Regulations for Issuance of License of Specific Purpose Cosmetics

This regulation has been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

Chapter 1 General Provisions

Article 1 These Regulations are prescribed pursuant to Paragraph 6 of Article 5 of the Cosmetics Hygiene and Safety Act (the "Act").

Article 2 Before the enforcement of the Act, cosmetics have obtained the license of medical or poisonous drugs per the Statute for Control of Cosmetic Hygiene shall be deemed as Specific Purpose Cosmetics within the valid term of such license.

Article 3 The terms used in these Regulations are defined as follows:

1. Specific purpose cosmetics: refers to cosmetics designated by public announcement of the central competent authority per Paragraph 1 of Article 5 of the Act, and used for sunscreen, hair-dyeing, permanent waving, antiperspirant, deodorant, tooth-whitening or other purposes.
2. Authorization letter: refers to a certificate issued by the original overseas manufacturer, the headquarter, or its contract manufacturer of specific purpose cosmetics, allows registration applicant to import and distribute such cosmetics.
3. Manufacture and Free Sale Certificate ("MFSC"): refers to a certificate issued by the country of origin proves the approved manufacturing and free sale.
4. Ingredients list: refers to a formula table of full ingredients issued by the manufacturer or the headquarter identifying names and content of ingredients.
5. Certificate of analysis: refers to documentation identifying characteristic, active ingredients, identification methods, quantitative methods, an acceptable range of content, test results, and other determination data.

Chapter 2 Manufacture and Import

Article 4 An applicant applies for the registration of the license for manufacturing specific purpose cosmetics per Paragraph 1 of Article 5 of the Act shall submit an application with following documents, and pay the fee to the central competent authority:

1. A copy of the factory registration certificate.
2. A copy of the license of the pharmacist in charge of supervision of manufacturing, or employment certificate and qualification of personnel who is stationed at the factory to supervise the dispensation and manufacturing.
3. Drafts of product labels, leaflets, and packaging.
4. The certificate of analysis.
5. For the contract manufacturer, a copy of company registration or business

registration certificate of the applicant and the OEM agreement.

A cosmetic manufacturing facility receives the certificate of cosmetic Good Manufacturing Practice by law, and applies for specific purpose cosmetics license for the same dosage form stated in such certificate, the certificate of analysis mentioned in Sub-paragraph 4 of the preceding Paragraph may be replaced with such certificate.

Article 5 An applicant applies for the registration of the license for importing specific purpose cosmetics per Paragraph 1 of Article 5 of the Act shall submit an application with following documents, information, and pay the fee to the central competent authority:

1. A copy of company registration or business registration certificate.
2. Drafts of product labels, leaflets, and packaging.
3. The authorization letter issued within the past two years.
4. The MFSC issued within the past two years.
5. An ingredient list issued within the past two years.
6. The certificate of analysis.
7. For the contract manufacturer, a certificate identifies the relationship between the hiring firm and contract manufacturer.

Article 6 The authorization letter stipulated under Sub-paragraph 3 of the preceding Article shall state the following information:

1. The name and address of the authorization letter submitter. If the letter is not issued by the original manufacturer, it shall additionally state the name and address of the original manufacturer.
2. The name and address of the agent.
3. The name and item of authorized products.
4. The intention of authorization.

The information mentioned in the preceding Paragraph shall be consistent with the application. If the authorization letter is written in the language other than Chinese or English, the Chinese or English translation shall be attached.

Article 7 The MFSC stipulated under Sub-Paragraph 4 of Article 5 shall state the following information:

1. The name of the product.
2. The name and address of the manufacturer.

The MFSC shall be authenticated by the overseas diplomatic mission. The MFSC issued by the government of the country of origin, or notarized by the local notary public may be exempted from authentication.

If MFSC is written in the language other than Chinese or English, the Chinese or English translation shall be attached.

The MFSC may be replaced with the free sale certificate issued by the country of the hiring firm and the manufacture certificate issued by the country of the contract

manufacturer.

The MFSC may be issued by either the authorities of the country of the hiring firm or contract manufacturer if specific purpose cosmetics is imported by the OEM.

If the country of origin of cosmetics in Japan and the MFSC only states the information of the vendor rather than the manufacturer, the copy of the manufacturing certificate carrying the name and the address of the manufacturer and the name of the product issued by the hygiene authority of the country of origin may be provided as substitution, while free sale certificate shall be attached.

Article 8 Ingredient list stipulated under Sub-paragraph 5 of Article 5 shall state the following information:

1. The name of the product.
2. The name and content of active ingredients, preservatives, pigments, or other ingredients.

The name of ingredients mentioned in the Sub-paragraph 2 of the preceding Paragraph shall refer to the International Nomenclature of Cosmetic Ingredients ("INCI") or its common chemical name in English. Its content shall be made by weight or volume percentage (i.e., W/W% or W/V%); provided that the content may be labeled as "appropriate amount" for other ingredients and pigments with no limits on the usage of same.

Ingredient list shall be authenticated by an overseas diplomatic mission. The list issued by the government of the country of origin, or notarized by the local notary public may be exempted from authentication.

Article 9 The certificate of analysis stipulated under Sub-paragraph 4 of Article 4 and Sub-paragraph 6 of Article 5 shall state the following information:

1. Characteristic: appearance, color, shape, and dosage form of the product.
2. Active ingredients: specific purpose ingredients in the product.
3. Method for identifying active ingredients.
4. Method for quantifying active ingredients.
5. Acceptable content range of active ingredients, and it shall be within 90% to 110% of the content.
6. The test results.
7. Other determination data.

If the active ingredients of oxidative hair- dyeing products are too low or unstable and therefore cannot be quantified precisely, the active ingredients stipulated under Sub-Paragraph 4 and 5 of the preceding Paragraph may be replaced with freebase (Alkalinity) or free ammonia (limited to active ingredients containing ammonia)

Article 10 When central competent authority designates specific purpose cosmetics by the public announcement per Paragraph 1 of Article 5 of the Act, the content of public

announcement shall contain the names, scopes, and limitations of active ingredients.

The active ingredient of cosmetics are not stipulated under preceding Paragraph; however, it is identified the characteristic of specific purpose cosmetic by the authorities of countries (areas) or regions recognized by the central competent authority, the applicant may apply for registration per the Act and attach the certificates used by those countries (areas) or regions.

Article 11 Applying for the license of specific purpose cosmetic shall attach relevant information per the Appendix if active ingredient of cosmetic is new substance, with new purpose or new maximum concentration. However, the condition mentioned in Paragraph 2 of the preceding Article shall exempt from it.

Article 12 Cosmetics applied for the license of specific purpose cosmetics shall not contain any ingredient prohibited from using per the public announcement made pursuant to Paragraph 1 of Article 6 of the Act.

Cosmetics mentioned in the preceding Paragraph contain bovine and sheep tissue composition shall attach certificates of products or raw materials from Bovine Spongiform Encephalopathy-free countries, regions, or zones.

Article 13 The license may be jointly applied if specific purpose cosmetics come from the same manufacturer, with the same purpose, same active ingredients and dosage form.

The joint application stipulated under the preceding Paragraph shall attach documents and data mentioned in Paragraph 1 of Article 4 and Article 5 separately in accordance with different products, except for those documents or data mentioned in Sub-Paragraph 1, 2, and 5 of Paragraph 1 of Article 4 and Sub-Paragraph 1 of Article 5.

Article 14 The central competent authority shall notify the applicant the result of the application stipulated under Article 4 and 5. The applicant, within three months after the arrival date of the notice, shall provide electronic files of approved labels, leaflets, and packaging, and pay the fee to the central competent authority to obtain the license.

Article 15 The items of registration stipulated under the preceding Article shall be as follows:

1. Product item.
2. Product name; model number and color code for serial products.
3. Active ingredients and content percentage.
4. Dosage form.
5. Leaflets, labels, packaging, and specifications.
6. Purpose.
7. Name of the applicant.
8. Name and address of the manufacturer.

Article 16 The license stipulated under Article 14 shall state validity term and items mentioned in Sub-paragraph of the preceding Article except for the items of Sub-paragraph 5.

Article 17 If the document or data attached to the application is deficient, or the fee is unpaid, the central competent authority shall request the applicant for the correction within the time limit.

The applicant who fails to correct the deficiency within the time limit under the preceding Paragraph may request an extension in writing to the central competent authority with reasons before the expiration of the time limit. The extension is one month upon the next day of the expiration of correction.

If the applicant fails to correct the deficiency per the preceding two Paragraphs, the application shall be refused.

Article 18 The application shall be disapproved if one of the following conditions applies:

1. Attached document or data is inconsistent with the content of the application.
2. Containing prohibited ingredients per Paragraph 1 of Article 6 of the Act, or the ingredients violate the limit on usage of ingredients set forth under Paragraph 2 of Article 6 of the Act.
3. The labeling of packaging, labels or, leaflets violates Article 7 of the Act.
4. Text or picture of the product name, packaging, labels or, leaflets has deception, exaggeration, or involving medical efficacy as set forth under Paragraph 1 and 2 of Article 10 of the Act.
5. Any conditions that may harm human health.
6. Other violation of laws, regulations or public announcement made by the central competent authority.

Article 19 If the license of specific purpose cosmetics is damaged or lost, the applicant may pay the fee to the central competent authority and apply for the replacement or reissue. The original license shall be attached if applying for the replacement.

Chapter 3 Modification of Registration, and Transfer and Modification of License

Article 20 If there is any change of the information of registration or license mentioned in Article 15 or 16, the applicant shall provide the original license and relevant documents and pay the fee to the central competent authority to apply for the modification per Paragraph 2 of Article 5 of the Act. After the central competent authority reviews and approves, the original license shall additionally state the modified registration, date, and returned the license with the stamp.

If the Modification mentioned in the preceding Paragraph is to increase items or color systems, those products shall be made by the same manufacturer, same active ingredients, same dosage form and purpose, and conforming to the limit on usage of specific purpose ingredients as set forth by the central competent authority.

Article 21 Applying for transfer of the license of specific purpose cosmetics, the transferor and transferee shall file a joint application with the original license and relevant certificates, and pay the fee to the central competent authority to apply for the

approval.

The original license shall identify the name of the transferee and the approval date when the central competent authority makes an approval mentioned in the preceding Paragraph.

Article 22 Applying for the revocation of the license of specific purpose cosmetics, the application with the original license and relevant documents shall be submitted to the central competent authority.

Chapter 4 Extension of License

Article 23 Applying for an extension of the term of validity of the license of specific purpose cosmetics per Paragraph 5 of Article 5 of the Act, the applicant shall submit an application with the following documents, and pay the fee to the central competent authority:

1. The original license.
2. The copy of the company or business registration certificate.
3. The Authorization letter issued within the past two years except for domestic manufacturing.

Article 24 If the extension is not applied before the expiration of the term of the license of specific purpose cosmetics per the preceding Article, the application shall re-apply for registration and license per Paragraph 1 of Article 5 of the Act. However, the applicant may submit an application with the following documents, and pay the fee to the central competent authority if re-apply license within six months after the term expired:

1. The original license.
2. The copy of the company or business registration certificate.
3. For domestic contract manufacturer, the manufacture agreement. For foreign contract manufacturer and import, the certificate identifies the relationship between the hiring firm and contract manufacturer.
4. For importer, MFSC, ingredient list and authorization letter issued within the past two years

The license with the new license number will be issued after the approval of the application mentioned in the preceding Paragraph.

Chapter 5 Supplementary.

Article 25 These Regulations shall take effect on July 1, 2019.

Appendix: Required Technical Information for registration of specific purpose cosmetics containing new substance, new purpose or new maximum concentration

item	information	New substance	New purpose	New maximum concentration (elevating maximum concentration)
origin of substances, research and develop history, foreign application status	origin of substances, research and develop history	○	○	○
	foreign application status	○	○	○
	Characteristic comparison information	○	○	○
Characteristics, specification of analysis	Chemical structure	○	╳	╳
	Physical/chemical Characteristics	○	╳	╳
	specification and method of analysis	○	○	○
Stability test	Long-term test	○	○	○
	Stress test	○	○	○
	Acceleration test	○	○	○
Safety test report	Acute toxicity test	○	Δ	Δ
	subacute toxicity test	○	Δ	Δ
	Chronic toxicity test	○	Δ	Δ
	Local sensitizing test	○	Δ	Δ
	Antigenicity test	○	Δ	╳
	*Mutagenicity test	Δ	╳	╳
	*Carcinogenicity test	Δ	╳	╳
	*Reproductive toxicity test	Δ	╳	╳
Test report of Absorption, Distribution, Metabolism, Excretion	Absorption	Δ	Δ	Δ
	Distribution	Δ	Δ	Δ
	Metabolism	Δ	Δ	Δ
	Excretion	Δ	Δ	Δ
Purpose-related information	Functionality or efficacy data	○	○	○
	Human test data	○	○	○
	Approval document Of other country	Δ	Δ	Δ

Notes：

1. 「○」means that the information under that item shall be provided.「△」means that it depends via a case-by-case basis.「╳」means that the information under that item is not necessary to be provided.
2. 「Foreign application status」: No need to provide if developed domestically.
3. 「Test specifications and results」: Including materials and preparations.
4. 「Stability test」:Including materials and preparations. No need to provide preparations for the ones bearing「*」mark.
5. Antigenicity tests shall include skin allergen tests and photoallergic tests; local irritation tests shall include skin irritation tests and mucosal stimulation tests.
6. Operation of stability tests may refer to international guideline or「Guidelines on the Drug Stability Study」as announced by the central health competent authority。
7. To conduct safety evaluation of cosmetics or cosmetic ingredients, cosmetics businesses shall comply with paragraph 4 and paragraph 6 of article 6 of the Act.