Proposed Draft of Regulations for Issuance of Permit License of Specific Purpose Cosmetics

This Draft 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 This Regulation is prescribed pursuant to Paragraph 6 of Article 5 of Cosmetics Hygiene and Safety Act (the "Act").

Article 2 Cosmetics, obtaining permit license of medical or poisonous drugs per the predecessor of the Act prior to enforcement of the Act, shall be deemed as Specific Purpose Cosmetics within the valid term of such permit.

Article 3 Terms used under this Regulations defined as below:

1. Specific Purpose Cosmetics: referring to Cosmetics as announced by the competent authorities per Paragraph 1 of Article 5 of the Act used for sunscreen, hair dying, permanent wave, antiperspirant, deodorant, teeth-whitening or other purposes.
2. Authorization Letter: referring to certificates of allowing applicant to import and distribution issued by oversea original manufacturer, the headquarter, or OEM importing Specific Purpose Cosmetics.
3. The Manufacture and Free Sale Certificates ("MFSC"): referring to certificates provided or issued by the country of original for manufacturing and free distribution in that country.
4. Ingredient List: referring to formula table of full ingredients issued by the manufacturer or the headquarter identifying name of ingredients and its content.
5. Certificate of Analysis: referring documentation identifying characteristic, active ingredients, identification methods, quantitative methods, acceptable range of concentration, test results and other determination data.

Chapter 2 Manufacture and Importation

Article 4 Applicants applying for registration of the permit for manufacturing Specific Purpose Cosmetics per Paragraph 1 of Article 5 of the Act shall file an application, attach below documents, data, and pay fees to the

competent authorities.

1. Copy of factory registration certificate.
2. Copy of license of the pharmacist in charge of manufacturing, or employment certificate and qualification of personnel deployed for resident supervisory of manufacturing.
3. Product labels, description and packaging design draft.
4. Certificate of Analysis.
5. For OEM, copy of company registration or business registration certificate of applicant and the OEM agreement.

Certificates of GMP lawfully obtained by premises where cosmetics manufactured can be substitution of the aforesaid Certificate of Analysis under Sub-Paragraph 4 of the preceding Paragraph if the applied permit of Specific Purpose Cosmetics carrying same dosage form as that of the cosmetics on the GMP certificate.

Article 5 Applicants applying for registration of the permit for importing Specific Purpose Cosmetics per Paragraph 1 of Article 5 of the Act shall file an application, attach below documents, data, and pay fees to the competent authorities.

1. Copy of company registration or business registration certificate.
2. Product labels, description and packaging design draft.
3. Authorization Letter issued within past two years.
4. MFSC issued within past two years.
5. Ingredient List issued within past two years.
6. Certificate of Analysis.
7. For OEM, the OEM agreement.

Article 6 Authorization Letter stipulated under Sub-Paragraph 3 of the preceding Article shall include:

1. The name and address of the assignor of Authorization Letter. If not issued by the original manufacturer, to include the name and address of the original manufacturer.
2. Name and address of the assignee.
3. Name and item of products authorized.
4. The authorizing intention.

The information provided per the preceding Paragraph shall be in line with what provided in the application. If Authorization Letter is written in the language other than Chines or English, the Chinese or English translation shall be attached.

If Specific Purpose Cosmetics is not imported by the original

manufacturer, the headquarter, or the OEM, the shipping voucher or other certificates that may confirm the source of products issued by the original manufacturer, the headquarter, or the OEM may be the substitution for Authorization Letter.

Article 7 MFSC stipulated under Sub-Paragraph 4 of Article 5 shall include:

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

MFSC shall be authenticated by oversea embassies except for that was issued by the government of country of original or notarized by the local notary public.

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

The free distribution certificate issued by the country of the assignor together with the manufacture certificate issued by the country of assigned manufacturer may be the substitution of MFSC.

MFSC may be issued by either the authorities of country of the assignor or the authorities of country of assigned manufacturer, if Specific Purpose Cosmetics is imported by the OEM. If the applicant is the secondary manufacturer, the relationship between the assignor and the assigned manufacturer shall be addressed

If cosmetics is manufactured in Japan and the MFSC only stipulates the vendor information without the information of the manufacturer, the copy of the manufacture certificate carrying the name and the address of the manufacturer and the name of the product issued by the health authorities of the country where cosmetic manufactured may be provided as substitution, while free distribution certificate shall be attached.

Article 8 Ingredient List stipulated under Sub-Paragraph 5 of Article 5 shall include:

1. Product name.
2. Name and content of active ingredients, preservative, pigments, or other relevant ingredients.

The name of ingredients provided for the Sub-Paragraph 2 of the preceding Paragraph shall refer to that provided under International Nomenclature of Cosmetic Ingredients (“INCI”) or its common English chemical name. Its content shall be made by weight or volume percentage (i.e. W/W% or W/V%); provided that the content may be labelled as “appropriate amount” for other ingredients and pigments if

no limits on usage of same.

Ingredient List shall be authenticated by oversea embassies except for that was issued by the government of country of original or notarized by the local notary public.

Article 9 Certificate of Analysis stipulated under Sub-Paragraph 4 of Article 4 and Sub-Paragraph 6 of Article 5 shall include:

1. Characteristic: appearance, color, sharp, and dosage form of products.
2. Active ingredients: specific purpose ingredients included in the product.
3. Method of identifying active ingredients included in the product.
4. Method of quantifying active ingredients included in the product.
5. Acceptable range of active ingredients included in the product shall be within 90% to 110% of the labelled content.
6. Test result.
7. Other determination data.

If the active ingredients of oxidation hair dye products are contained too low or unsteady and therefore cannot be quantified exactly, the freebase (Alkalinity) or free ammonia (limited to active ingredients containing ammonia) may be the substitution to be stipulated under Sub-Paragraph 4 and 5 of the preceding Paragraph.

Article 10 Active ingredients of Specific Purpose Cosmetics shall conform to the acceptable ranges announced by the competent authorities. If the active ingredients are not stipulated but is listed as active ingredients per the announcement made by the authorities of countries (areas) recognized by the competent authorities, after providing such announcement, the permit to be issued per this Regulation may be approved after applying for registration per this Regulation.

Article 11 When applying for Specific Purpose Cosmetics with new active ingredients, or active ingredient with new usage or new maximum concentration, its application shall attach relevant information per the appendix. For applications, with active ingredient not in the list (the acceptable ranges) in the preceding article, in accordance with preceding article, this provision shall not apply.

Article 12 Cosmetics products applied for permit license of Specific Purpose Cosmetics shall not contain any ingredient prohibited from being used via the announcement made by the competent authorities per Paragraph 1 of Article 6 of the Act.

Cosmetics products of the preceding Paragraph containing bovine and sheep tissue composition shall attach certificates identifying source of materials or source of products not from infected countries or zones of Bovine Spongiform Encephalopathy.

Article 13 The applications of permit license of Specific Purpose Cosmetics may be combined when manufacturing or importing Specific Purpose Cosmetics from the same manufacturer, for the same usage, and with the same active ingredients and dosage form.

The combined application in the preceding Paragraph shall attach documents and data set forth under Sub-Paragraph of each Article for each individual product except for those of Sub-Paragraph 1, 2, and 5 of Article 4 and Sub-Paragraph 1 of Article 5.

Article 14 The applicant shall be notified the result of the application reviewed by the competent authorities per Article 4 and 5. The applicant after being notified the approval of permit license and registration shall provide approved soft copy of labels, description, and packaging, and pay the fees to the competent authorities to obtain the permit license within 3 months upon execution of the notice.

Article 15 Registration under the preceding Paragraph shall include:

1. Product item.
2. Product name: model number and color code for series products.
3. Active ingredients and its concentration in percentage.
4. Dosage form.
5. Description, labels, and specifications.
6. Purpose.
7. Name of applicant.
8. Name and address of manufacturer.

Article 16 The permit under Article 14 shall stipulate its valid term and other items set forth under Sub-Paragraph of the preceding Article except for Sub-Paragraph 5.

Article 17 If any document or data is missing or the fees is unpaid, the competent authorities shall notify the applicant to cure same within the set deadline. The applicant shall cure all at once.

The applicant who fails to cure same within the set deadline of the preceding Paragraph may request for extension to the competent authorities with reasons in writing prior to the expiration of the set deadline. The extension is 1 month upon the next day of the expiration of aforesaid set deadline and may only be requested once.

If the applicant fails the cure same per the preceding two Paragraphs, the application shall be rendered inadmissible.

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

1. Text of documents or data provided contrary to those of the application.
2. Ingredients prohibited from being used under Paragraph 1 of Article 6 of the Act contained; or violation of limit on usage of ingredients set forth under Paragraph 2 of Article 6 of the Act.
3. Packaging, labels or description not labelled per Article 7 of the Act.
4. Text or graphic design used in the name, packaging or description are deceptive, exaggerated, or involving medical efficacy as set forth under Paragraph 1 and 2 of Article 10 of the Act.
5. Any conditions that may be harmful to human health.
6. Other violation of laws, regulations or announcement made by the competent authorities.

Article 19 If permit license of Specific Purpose Cosmetics are damaged or lost, the applicant may pay fees to the competent authorities for replacement or new permit license. If applying for new permit license, the original permit shall be attached.

Chapter 3 Modification of Registration and Transfer and Modification of Permit license

Article 20 If there is any change of the information provided for registration or permit license under Article 15 or 16, the applicant shall provide original permit and relevant supporting documents and pay fees to the competent authorities to apply for changes per Paragraph 2 of Article 5 of the Act. After reviewed by the competent authorities, the original permit shall address the changes and date then returned with stamps.

If the changes of the preceding Paragraph are to increase more items or color systems, those products shall be made by the same manufacturer, with same active ingredients, same dosage form and usage, and conforming to limit on usage of specific purpose ingredients as set forth by the competent authorities.

Article 21 When applying for transfer of permit license of Specific Purpose Cosmetics, the transferor and transferee shall file a joint application, attach original permit and relevant supporting documents, and pay

fees to the competent authorities to obtain the approval.

The original permit shall address the name of the assignor and the approval date when issuing the approval by the competent authorities per the preceding Paragraph.

Article 22 When applying for revocation of permit license of Specific Purpose Cosmetics, the application shall be filed attaching the original permit together with relevant documents to be submitted to the competent authorities.

Chapter 4 Extension of Permit license

Article 23 When applying for extension of the term of permit license of Specific Purpose Cosmetics per Paragraph 5 of Article 5 of the Act, the applicant shall file the application, attach below documents and data, and pay fees to the competent authorities:

1. Original permit license.
2. Copy of company or business registration certificates.
3. Authorization Letter issued within past two years except for manufactured domestically.

Article 24 If the extension is not applied prior to the expiration of the term of permit license of Specific Purpose Cosmetics per the preceding Article, the application shall re-apply for registration and permit license per Paragraph 1 of Article 5 of the Act. Provided that, if it is within 6 months after the expiration, the applicant may file the application, attach below documents and data, and pay fees to the competent authorities when re-applying for the permit license:

1. Original permit license.
2. Copy of company or business registration certificates.
3. For OEM, the OEM agreement.
4. For the importer, MFSC, Ingredient List and Authorization Letter issued within past 2 years

The new registration number will be issued to the permit after being approved per the preceding Paragraph.

Chapter 5 Supplementary.

Article 25 This Regulation takes effect starting from the date of promulgation.