raw materials. Raw material names include the standard Chinese name, the International Nomenclature of Cosmetic Ingredients (abbreviated as INCI name), or the English name. The raw material names used in the formula ingredients shall adopt the standard Chinese name, INCI name, or English name as listed in the Inventory of Existing Cosmetic Ingredients in Use. If the formula contains new cosmetic ingredients under safety monitoring, the name of the raw material that has already been registered or filed shall be used. If the INCI name of the ingredients marked on the original packaging of imported products is inconsistent with the ingredient names in the formula, an explanation shall be provided.

For the following situations, relevant information shall be indicated in the remarks column of the product formula table:

-If hydrocarbons derived from petroleum or coal tar are used (excluding single components), the Chemical Abstracts Service number (abbreviated as CAS number) of the related raw material shall be indicated.

-If colorants are used, the Colour Index number (abbreviated as CI number) specified in the *Cosmetic Safety Technical Standards* shall be indicated in the raw material name column of the product formula, except where there is no CI number.

-If the colorant used is a lake pigment, “(lake)” shall be marked after the colorant, and the type of lake pigment used shall be explained in the remarks column of the formula.

-If propellants that come into direct contact with the product contents are included, the type and amount of propellant shall be indicated in the remarks column of the formula.

-If nano raw materials are used, “(nano-grade)” shall be marked after the name of such ingredients.

2. Percentage content:

The product formula shall provide the content of all raw materials, calculated as a mass percentage. All raw materials shall be listed in descending order of their content. For raw materials composed of two or more components (excluding fragrance), the composition and the corresponding content of each component shall be specified.

3. Purpose of use:

The main purpose of use shall be indicated based on the actual function of each raw material in the product. For products applying for claims such as freckle removal and whitening, sun protection, hair dyeing, perming, or hair loss prevention, the corresponding functional ingredients shall be specified in the "purpose of use" column of the formula table. If the functional ingredient is not a single component, the specific functional components shall be clearly indicated in the "purpose of use" column of the formula table.

4. Remarks column:

In the following cases, explanations shall be provided in the remarks column:

-If denatured ethanol is used, the name and dosage of the denaturant shall be specified.

-If category-type raw materials are used, the specific raw material name shall be indicated.

-If raw materials are directly derived from plants, the specific plant part used shall be specified.

(II) The registrant, filing person, or domestic responsible person shall fill in the manufacturer information for the raw materials used in the product and upload the raw material safety information file issued by the raw material manufacturer. If the raw material manufacturer has submitted safety-related information on raw materials in accordance with the *Guidelines for Submission of Cosmetic Raw Material Safety Information*, and the raw material safety-related information has already been submitted, the registrant, filing person, or domestic responsible person may fill in the raw material submission code to associate the raw material safety information file.

(III) For cosmetic products using new raw materials that are still under safety monitoring, the registrant, filing person, or domestic responsible person may only submit a registration application or file a record after confirmation by the registrant or filing person of the new raw material.

(IV) Fragrance in product formulas may be filled in using one of the following two methods, and the corresponding documents shall be submitted accordingly:

1. If only "fragrance" is listed as a raw material in the formula table, there is no need to submit the types and contents of the specific fragrance components. However, if the product label identifies specific fragrance components, or if the label on the original packaging of imported products indicates specific fragrance components, the types of those components shall be explained in the remarks column of the formula table.

2. If both "fragrance" and the specific fragrance components are listed in the formula table, documentation issued by the fragrance raw material manufacturer listing all fragrance components and their respective contents shall be submitted.

(V) For products using patch or mask-type carrier materials, the main material composition of the carrier shall be specified in the remarks column. In addition, documents shall be provided that include the source, manufacturing process, and quality control specifications of the carrier materials.

(VI) For product formulas that use extracts from animal organs, tissues, or blood products as raw materials, the following shall be provided:

-The source of the materials,

-Their composition,

-The preparation process, and

-Relevant documents proving that such use is permitted in the raw material's country of manufacture.

Article 30

The product execution standards shall include the full ingredients, brief description of the production process, sensory indicators, microbiological and physicochemical indicators and their quality control measures, usage methods, storage conditions, shelf life, and other contents. These shall comply with relevant national laws and regulations, mandatory national standards, and technical specifications.

1-Product Name, Includes the Chinese name and the foreign name of imported products.

2-Full Ingredients, Includes the serial number of all raw materials used in the production of the product, the raw material names, and their intended purposes. All raw materials shall be arranged in descending order by content.

3-Brief Description of Production Process

-The main steps of the actual production process shall be briefly described, including feeding (adding raw materials), mixing, filling, etc. If pre-mixing of two or more raw materials or filling and other production steps are completed cooperatively by different manufacturing enterprises, this shall be noted.

-The main production process parameter ranges shall be reflected. All raw materials shall be clearly listed in the production steps, and the names or serial numbers of raw materials used shall be consistent with those listed in the product formula. If the same raw material is used at different stages of production, this shall be distinguished. If auxiliaries such as water or volatile solvents are used in the production process but removed in subsequent steps, this shall be noted.

4-Sensory Indicators

The color, texture, odor, and other indicators of the product contents shall be described separately. For set products, the sensory indicators of each component shall be described separately. For products using patch or film-type carrier materials, the color and texture of both the patch/film material and the soaking liquid shall be described separately.

-Color refers to the objective hue of the product contents. If the same product has multiple distinguishable colors, each shall be described. If colors are hard to distinguish, the main visual or usage color presented by the product or the color range may be described.

-Texture refers to the form or physical state of the product contents.

-Odor refers to whether the product contents have a smell.

5-Microbiological and Physicochemical Indicators and Quality Control Measures

-Actual controlled microbiological and physicochemical indicators of the product shall be submitted. These indicators must comply with the requirements of the "Cosmetic Safety Technical Specification" and the "Cosmetic Registration and Filing Inspection Work Specification."

-Corresponding quality control measures shall be submitted based on the actual controlled microbiological and physicochemical indicators of the product.

-If inspection methods are used as quality control measures, the inspection frequency shall be specified. If the methods used are exactly the same as those in the "Cosmetic Safety Technical Specification," the name of the inspection method in the Specification shall be indicated. If the methods differ from those in the Specification, the inspection method name shall be given along

with an explanation of whether the method has been validated against the Specification's method. Complete inspection methods and validation documents shall be filed for reference.

-If non-inspection methods are used as quality control measures, specific implementation plans shall be clarified, along with explanations on the rationality of these measures to ensure the product complies with the "Cosmetic Safety Technical Specification."

6-Usage Methods: The usage methods of the cosmetics shall be explained. If there are special requirements for the user group or the application site, these shall be specified. Safety warning statements shall comply with the cosmetic labeling management regulations and the "Cosmetic Safety Technical Specification" and other relevant laws and regulations.

7-Storage Conditions: Storage conditions shall be set based on the product packaging and the stability characteristics of the product itself.

8-Shelf Life: The shelf life of the product shall be set based on product packaging, product stability, or related experimental results.

Article 31

The registrant, filing party, or domestic responsible person shall fill out the Product Label Sample Form item by item. The contents filled in — such as the usage method, safety warning language, storage conditions, and period of use — shall comply with the standards implemented for the product.

For imported cosmetics, the sales packaging (including instructions) from the country (or region) of production shall be submitted, along with a Chinese translation of the foreign-language labels.

Article 32

When handling the filing of general cosmetics or before the market launch of special cosmetics, the registrant, filing party, or domestic responsible person shall upload images of the product's sales packaging labels. The images shall meet the following requirements:

1-The images shall include flat images of all visible surfaces of the packaging and 3D display images showing the product's appearance. The images shall be complete and clear.The flat images shall allow for easy identification of all labeled content; If all labeled content cannot be clearly displayed, zoomed-in images or packaging design diagrams shall also be submitted.

2-For electronic labels, the electronic label content shall be submitted, and the code image on the sales packaging shall be the preset code image generated by the registration and filing information service platform.

3-The label content and instructions for use in the uploaded images shall not exceed the content specified in the Product Label Sample Form.

4-If there are multiple types of sales packaging, images of all the packaging labels shall be submitted. However, if one or more of the following situations apply, only one type of packaging label image needs to be submitted, and the others do not need to be uploaded repeatedly:

-Only the net content specification is different;

-Only additional markings for sales channels, promotions, holiday editions, or gifts are added to the uploaded packaging;

-Only the color of the packaging is different;

-A registered or filed product is sold in combination as a set or gift box, and the combination process does not involve contact with the product contents; except for the addition of a combination product name, other labeling content does not exceed that of each product's label;

-The differences from the uploaded packaging can be clearly described in text and have been noted and explained.

Article 33

The product inspection report for a registered or filed product shall be issued by a cosmetic registration and filing inspection institution and shall comply with the relevant regulations such as the Cosmetic Safety Technical Specifications and the Cosmetic Registration and Filing Inspection Work Specifications.

1-The product inspection report shall include: Microbiological and physicochemical tests, Toxicological tests, Human safety test report, and Human efficacy test report, etc.

-The sample for testing must be of the same product name and batch number.

-The product information stated in the product inspection report shall be consistent with the relevant information of the registered or filed product. If, due to name changes or other reasons, the product name, company name, etc., in the inspection report are inconsistent with the registration or filing information, but do not affect the test results, an explanation shall be provided, along with the submission of a Report Amendment Application Form and a supplemental inspection report or correction letter issued by the inspection and testing institution.

-If the same product is produced by multiple manufacturing enterprises, one manufacturing enterprise shall submit a complete product inspection report based on its sample, and the microbiological and physicochemical inspection reports of the samples from the other manufacturing enterprises shall also be submitted.

-For multi-shade series general cosmetics, toxicological testing may be conducted by sampling in accordance with the *"Cosmetics Registration and Filing Inspection Work Specifications"* and may be filed as a group of products. Each product shall be accompanied by: a list of the series of products, a base formula, a colorant table, and a list of the sampled products.

-For cosmetics claiming new efficacy, testing shall be carried out in accordance with the *"Cosmetics Registration and Filing Inspection Work Specifications"* and relevant technical regulatory documents.

2- If the manufacturer of general cosmetics has obtained relevant certification of the production quality management system issued by the competent authority of the country (or region) in which it is located, and the product safety risk assessment results can fully confirm the safety of the product, submission of the toxicological test report for that product may be waived, except in the following circumstances:

-The product claims to be for use by infants or children;

-The product uses new cosmetic ingredients that are still under safety monitoring;

-Based on quantitative grading and scoring results, the filing person, domestic responsible person, or manufacturing enterprise is listed as a key supervision target.

-If the product is produced by multiple manufacturing enterprises, then only when all manufacturers have obtained the relevant certification of the production quality management system issued by the competent authority of the country (or region) can the toxicological test report be waived.

3-When applying for registration of special cosmetics, a human efficacy test report that complies with the regulations related to the evaluation of cosmetic efficacy claims shall be submitted.

-The efficacy test report for the claimed efficacy of special cosmetics shall be issued by a cosmetic registration and filing inspection institution.

-For multi-shade series sunscreen cosmetics, human efficacy testing may be conducted by sampling in accordance with the *"Cosmetics Registration and Filing Inspection Work Specifications"*, and the series can be registered as a group of products. Each product's documentation shall include: a list of the series products, the base formula, a table of colorants, and a list of sampled products.

Article 34

The registrant or filer shall carry out product safety assessment in accordance with the requirements of the technical guidelines related to cosmetic safety assessment, and shall prepare a product safety assessment report.

Cosmetics that must be used in conjunction with instruments or tools (excluding tools such as brushes, air cushions, perming tools, etc., which are used only to assist in application) shall have their safety assessed under the conditions of use with the instruments or tools.

Explanatory materials shall also be provided regarding whether, during product use, the instrument or tool: has cosmetic functions, participates in the re-processing of the cosmetic, or alters the mechanism of action between the product and the skin, etc.

Article 35

Cosmetics that contain two or more independent formulas that must be used together or whose packaging containers cannot be separated, shall have the formulas filled out separately and be registered or filed as one product.

If one (or more) of the formulas is a special cosmetic, it shall be registered as a special cosmetic. If one (or more) of the formulas is produced overseas, the product shall be registered or filed as an imported cosmetic.

Article 36

The cosmetics registrant or filer shall retain samples of each batch of produced cosmetics for future inspection. The number of retained samples shall be sufficient to meet the requirements for conducting registration or filing inspections. Special cosmetics shall retain 1 sealed sample sealed by the first inspection institution for registration and filing. If an imported special cosmetic submits a pilot sample for product registration inspection, it shall retain one sealed pilot sample (sealed by the inspection institution) and one unopened commercial product sample. General cosmetics shall retain 1 commercial product sample by the domestic filer or domestic responsible person. For imported general cosmetics with sales packaging designed specifically for the Chinese market, 1 commercial product sample from the country of origin shall be retained by the domestic responsible person.

Article 37

Special cosmetics and general cosmetics intended for export shall be filed on the registration and filing information service platform.

The manufacturer shall submit the following materials:

1-Product name;

2-Target export country (region);

3-Product label images, including: a 3D image of the front view of the product's sales packaging, a flat view of the product packaging, and the product instructions (if available).

Chapter 4: Requirements for Changes

Article 38

If the registration items of a registered product change, the corresponding materials shall be submitted before the production or import of the product intended to be changed. After completing the corresponding change, production or import may proceed. If the filing items of a filed product change, the corresponding materials shall be submitted before the product intended to be changed is marketed or imported. After completing the corresponding change, marketing or imports may proceed. Products produced, marketed, or imported before the change may be sold until the expiration of their shelf life.

Article 39

If the name, domicile, or other information of the registrant, filer, domestic responsible person, or manufacturer of a registered or filed product changes (production site unchanged), the information shall be updated in accordance with the relevant requirements of Chapter 2, Section 2 of these management regulations. A one-time change shall be made to the relevant special cosmetic registration certificate or ordinary cosmetic filing information, as well as the above-mentioned related information on the product label proof.

Article 40

If the product name of a registered or filed product changes, a reasonable explanation shall be provided and the following materials submitted:

1-Special cosmetic change application form or ordinary cosmetic change information form;

2-Product name related materials submitted in accordance with Article 28 of these management regulations.

Article 41

If the production site changes or is added, the following materials shall be submitted:

1-Special cosmetic change application form or ordinary cosmetic change information form;

2-Microbiological and physicochemical test reports for products produced at the proposed changed site;

3-If the filed product is evaluated for safety only through product safety assessment, and the proposed added manufacturer cannot provide production quality management system certification issued by the government authority of the country (region) where it is located, relevant toxicological test data for the product shall be submitted;

4-If the entrusted production relationship of the product undergoing change is altered, domestic products shall confirm the changed entrusted production relationship in accordance with Article 27(3) of these management regulations; imported products shall submit entrusted relationship documents or proof that they belong to the same group company, as well as product quality assurance documents issued by the corporate group.

Article 42

If the manufacturer of the raw materials used in a registered or filed product, or the quality specifications of the raw materials, increase or change, but the content of the raw materials in the formula and the types and proportions of specific components in the raw materials do not change, the raw material manufacturer information and raw material safety information shall be updated and maintained through the registration and filing information platform. If the product safety evaluation data involved changes, the product safety evaluation data shall also be changed accordingly.

If the manufacturer of the raw materials used in a registered or filed product, or the quality specifications of the raw materials, increase or change, and the content of the raw materials in the formula, the main functional ingredient content, and solvent in the raw materials do not change, but the type or content of trace stabilizers, antioxidants, preservatives, and other components added to ensure raw material quality change, the following materials shall be submitted:

1-Special cosmetic change application form or ordinary cosmetic change information form;

2-Product formula;

3-Explanation of the changes, including reasons for changes and the purpose of changed components in the raw materials;

4-Product safety evaluation data of the proposed changed product;

5-If the standards implemented by the product change, the standards to be implemented by the proposed changed product shall be submitted;

6-If the proposed changes involve changes to the product label proof such as full ingredient listing or safety warning language, the product label proof of the proposed changed product shall be submitted.

Article 43

If the manufacturing process description, microbiological and physicochemical indicators and quality control measures, usage methods, safety warning language, storage conditions, shelf life, or other standards implemented by the product change, the following materials shall be submitted:

1-Special cosmetic change application form or ordinary cosmetic change information form;

2-The standards to be implemented by the proposed changed product;

3-If the manufacturing process description changes, an explanation of the change shall be submitted along with the microbiological and physicochemical test report of the proposed changed product;

4-If the product usage method changes, product safety evaluation data of the proposed changed product shall be submitted;

5-If the product shelf life is extended, stability study data of the proposed changed product shall be submitted;

6-If the content of product safety evaluation data changes, the product safety evaluation data shall be submitted;

7-If changes involve imported products' original sales packaging and labels, the original sales packaging (including instructions) and Chinese translations of foreign labels of the proposed changed product shall be submitted;

8-If product label proof changes are involved, the product label proof change shall also be carried out according to Article 44.

Article 44

If the product label proof content changes, the following materials shall be submitted:

1-Special cosmetic change application form or ordinary cosmetic change information form;

2- The proposed changed product label proof;

3-For sunscreen cosmetics adding PA, broad-spectrum sunscreen, or post-bath SPF marks, the corresponding efficacy test report of the proposed changed product shall be submitted;

4-For freckle-removal and whitening cosmetics adding freckle-removal or whitening efficacy claims, the corresponding human efficacy test report of the proposed changed product shall be submitted;

5-If changes involve imported products' original sales packaging and labels, the original sales packaging (including instructions) and Chinese translations of foreign labels of the proposed changed product shall be submitted.

Article 45

If the content of the product safety evaluation data changes, the following materials shall be submitted:

1-Special cosmetic change application form or ordinary cosmetic change information form;

2-The proposed changed product safety evaluation data;

3-If the cosmetic safety evaluator changes, relevant information of the proposed changed cosmetic safety evaluator shall be submitted.

Article 46

If the product classification changes, the following materials shall be submitted:

1-Special cosmetic change application form or ordinary cosmetic change information form;

2-Supplement or update data according to the requirements of the proposed changed product classification;

3- If a registered special cosmetic proposes to add efficacy claims such as hair dyeing, perming, freckle removal and whitening, sun protection, hair loss prevention, or new efficacy claims, supplementary materials shall be submitted according to the requirements of Chapter 3.

Article 47

If the registrant changes due to company merger, absorption, establishment of new merged entity, or division, the new domestic registrant or the domestic responsible person with corresponding user rights of the new overseas registrant shall submit the following materials to carry out a one-time change of the involved special cosmetic registration certificate:

1-Statement and related documents of company merger and cancellation, division, establishment of wholly-owned subsidiaries, or operation by different subsidiaries within the same group;

2-Original notarized statement from interested parties (such as original registrant, new registrant, domestic responsible person, etc.) and their legal representatives confirming no objection to the ownership of the special cosmetic registration certificate.

Article 48

When changing the domestic responsible person, the following materials shall be submitted:

1-List of products for which the domestic responsible person is to be changed;

2-Informed consent letter stamped by the original domestic responsible person agreeing to the change of domestic responsible person, or judgment documents proving the effective change of domestic responsible person;

3-Commitment letter from the proposed domestic responsible person to undertake the relevant responsibilities for the products (including products already on the market before the change) originally held by the original domestic responsible person.

Article 49

For changes involving other matters, a description of the proposed changes shall be submitted, and relevant materials shall be submitted based on the specific circumstances.

Article 50

If the sales packaging of a registered or filed product changes, according to the principles of Article 32, before the product with the new sales packaging is marketed, upload the label images of the product sales packaging again or provide notes explaining the proposed changed parts.

Article 51

After the change of registered special cosmetics is completed, when receiving the changed paper product registration certificate, the original product registration certificate shall be returned.

Chapter 5 : Requirements for Renewal, Cancellation, and Other Matters

Article 52

To apply for an extension of the validity period of a special cosmetic product registration certificate, the following materials shall be submitted:

1-Application form for registration extension;

2-Product self-inspection statement, with main contents including:

3-Proof of production (import) and sales (limited to the last registration cycle);

4-Supervision sampling inspection, investigation and handling, recall situation (limited to the last registration cycle);

5-Statistical analysis of adverse reactions of the product and measures taken;

6-Other content that needs to be explained.

7-Product inspection report shall be submitted according to the current regulations and standards adjustments.

Article 53

The annual report of general cosmetics shall include the following contents:

1-Overview of product production and import, as well as any suspension of production during the period;

2-Self-inspection of the product's compliance with laws, mandatory national standards, and technical specifications.

Article 54

To apply for a reissue of a product registration certificate, the following materials shall be submitted:

1-Reissue application form;

2-If the original product registration certificate is damaged and a reissue is requested, the original certificate shall be returned when collecting the new one;

3-If the original product registration certificate is lost, a letter of commitment shall be submitted.

Article 55

To withdraw a registration application, the registrant shall submit a withdrawal application form.

Article 56

To cancel an already registered special product registration certificate, the registrant shall submit a cancellation application form.

Article 57

If the address of the filer or the domestic responsible person changes and this results in a change of the filing management department for a previously filed general product, the filer may cancel the original filing information on their own initiative and reapply for filing, using the original filing materials.

Article 58

In the event that a special cosmetic product has been denied registration due to reasons unrelated to safety, a subsequent application for registration may reference and include copies of the original registration materials. The applicant shall also submit a formal statement affirming that the grounds for the previous denial were not related to product safety, accompanied by a detailed explanation of the reasons for the initial denial.

Article 59

If a general product is filed again after cancellation, an explanation of the situation

shall be submitted. For cancellations not related to safety reasons, copies of the original filing materials may be used for re-filing.

Chapter 6: Supplementary Provisions

Article 60

These administrative regulations shall come into effect on May 1, 2021.