Provisions for the Acceptance of Application for Administrative Licence for Cosmetics

Article 1

These Provisions are formulated for the purposes of regulating acceptance of applications for the administrative licence for cosmetics and ensuring acceptance of applications for the administrative licence for cosmetics in an open, fair and just procedure.

Article 2

Administrative licence for cosmetics refers to approval for the use of new cosmetic ingredients, manufacturing of domestic special-purpose cosmetics and initial import of cosmetics.

Article 3

These regulations shall apply to the acceptance of applications for the administrative licence for cosmetics set out in *The Regulations Concerning the Hygiene Supervision over Cosmetics* and their implementation rules.

Article 4

The State Food and Drug Administration (SFDA) shall be responsible for administering acceptance of applications for the administrative licence for cosmetics.

Article 5

The applicant for the administrative licence of domestic cosmetics shall be the manufacturer of cosmetics. The applicant for the administrative licence of domestic cosmetics in respect of the use of new ingredients shall be the manufacturer of cosmetic ingredients or the manufacturer of cosmetics.

The applicant for the administrative licence of imported cosmetics shall be the manufacturer of imported cosmetics. The applicant for the administrative licence of imported cosmetics in respect of the use of new ingredients shall be the manufacturer of the new ingredients of imported cosmetics or the manufacturer of cosmetics. The applicant shall designate an entity lawfully incorporated in China and having an independent corporate status (Chinese Agent) to act as its agent to handle application matters on behalf thereof. The applicant may replace its Chinese Agent.

Article 6

The applicant and the Chinese Agent shall apply for the administrative licence for cosmetics in accordance with relevant laws, regulations, standards and specifications of the State, and be responsible and legally liable for application materials submitted.

Article 7

The applicant shall file with SFDA its application for the administrative licence for cosmetics and submit relevant materials in accordance with these Provisions.

Article 8

Prior to initial application, the original of the power of attorney appointing the Chinese Agent shall be registered with the administrative acceptance body of SFDA (the Acceptance Authority).

The applicant for the administrative licence for cosmetics shall complete the application form through the online application system on the SFDA website.

Article 9

The approval document (registration certificate) for the administrative licence for cosmetics shall remain valid for four years.

The applicant for extension of the validity of the approval document (registration certificate) for the administrative licence for cosmetics shall file its application four months prior to expiration thereof.

Where such application for extension is not filed within the specified time limit due to re-issuance of the approval document (registration certificate) for the administrative licence for cosmetics, the applicant shall file the application for extension fifteen days following re-issuance of the approval document (registration certificate) for the administrative licence for cosmetics, provided that the application for re-issuance is filed four months prior to expiration of the approval document (registration certificate) for the administrative licence for cosmetics.

Article 10

The applicant for change approval within the validity of the approval document (registration certificate) for the administrative licence for cosmetics shall file the application pursuant to relevant requirements and submit relevant materials. In the case of any formula change or any other change that may involve safety of cosmetics, an application shall be filed in such a way as is required for a new product. Where the original name remains in use after such changes, an appropriate indication thereof shall be provided on the external packaging of product to distinguish from the pre-change product.

Article 11

Where the approval document (registration certificate) for the administrative licence for cosmetics is damaged or lost, an application for re-issuance thereof shall be filed on a timely basis without any concurrent application for extension or change.

Article 12

After receipt of the approval document (registration certificate) for the administrative licence for cosmetics issued by SFDA, an application for correction shall be filed in a single package in the case of:

(1) any printing error of the approval document (registration certificate) for the

administrative licence for cosmetics;

(2) any numbering error of the approval document (registration certificate) for the administrative licence for cosmetics; and/or

(3) any other error in the approval document (registration certificate) for the administrative licence for cosmetics.

The scope of correction under this Article 12 shall exclude any error on the part of the applicant.

Article 13

The applicant may file a re-application under the original name of the product if it:

(1) fails to apply for extension of the approval document (registration certificate) for the administrative licence for cosmetics within the specified time limit;

(2) files such re-application after termination of application;

(3) has applied for deregistration of the original approval document (registration certificate) for the administrative licence for cosmetics; or

(4) files such re-application after the application for administrative licence is rejected.

Re-application shall not be filed if the product is disapproved due to the presence of any prohibited substance, any restricted substance in excess of an applicable limit, unacceptable results of the hygienic safety test and any other reasons in relation to product safety.

Article 14

For the purposes of application hereunder, where the manufacturer delegates manufacturing (including sub-packaging) of cosmetics to a contract manufacturer beyond the territory of China, such cosmetics shall be deemed domestic if the last operation of exposed content is conducted within the territory of China, or deemed imported if the last operation of exposed content is conducted beyond the territory of China.

In the case of any change in the cross-border contract manufacturing relationship that occurs after the approval document (registration certificate) for the administrative licence for cosmetics is issued, a re-application shall be filed in accordance with provisions regarding change of manufacturing site.

Article 15

Two or more dosage forms that must be used together shall be deemed as a single product for the purpose of application hereunder. Where parts of a product are manufactured by different manufacturers across borders, application materials shall be provided as are separately required for domestic product and imported product. Upon application, an indication shall be provided to identify the product as domestic or imported. The names, manufacturers and places of manufacture of the domestic dosage form and the imported dosage form respectively shall be indicated in the “Remarks” section of the approval document (registration certificate) for the administrative licence for cosmetics.

Article 16

The Acceptance Authority shall, when receiving application materials for the administrative licence for cosmetics, issue the Receipt of Application Materials to the applicant, conduct a formality examination of the application materials and decide to accept or request further information or correction within five working days.

The Acceptance Authority shall make a decision of acceptance and issue the Notice of Acceptance if application materials are complete and compliant. The Acceptance Authority shall issue the Notice of Request for Addition and/or Correction that notifies the applicant of all additions and/or corrections requested if the application materials are non-compliant. The Acceptance Authority failing to issue such notices shall be deemed to have accepted application as from the date of receiving the application materials. Where the application materials remain non-compliant after incorporating additions and/or corrections, the Acceptance Authority may request further additions and/or corrections.

Article 17

The Acceptance Authority shall make a decision of rejection and issue the Notice of Rejection to the applicant if:

(1) the subject matter of the application is not subject to administrative license;
(2) the subject matter of the application is beyond the scope of the administrative license function of SFDA;
(3) the application for extension is filed beyond the specified limit, unless in the circumstances set out in Article 9 of these Provisions; or
(4) the application is otherwise beyond the scope of acceptance.

Article 18

The Notice of Acceptance, the Notice of Request for Addition and/or Correction and the Notice of Rejection issued by the Acceptance Authority shall indicate the date of issue and bear the administrative licence seal of SFDA. Such notices shall be made in duplicate, one being given to the applicant and the other being kept on file.

Article 19

After the application materials are accepted, any addition or modification to the application materials made by the applicant pursuant to the review opinion shall be directly submitted to the review body of SFDA. In the case of application through an agent, the copy of the power of attorney of the registered Chinese Agent for administrative license purposes shall be attached. All additional information shall be provided in a single package pursuant to the review opinion, and indicate the date of addition and the entity, and bear its common seal. Additional information shall not include any alteration of any part of the application materials that is not covered by review opinion.

Article 20

The applicant may, after submitting application materials for administrative license to SFDA and before SFDA makes the decision of acceptance, apply in writing for termination of the application and return of all application materials. Where the application is accepted, the applicant may, before the technical review opinion is given, request withdrawal of the application for administrative license and return of all application materials. The applicant may file a written request for return of the following materials within six months of receiving the "Rejection of Application for Administrative License" or the "Rejection of Application for Extension/Change":

(1) documentary evidence for the permission of product manufacturing and sale in the country (or region) of origin, and the GMP certificate of the cosmetics manufacturer and their notarial deed, unless more than one product is included in a single application under the original of a single document or certificate;
(2) the valid original approval document (registration certificate) for the administrative licence for cosmetics; and
(3) application materials for extension.

Article 21

SFDA shall, within sixty days of acceptance, review the applicant-furnished safety assessment data relating to substances contained in the subject product that may pose any safety risk.

Article 22

Where the applicant or the Chinese Agent provides any false application data or samples, SFDA will reject its application or refuse to license, give a disciplinary warning against the applicant or the Chinese Agent and refuses to accept such application for administrative license within one year pursuant to Article 78 of the *Administrative License Law of the People's Republic of China*.

Article 23

These Provisions shall be subject to interpretation by SFDA.

Article 24

These Provisions shall enter into force on 1st April 2010. In the case of any discrepancy between these Provisions and the previously issued provisions for acceptance for applications for the hygienic administrative licence for cosmetics, these Provisions shall prevail.

Appendix:

Requirements on Application Materials

for Administrative Licence for Cosmetics

Article 1

Any applicant for the administrative licence for cosmetics shall provide relevant materials in accordance with the *Provisions for Acceptance of Applications for Administrative License for Cosmetics*. Application materials shall meet the following general requirements:

(1) with regard to initial application for the administrative licence of special-purpose cosmetics, application materials shall be submitted in one original and four copies, which copies shall be legible and consistent with the original;
(2) with regard to application for registration, extension, alteration or re-issuance approval, application materials shall be submitted in one original;
(3) except for test reports, documents of notarization and official certificates and third-party certificates, the original of application material shall be under the common seal or paging seal of the applicant on a page-by-page basis;
(4) application materials shall be printed on A4 paper with distinct identification marks, arranged in the required order of sequence and bound up;
(5) China's legal units of measurement shall be used;
(6) the content of application shall be complete and clear, and the same items shall be maintained consistently;
(7) all texts in a foreign name (excluding foreign address, website, registered trademark, patent name, SPF, PFA or PA, UVA and UVB where the foreign name must be used) shall be correctly translated into Chinese that shall be put before the original foreign name version;
(8) the product formula shall be submitted in both paper and electronic forms; and
(9) the contents of paper and electronic documents shall be consistent.

Article 2

Any applicant for the administrative licence of domestic special-purpose cosmetics shall submit:

(1) the application form for the administrative licence of domestic special-purpose cosmetics;
(2) the basis of nomenclature of the product;
(3) requirements on product quality and safety control;
(4) the product packaging design (including product label and product specification);
(5) test reports and relevant data issued by SFDA-approved testing agencies;
(6) safety assessment data relating to substances contained in the product that may pose any safety risk;
(7) the review opinion on hygienic conditions of manufacturing issued by the provincial food and drug administration authority;
(8) active ingredients and underlying scientific literature in the case of application regarding hair growth, fitness or breast enhancement; and
(9) other data that may help in application for administrative license.

In addition, one piece of sample sealed, and remaining sealed, by the provincial food and drug administration authority shall be provided.

Article 3

Any applicant for the administrative licence of imported special-purpose cosmetics shall submit:

(1) the application form for the administrative licence of imported special-purpose cosmetics;
(2) the basis of nomenclature for the Chinese name of the product;
(3) the product formula;
(4) a brief description and illustration of the manufacturing process;
(5) requirements on product quality and safety control;
(6) the original packaging of the product (including the product label and product specification); where a package is exclusively designed for the Chinese market, such packaging of product (including the product label and product specification) shall be provided;
(7) test reports and relevant data issued by SFDA-approved testing agencies;
(8) safety assessment data relating to substances contained in the product that may pose any safety risk;
(9) active ingredients and underlying scientific literature in the case of application regarding hair growth, fitness or breast enhancement; and
(10) a copy of the registered power of attorney and a copy of the business licence of the Chinese Agent, both under common seal;
(11) the letter of undertaking evidencing compliance of the cosmetic ingredients and their sources with requirements on restriction or prohibition of high-risk substances in BSE-affected regions;
(12) documentary evidence of product manufacturing and sale in the country (or region) of origin; and
(13) other data that may help in application for administrative license.

One sample of commercially available product that is and remains sealed by the testing agency shall also be provided.

Article 4

Any applicant for registration of imported general-purpose cosmetics shall submit:

(1) the application form for the administrative licence of imported general-purpose cosmetics;
(2) the basis of nomenclature for the Chinese name of the product;
(3) the product formula;
(4) requirements on product quality and safety control;
(5) the original packaging of the product (including the product label and product specification); where a package is exclusively designed for the Chinese market, such packaging of product (including the product label and product specification) shall be provided;
(6) test reports and relevant data issued by SFDA-approved testing agencies;
(7) safety assessment data relating to substances contained in the product that may pose any safety risk;

(8) a copy of the registered power of attorney and a copy of the business licence of the Chinese Agent, both under common seal;
(9) the letter of undertaking evidencing compliance of the cosmetic ingredients and their sources with requirements on restriction or prohibition of high-risk substances in BSE-affected regions;
(10) documentary evidence of product manufacturing and sale in the country (or region) of origin; and
(11) other data that may help in registration.

One sample of commercially available product that is and remains sealed by the testing agency shall also be provided.

Article 5

Any applicant for the administrative licence of new cosmetic ingredients shall submit:

(1) the application form for the administrative licence of new cosmetic ingredients;
(2) the development report:
  (i) background and process of ingredient research and development, and relevant technical data;
  (ii) source, physical and chemical properties, chemical structure, molecular formula and molecular weight of ingredients; and
  (iii) purpose, basis, scope and limit of ingredients in cosmetics.
(3) a brief description and illustration of the manufacturing process;
(4) requirements on ingredient quality and safety control, including specifications, testing methods, and substances that may pose any safety risk and their control;
(5) toxicological safety evaluation data, including safety assessment data relating to substances contained in the ingredients that may pose any safety risk;
(6) in the case of application through a Chinese Agent, a copy of the registered power of attorney and a copy of the business licence of the Chinese Agent, both under common seal; and
(7) other data that may help in application for administrative license.

One piece of sample submitted for review shall also be provided.

Article 6

The following materials shall be provided in either of the following circumstances, in addition to the materials set out above:

(1) if the product is manufactured on a contract basis:
  (i) the contract manufacturing agreement made with the contract manufacturer;
  (ii) in the case of imported product, the quality management system certificate or GMP certificate of the contract manufacturer or the qualification certificate for cosmetics manufacturing that complies with legal and regulatory requirements of the country (or region) where the manufacturer is located;

(iii) in the case of domestic product manufactured on a contract basis by domestic enterprise for an overseas manufacturer, the power of attorney appointing the Chinese Agent;

(iv) in the case of imported product manufactured on a contract basis by overseas enterprise for a domestic manufacturer, the product packaging design; the power of attorney appointing the Chinese Agent, certificates of manufacturing and sale and original packaging of the product may not be submitted;

(2) in the case that the actual manufacturer and the manufacturer (applicant) of the cosmetics are under the same control of a parent company, the certificate that demonstrates their same control by the parent company and the product quality assurance certificate issued by the parent company.

Article 7

Multiple actual manufacturers of a single product may file a single application, and one of such actual manufacturers shall submit all the foregoing materials for its product. In addition, the following materials shall also be submitted:

(1) in the case of contract manufacturing, the contract manufacturing agreement; in the case of imported product, the quality management system certificate or GMP certificate of the contract manufacturer or the qualification certificate for cosmetics manufacturing that complies with the legal and regulatory requirements of the country (or region) where the manufacturer is located;

(2) in the case of a manufacturer under common control by a parent company, the certificate of such common control and the product quality assurance document issued by the parent company;

(3) original packaging of the product manufactured by other actual manufacturers; the packaging design may be submitted in the case of domestic product;

(4) the hygienic (microbiological and hygienic chemical) test report for product manufactured by other actual manufacturers;

(5) in the case of domestic product, the review opinion on manufacturing hygiene conditions issued by the provincial food and drug administration authorities where the other actual manufacturers are located;

(6) in the case of imported product, the letter of undertaking evidencing compliance of the cosmetic ingredients of other manufacturers and their sources with the requirements on restriction or prohibition of high-risk substances in BSE-affected regions.

Article 8

The applicant desiring a second application after the application for the administrative licence is terminated or rejected shall file a reapplication accompanied by relevant materials. Where the reapplication follows termination of application, reasons for such termination and reapplication shall also be provided; where the reapplication follows a rejection of application, a copy of the decision of the rejection of application for the administrative licence (or change/extension thereof) shall also

be submitted.

Where such rejection does not involve product safety, a copy of the initial test report or, in the case of domestic special-purpose cosmetics, a copy of the initial review opinion on manufacturing hygiene conditions may be used for reapplication, unless the initial application materials have been returned to the applicant.

Article 9

The applicant for extension of the validity of the administrative licence (or registration) shall submit:

(1) the application form for the extension of the administrative licence for cosmetics;
(2) the original of the approval document (registration certificate) for the administrative licence for cosmetics
(3) the basis of nomenclature for the Chinese name of the product (unless it has been provided during the initial application and the name remains unchanged);
(4) the product formula;
(5) requirements on product quality and safety control;
(6) the packaging of the commercially available product (including the product label and product specification); in the case of domestic product not commercially available, the designed product packaging (including the product label and product specification) may be provided;
(7) in the case of domestic product, the opinion on manufacturing, commercial availability and supervision of product, or the review opinion on the commercial unavailability of product issued by the provincial food and drug administration authority where the applicant is located;
(8) in the case of application through a Chinese Agent, a copy of the registered power of attorney and a copy of the business licence of the Chinese Agent, both under common seal; and
(9) other data that may help in application for administrative license.

A sealed sample of commercially available product shall also be provided.

Article 10

The applicant for change in the administrative licence shall submit:

(1) the application form for change in the administrative licence for cosmetics;
(2) the original of the approval document (registration certificate) for the administrative licence for cosmetics
(3) in the case of application through a Chinese Agent, a copy of the registered power of attorney and a copy of the business licence of the Chinese Agent, both under common seal; and
(4) the following materials, as the case may be:
  (i) for change of product name:
    (a) for change of the Chinese name of the product, reasons for such change shall be stated in the change application form, and the basis of nomenclature for the proposed new name and the proposed new packaging

design (including the product label and product specification) shall be provided; the foreign name of the imported product shall not be changed; or

(b) for change in SPF, PFA or PA of sun protection product, the relevant SPF, PFA or PA test report shall be provided together with the proposed new packaging design (including the product label and product specification).

(ii) for change in the name or address of the manufacturer (including such change at its own discretion as a result of acquisition or merger):

(a) for change in the name or address of the manufacturer of domestic product, the original or a notarized copy of the certificate evidencing such change issued by the local administration for industry and commerce, and a copy of the hygiene licence of the manufacturer;

(b) for change in the name or address of the manufacturer of imported product, the relevant certificate evidencing such change issued by a competent authority or agency in the country of origin; if such change is lawfully due to a business acquisition or merger, a copy of the acquisition or merger agreement signed by both parties may be provided, with the certificate correctly translated into Chinese text notarized by a notary office in China;

(c) for adjustment within a domestic parent company, a relevant certificate issued by the local administration for industry and commerce shall be provided; if any investment by Taiwan, Hong Kong or Macao or foreign investors is involved, a notarized copy of the *Certificate of Approval for Establishment of Enterprises with Foreign Investment in the People's Republic of China* or the *Certificate of Approval for Establishment of Enterprises with Investment by Taiwan, Hong Kong and Overseas Chinese in the People's Republic of China*; or

(d) for change in manufacturing site, the hygienic (microbiological and hygienic chemical) test report for product manufactured by the proposed new manufacturer shall be provided; in the case of domestic product, the review opinion on manufacturing hygiene conditions issued by the provincial food and drug administration authorities where the proposed new manufacturer is located shall be provided.

(iii) for change in the Chinese name of the manufacturer of imported product (with the foreign name remaining unchanged):

(a) the reasons for change in the Chinese name of the manufacturer; and

(b) the proposed new packaging design of the product (including the product label and product specification).

(iv) for replacement of the Chinese Agent:

(a) the original of the power of attorney appointing the proposed substitute Chinese Agent shall be submitted first for registration;

(b) a copy of the power of attorney appointing the proposed substitute Chinese Agent shall be submitted first for registration;

(c) in the case of change in the name or address of the Chinese Agent, the original or a notarized copy of the certificate evidencing such change

issued by the local administration for industry and commerce shall be provided;

(d) a notarized statement terminating the Chinese Agent issued by the manufacturer shall be provided.

(v) for replacement of the actual manufacturer:

(a) in the case of contract manufacturing, the contract manufacturing agreement; in the case of imported product, the quality management system certificate or GMP certificate of the contract manufacturer, or the qualification certificate for cosmetics manufacturing that complies with legal and regulatory requirements of the country (or region) where the manufacturer is located;

(b) in the case of a manufacturer under common control by a parent company, the certificate of such common control and the product quality assurance document issued by the parent company;

(c) the original packaging of the product manufactured by the proposed substitute manufacturer;

(d) the hygienic (microbiological and hygienic chemical) test report for the product manufactured by the proposed substitute manufacturer;

(e) in the case of domestic product, the review opinion on manufacturing hygiene conditions issued by the provincial food and drug administration authorities where the proposed substitute manufacturer is located;

(f) in the case of imported product, the letter of undertaking evidencing the compliance of the cosmetic ingredients of the substitute manufacturer and their sources with the requirements on restriction or prohibition of high-risk substances in BSE-affected regions.

(vi) for change in the type of special-purpose cosmetics, appropriate materials shall be provided in accordance with requirements applicable to the relevant type; or

(vii) for any other change, the reasons shall be stated in detail and relevant documentary evidence shall be provided.

Article 11

The applicant for re-issuance of the approval document (registration certificate) for the administrative licence shall submit:

(1) the application form for re-issuance of the approval document (registration certificate) for the administrative licence for cosmetics;

(2) the original of the approval document (registration certificate) for the administrative licence for cosmetics if it is damaged;

(3) the original of the declaration of loss published in newspapers of provincial or larger circulation if the approval document (registration certificate) for administrative license is lost; the application for re-issuance due to loss shall be filed at least twenty days after publication of the declaration of loss;

(4) in the case of application through a Chinese Agent, a copy of the registered power of attorney issued to the Chinese Agent and a copy of the business

licence of the Chinese Agent under common seal.

Article 12

The applicant for correction of errors in the approval document (registration certificate) for the administrative licence shall :

(1) submit the application form for the correction of errors in the approval document (registration certificate) for the administrative licence for cosmetics;
(2) submit a copy of the approval document (registration certificate) for the administrative licence for cosmetics signed by the applicant; and
(3) surrender the original of the approval document (registration certificate) for the administrative licence for cosmetics upon receiving the new approval document (registration certificate).

Article 13

The following materials shall be provided when additional materials are submitted to the review body of SFDA:

(1) the notice of review opinion; and
(2) additional materials in the same sequence as the questions are listed in the review opinion.

Article 14

The product formula data shall meet the following requirements:

(1) the formula shall be provided in the form of a single table that contains the serial numbers, INCI names (except for domestic product), standard Chinese names, percentage contents and purposes of ingredients, in Song Ti font sized sub-five;
(2) names of ingredients shall be provided, contents shall be presented in percentage, and the content of the active ingredient shall be indicated (absence of such indication will be deemed to be a 100% content of active ingredient); composite ingredients shall be stated in composite form, with the content of each component thereof indicated in percentage; any special circumstances shall be stated, such as the presence of crystal water and different molecular or structural formula of ingredients; all ingredients shall be listed in descending order by content;
(3) the Chinese name of each ingredient (including each component of composite ingredients) shall be the standard Chinese name defined in the *Catalogue of Standard Chinese Names of International Cosmetic Ingredients*; if the INCI name is unavailable or the standard Chinese name is not defined in the *Catalogue of Standard Chinese Names of International Cosmetic Ingredients*, the name provided in the Chinese Pharmacopoeia or the chemical or Latin name of the plant shall apply; the trade name or colloquial name shall not be used, except for composite ingredients;
(4) for any colorant, the colorant index (CI) defined in the Hygienic Standard for Cosmetics shall be provided, unless such CI is not defined;

(5) where any animal organ or tissue or blood extract is contained, the source of the ingredient, quality specifications and the certificate evidencing permit of its use in the country of origin shall be provided;
(6) where the product formula contains any hydrocarbon derived from petroleum or coal tar (except for any single component), the Chemical Abstract Service index numbers (CAS numbers) of the relevant ingredients shall be stated in the product formula;
(7) where the *Hygienic Standard for Cosmetics* imposes any specification requirements on any ingredient falling under the category of restricted substance, the quality specification certificate of such ingredient issued by the ingredient manufacturer shall be provided;
(8) for any sub-packaged or assembled product that comprises multiple dosage forms (such as hair dye and perm products) or any product that is included in an integral packaging and comprises differently formulated contents, each formula shall be provided;
(9) with regard to the verification certificate for the formula of imported product issued by the testing agency, the date of verification shall be consistent with the date of acceptance of the tested sample;
(10) with regard to any product claiming to be designed for pregnant women, lactating women or infants, the formula design principle based on safety considerations (including the overall analysis report on formula), principles of and requirements on ingredient selection, and the manufacturing process and quality control process shall be provided.

Article 15

The safety assessment data relating to substances contained in the product that may pose any safety risk shall be provided in line with the ingredients and product characteristics of the cosmetics and include the following:
(1) the name of the substance contained in the product that may pose any safety risk (including any substance introduced by ingredients or generated in the manufacturing process), relevant testing methods and test data;
(2) the safety risk assessment report on the substance contained in the product that may pose any safety risk;
(3) technical data on any technology that is currently available and able to reduce the content of the substance contained in the product that may pose any safety risk and, where necessary, process improvement measures;
(4) where any ingredient is of a plant origin, any possible contaminants such as residual pesticide or any impurities introduced in the extraction process shall be disclosed.

Article 16

Requirements on product quality and safety control shall include the following:
(1) sensory indicators, such as colour, odour or appearance;
(2) microbial indicators (unless not required for testing), hygienic chemical

indicators;

(3) the pH value (excluding water-in-oil - oily product, powdered, puff-cake and wax-based products) and its testing method of any hair perm, hair removal or freckle product, or any product claiming to contain α-hydroxy acid or any product that does claim to contain α-hydroxy acid but whose content of α-hydroxy is ≥3% (w/w);

(4) in the case of imported product, the requirements on product quality and safety control applied in the country of origin (both foreign text and Chinese translation) shall be provided; where the requirements on product quality and safety control applied in the country of origin do not include requirements set out in Item (1), (2) or (3) of this Article 16, the requirements on product quality and safety control containing relevant indicators shall be also be provided; and

(5) the applicant shall provide a letter of undertaking evidencing compliance with the *Hygienic Standard for Cosmetics*.

Article 17

The review opinion on hygienic conditions of manufacturing of domestic special-purpose cosmetics shall include:

(1) the application form for the review of hygienic conditions of manufacturing of cosmetics;

(2) the review form for hygienic conditions of manufacturing of cosmetics;

(3) the product formula;

(4) a description and illustration of the manufacturing process;

(5) a list of manufacturing equipment; and

(6) a copy of the hygiene licence of the manufacturer.

Article 18

Test reports and relevant data issued by SFDA-approved testing agencies shall meet the following requirements:

(1) The test reports for cosmetic license shall include hygienic safety test reports (microbial, hygienic chemical and toxicological) and human safety test reports; the tested samples shall be manufactured in the same batch or on the same date and in the same name of product;

(2) The following materials shall be provided if sun protection indices (SPF, PFA or PA) or the new ingredient test report issued by an overseas laboratory is used:

(i) where the laboratory issuing such reports has been certified, the certification document shall be provided;

(ii) where the laboratory issuing such reports has not been certified, the certificate evidencing its compliance with the Good Clinical Practice (GCP) or the Good Laboratory Practice (GLP) shall be provided; and

(iii) other data that may help demonstrate the qualification of the laboratory.

With regard to each and every initial submission of overseas test reports, the

original of the foregoing documents or a copy (including translation) thereof accredited by the guild, Chinese embassy (or consulate) or notary office in the country (or region) of the issuing laboratory shall be provided; if such copy is approved by SFDA, only such copy is required for reapplication.

Where the original of the test report issued by an overseas laboratory is required and the product series meets random inspection requirements, the original shall be provided for at least one product and copies may be provided for other products together with a reference to the name of the product for which the original is provided.

Where the test report issued by an overseas laboratory is used, the documentary evidence that matches the tested sample and the test report and is issued by the relevant laboratory shall also be provided.

(3) The test report issued by an approved testing agency shall include:

(i) the application form for testing;

(ii) the letter of acceptance for testing;

(iii) the product specifications;

(iv) the hygienic safety test report (microbial, hygienic chemical and toxicological); and

(v) the following documents, if applicable:

(a) human safety test report (patch test or human usage test);

(b) test report on sun protection indices (SPF, PFA or PA);

(c) other additional test reports (test report on asbestos contained in cosmetics).

Article 19

The letter of undertaking evidencing the compliance of the cosmetic ingredients and their sources with the requirements on restriction or prohibition of high-risk substances in BSE-affected regions shall be issued pursuant to relevant provisions.

Article 20

The original packaging of the imported product shall be provided for both the foreign and Chinese versions together with a Chinese label of the product (including specifications of the product) that meets the relevant laws and regulations of China.

Article 21

Documentary evidence of manufacturing and sale in the country (or region) of origin shall meet the following requirements:

(1) It shall be issued by the competent government authority or guild in the country (or region) of origin of product; a copy accredited by the issuing organization or Chinese embassy (or consulate) may be provided if the original is not available;

(2) It shall indicate the name of the product, the name of the manufacturer, the name of the issuing organization (including its common seal or signature of its legal representative or his proxy) and the date of issue;

(3) The name of the product and the name of the manufacturer indicated shall be identical to those provided in the application materials; in the case of manufacturing on a contract basis or otherwise and inconsistency of the manufacturer indicated between the documentary evidence and application materials, the applicant shall issue a supporting document to provide reasonable explanations; in the case of any product comprising multiple dosage forms that must be used together, the documentary evidence of manufacturing and sale may be provided only for the imported part of the product; and

(4) Any documentary evidence of manufacturing and sale made in a foreign language shall be correctly translated into Chinese text notarized by a notary office in China.

Article 22

The quality management system certificate or GMP certificate of the contract manufacturer or the qualification certificate for cosmetics manufacturing that complies with legal and regulatory requirements of the country (or region) where the manufacturer is located shall meet the following requirements:

(1) It shall be issued or certified by a certification agency or a third party; a copy notarized by a notary office in China or accredited by the Chinese embassy (or consulate) may be provided if the original is not available; and

(2) The name and address of the manufacturer indicated shall be identical to those provided in the application materials.

Article 23

The power of attorney appointing the Chinese Agent shall meet the following requirements:

(1) The power of attorney shall be executed by the cosmetics manufacturer and the Chinese Agent (either signed or sealed by the head of the cosmetics manufacturer, and signed and sealed by the legal representative of the Chinese Agent) and notarized by a notary office; where the power of attorney is made in a foreign language, a notarized Chinese translation shall be provided;

(2) The power of attorney shall include: the name of the appointing entity, the name of the Chinese Agent appointed, the term of authorization (at least four years), the scope of the product under authorization, and the scope of authorization; the scope of authorization shall include authorizing the Chinese Agent to act as an agent for the application and may also include authorizing the Chinese Agent to affix a seal to application materials on behalf of the manufacturer; and

(3) The original of the power of attorney (including a Chinese translation) shall be submitted and put on file for future review.

Article 24

The documentary evidence of manufacturing and sale, the quality management system certificate or GMP certificate, the certificate evidencing that manufacturers in

different countries are under common control by a parent company and the contract manufacturing agreement may include more than one product. Where such products are included in a single application, the original shall be provided for one product and copies may be used for other products together with a written reference to the name of product for which the original is provided; where such products are not included in a single application, the original shall be provided for one product and notarized copies shall be provided for other products together with a written reference to the name of the product for which the original is provided.

Article 25

The sample submitted for review sealed by a provincial food and drug administration authority or testing agency shall be submitted in complete packaging that indicates the same name of product, date of manufacture/batch number (or shelf life/expiry date) and test acceptance number as those of the tested sample, and product specification. Where the product specification is not provided or printed on the product container due to the small size of the product (such as lipstick or pomade), relevant explanations shall be contained in the product packaging part of the application materials. External packaging of the sample of imported product shall carry an additional Chinese name label on the product without covering any foreign identification information. The sample of imported product manufactured by overseas manufacturers on a contract basis for domestic enterprise shall be submitted for review in such as way as if it were domestic product.

Article 26

Samples that fall under any of the following categories shall meet the following application requirements:

(1) Where a single sample packaging contains two or more separate small containers or two or more separable samples (such as eye shadow, puff cake and blusher) that are included in a single application, their product formula and test reports shall be submitted separately; where samples are not separately packaged in small containers or inseparable, one test report and separate product formulae shall be provided.

(2) Where samples that are different in physical states and ingredients are contained in an integral composite packaging and submitted for application under the same product, their product formulae and test reports shall be provided separately;

(3) Two or more dosage forms that have to be used together shall be deemed as a single product for the purpose of application hereunder. Either a mixed test report or separate test reports may be submitted for these dosage forms, depending on whether such dosage forms are mixed before use.

Article 27

Where an application is filed for a toxicological sample test of general-purpose cosmetics available in multiple colours that are identical in basic formula, such

cosmetics in multiple colours may be included as a group of products in a single application. The application materials for each product shall include the schedule of product series, basic formula, schedule of colorants and list of products sampled and tested.

The sampling rate for a toxicological sample test of general-purpose cosmetics available in multiple colours shall be 30%, subject to a minimum of 10 samples; sampling shall give precedence to those containing organic colorant and/or having the highest content of colorant.

Article 28

Where an application is filed for a sun protection (SPF, PFA or PA) test of sun protection cosmetics available in multiple colours that are identical in basic formula, such cosmetics in multiple colours may be included as a group of products in a single application. The application materials for each product shall include the schedule of product series, basic formula, schedule of colorants and list of products sampled and tested.

The sampling rate for a sun protection test of sun protection cosmetics available in multiple colours shall be 20%, subject to a minimum of 5 samples; sampling shall give precedence to those having the lowest content of colorant (or without a basic formula of colorant).

Article 29

In the case of cosmetics that are under the same name but different in fragrance or sun protection indices (SPF, PFA or PA), one licence approval document shall be obtained for each product, with application materials submitted separately.

Annexes:

1. Application Form for Administrative Licence of Domestic Special-purpose Cosmetics
2. Application Form for Administrative Licence of Imported Special-purpose Cosmetics
3. Application Form for Registration of Imported General-purpose Cosmetics
4. Application Form for Administrative Licence of New Cosmetic Ingredients
5. Application Form for Change in Administrative Licence for Cosmetics
6. Application Form for Extension of Administrative Licence for Cosmetics
7. Application Form for Re-issuance of Approval Document (Registration Certificate) for Cosmetic Licence
8. Application Form for Correction of Errors in Approval Document (Registration Certificate) for Administrative Licence for Cosmetics

Annex 1:

Application Form for Administrative Licence for Domestic Special-purpose Cosmetics

Name of Product_____

State Food and Drug Administration

Instructions

1. This application form is downloadable from the SFDA website at http://www.sfda.gov.cn.
2. This application form and all other application materials shall be printed.
3. This application form shall be filled out completely and legibly without any alteration.
4. Please carefully read the relevant laws and regulations and provisions governing the acceptance of applications prior to filling out this application form.
5. In the “Type of Product” cell, please specify the type of the special-purpose cosmetics, such as sun protection or hair growth.
6. An electronic form containing the same data as provided in the paper form shall be submitted simultaneously.

<table>
<tr><td>Name of Product</td><td colspan="5"></td></tr>
<tr><td>Type of Product</td><td colspan="5"></td></tr>
<tr><td>Product Test Acceptance No.</td><td colspan="5"></td></tr>
<tr><td rowspan="4">Manufacturer</td><td>Name</td><td colspan="4"></td></tr>
<tr><td>Address</td><td colspan="2"></td><td>Postal Code</td><td></td></tr>
<tr><td>Phone Number</td><td colspan="2"></td><td>Contact Person</td><td></td></tr>
<tr><td>Hygiene Licence No. of Manufacturer</td><td></td><td>Expired on</td><td colspan="2">Date/month/year</td></tr>
<tr><td colspan="6">Letter of Undertaking

We, the undersigned, hereby undertake that the information contained in and attached to this application form is true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the Hygienic Standard for Cosmetics. We are willing to assume any legal liability for and all consequences of any misrepresentation.

_____ _____
Manufacturer (Stamp) Legal Representative (Signature)

Date:</td></tr>
</table>

Documents attached (Please mark "√" in the appropriate box)

- □ 1. Application form for the administrative licence of domestic special-purpose cosmetics
- □ 2. Basis of nomenclature of product
- □ 3. Requirements on product quality and safety control
- □ 4. Product packaging design (including product label and product specification)
- □ 5. Test reports and relevant data issued by SFDA-approved testing agency
- □ 6. Safety assessment data relating to substances contained in the product that may pose any safety risk
- □ 7. Review opinion on hygienic conditions of manufacturing issued by the provincial food and drug administration authority
- □ 8. Active ingredients and underlying scientific literature, in the case of application regarding hair growth, fitness or breast enhancement.
- □ 9. One piece of sample sealed, and remaining sealed, by the provincial food and drug administration authority, and other data that may help in the application for administrative license.

Please provide the following information if the actual manufacturer is other than the above signed or there is more than one manufacturer:

Name of actual manufacturer:

Address of actual manufacturer:

Hygiene licence number of actual manufacturer:

Relationship between manufacturer and actual manufacturer:

□ Contract manufacturing

□ Under common control

Others:

Annex 2:

Application Form for Administrative Licence for Imported Special-purpose Cosmetics

Chinese Name of Product_____

State Food and Drug Administration

Instructions

1. This application form is downloadable from the SFDA website at http://www.sfda.gov.cn.
2. This application form and all other application materials shall be printed.
3. This application form shall be filled out completely and legibly without any alteration.
4. Please carefully read the relevant laws and regulations and provisions governing the acceptance of applications prior to filling out this application form.
5. In the “Type of Product” section, please specify the type of special-purpose cosmetics, such as sun protection or hair growth.
6. An electronic form containing the same data as provided in the paper form shall be submitted simultaneously.

Name of Product	Chinese name				
	Foreign name				
Type of product					
Product test acceptance No.					
Manufacturer	Chinese name				
	Foreign name				
	Address		Country (or region) of origin		
	Phone number		Contact person		
Chinese Agent	Name				
	Address				
	Fax number		Postal code		
	Phone number		Contact person		

Letter of Undertaking

We, the undersigned, hereby undertake that the information contained in and attached to this application form is true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Manufacturer (Stamp)

Legal Representative (Signature)

Date:

Letter of Undertaking

We, the undersigned, hereby declare that we understand the requirements set forth in the *Provisions for Acceptance of Applications for Administrative Licence for Cosmetics* concerning application for the administrative licence for cosmetics in accordance with applicable laws, regulations, standards and specifications of the State as well as the responsibility and legal liability for application materials. We have reviewed the content of application and materials attached and undertake that all application materials we submit are true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Chinese Agent (Stamp)

Legal Representative (Signature)

Date:

Documents attached (Please mark "√" in the appropriate box)

- □ 1. Application form for administrative licence of imported special-purpose cosmetics
- □ 2. Basis of nomenclature for the Chinese name of product
- □ 3. Product formula
- □ 4. Brief description and illustration of manufacturing process
- □ 5. Requirements on product quality and safety control
- □ 6. Original packaging of product (including product label and product specification); where a package is exclusively designed for the Chinese market, such packaging of product (including product label and product specification) shall be provided
- □ 7. Test reports and relevant data issued by SFDA-approved testing agency
- □ 8. Safety assessment data relating to substances contained in the product that may pose any safety risk
- □ 9. Active ingredients and underlying scientific literature, in the case of application regarding hair growth, fitness or breast enhancement
- □ 10. A copy of the registered power of attorney and a copy of the business licence of the Chinese Agent, both under common seal
- □ 11. Letter of undertaking evidencing compliance of cosmetic ingredients and their sources with requirements on restriction or prohibition of high-risk substances in BSE-affected regions
- □ 12. Documentary evidence of product manufacturing and sale in the country (or region) of origin
- □ 13. One sample of commercially available product that is and remains sealed by the testing agency, and other data that may help in the application for administrative license

Please provide the following information if the above-signed manufacturer is not in the country (or region) of origin or there is more than one country of manufacturing or Chinese Agent:

Name of actual manufacturer:

Address of actual manufacturer:

Country of actual manufacturer:

Relationship between manufacturer and actual manufacturer:

□ Contract manufacturing

□ Under common control

Others:

Annex 3:

Application Form for Registration of Imported General-purpose Cosmetics

Chinese Name of Product_____

State Food and Drug Administration

Instructions

1. This application form is downloadable from the SFDA website at http://www.sfda.gov.cn.
2. This application form and all other application materials shall be printed.
3. This application form shall be filled out completely and legibly without any alteration.
4. Please carefully read the relevant laws and regulations and provisions governing the acceptance of applications prior to filling out this application form.
5. An electronic form containing the same data as provided in the paper form shall be submitted simultaneously.

<table>
<tr><td rowspan="2">Name of Product</td><td>Chinese name</td><td colspan="4"></td></tr>
<tr><td>Foreign name</td><td colspan="4"></td></tr>
<tr><td>Product test acceptance No.</td><td colspan="5"></td></tr>
<tr><td rowspan="4">Manufacturer</td><td>Chinese name</td><td colspan="4"></td></tr>
<tr><td>Foreign name</td><td colspan="4"></td></tr>
<tr><td>Address</td><td colspan="2"></td><td>Country (or region) of origin</td><td></td></tr>
<tr><td>Phone number</td><td colspan="2"></td><td>Contact person</td><td></td></tr>
<tr><td rowspan="4">Chinese Agent</td><td>Name</td><td colspan="4"></td></tr>
<tr><td>Address</td><td colspan="4"></td></tr>
<tr><td>Fax number</td><td colspan="2"></td><td>Postal code</td><td></td></tr>
<tr><td>Phone number</td><td colspan="2"></td><td>Contact person</td><td></td></tr>
</table>

Letter of Undertaking

We, the undersigned, hereby undertake that the information contained in and attached to this application form is true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Manufacturer (Stamp)

Legal Representative (Signature)

Date:

Letter of Undertaking

We, the undersigned, hereby declare that we understand requirements set forth in the *Provisions for Acceptance of Applications for Administrative Licence for Cosmetics concerning application for the administrative licence for cosmetics in accordance with applicable laws, regulations, standards and specifications of the State as well as the responsibility and legal liability for application materials.* We have reviewed the content of the application and materials attached and undertake that all application materials we submit are true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Chinese Agent (Stamp)

Legal Representative (Signature)

Date:

Documents attached (Please mark "√" in the appropriate box)

- □ 1. Application form for administrative licence of imported general-purpose cosmetics
- □ 2. Basis of nomenclature for the Chinese name of product
- □ 3. Product formula
- □ 4. Requirements on product quality and safety control
- □ 5. Original packaging of product (including product label and product specification); where a package is exclusively designed for the Chinese market, such packaging of product (including product label and product specification) shall be provided
- □ 6. Test reports and relevant data issued by SFDA-approved testing agency
- □ 7. Safety assessment data relating to substances contained in the product that may pose any safety risk
- □ 8. A copy of the registered power of attorney and a copy of the business licence of the Chinese Agent, both under common seal
- □ 9. Letter of undertaking evidencing compliance of cosmetic ingredients and their sources with requirements on restriction or prohibition of high-risk substances in BSE-affected regions
- □ 10. Documentary evidence of product manufacturing and sale in the country (or region) of origin
- □ 11. One sample of commercially available product that is and remains sealed by the testing agency, and other data that may help in registration process

Please provide the following information if the above-signed manufacturer is not in the country (or region) of origin or there is more than one country of manufacturing or Chinese Agent:

Name of actual manufacturer:

Address of actual manufacturer:

Country of actual manufacturer:

Relationship between manufacturer and actual manufacturer:

□ Contract manufacturing

□ □ Under common control

Others:

Annex 4:

Application Form for Administrative Licence for New Cosmetic Ingredients

Chinese Name of Product_____

State Food and Drug Administration

Instructions

1. This application form is downloadable from the SFDA website at http://www.sfda.gov.cn.
2. This application form and all other application materials shall be printed.
3. This application form shall be filled out completely and legibly without any alteration.
4. Please carefully read the relevant laws and regulations and provisions governing the acceptance of applications prior to filling out this application form.
5. An electronic form containing the same data as provided in the paper form shall be submitted simultaneously.

Name of new ingredient	Chinese name				
	Foreign name				
Purpose of new ingredient					
Manufacturer	Chinese name				
	Foreign name				
	Address			Country (or region) of origin	
	Phone number		Contact person		
Chinese Agent	Name				
	Address				
	Fax number		Postal code		
	Phone number		Contact person		

Letter of Undertaking

We, the undersigned, hereby undertake that the information contained in and attached to this application form is true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Manufacturer (Stamp)

Legal Representative (Signature)

Date:

Letter of Undertaking

We, the undersigned, hereby declare that we understand requirements set forth in the *Provisions for Acceptance of Applications for Administrative Licence for Cosmetics concerning application for the administrative licence for cosmetics in accordance with applicable laws, regulations, standards and specifications of the State as well as the responsibility and legal liability for application materials.* We have reviewed the content of the application and materials attached and undertake that all application materials we submit are true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Chinese Agent (Stamp)

Legal Representative (Signature)

Date:

Note: In the case of application through a Chinese Agent, the letter of undertaking of the Chinese Agent shall be provided.

Documents attached (Please mark "√" in the appropriate box)

- □ 1. Application form for administrative licence of new cosmetic ingredients
- □ 2. Development report
- □ 3. Description and illustration of the manufacturing process
- □ 4. Requirements on product quality and safety control
- □ 5. Toxicological safety evaluation data
- □ 6. In the case of application through a Chinese Agent, a copy of the registered power of attorney issued to the Chinese Agent and a copy of the business licence of the Chinese Agent under common seal
- □ 7. One piece of sample submitted for review and other data that may help in application for administrative license

Others

Annex 5:

Application Form for Change in Administrative Licence for Cosmetics

Chinese Name of Product_____

State Food and Drug Administration

Instructions

1. This application form is downloadable from the SFDA website at http://www.sfda.gov.cn.
2. This application form and all other application materials shall be printed.
3. This application form shall be filled out completely and legibly without any alteration.
4. Please carefully read the relevant laws and regulations and requirements on application materials prior to filling out this application form.
5. All items provided in the table are those set forth in the approval document for hygiene license issued by the State Food and Drug Administration or the Ministry of Health.
6. An electronic form containing the same data as provided in the paper form shall be submitted simultaneously.

Name of Product				
Product Test Acceptance No.				
Manufacturer	Name			
	Address			
	Phone Number		Contact Person	
Chinese Agent	Name			
	Address			
	Fax number		Postal code	
	Phone number		Contact person	

Hygiene Licence No. of Manufacturer			Expired on	Date/month/year
Original approval document no.			Expired on	Date/month/year

Documents and certificates attached:

- □ 1. Application form for change in administrative licence for cosmetics
- □ 2. Original of the approval document (registration certificate) for the administrative license for cosmetics
- □ 3.In the case of application through a Chinese Agent, a copy of the registered power of attorney appointing the Chinese Agent and a copy of the business licence of the Chinese Agent, both under common seal
- □ 4. Other data required for change

Letter of Undertaking

We, the undersigned, hereby undertake that the information contained in and attached to this application form is true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Manufacturer (Stamp)

Legal Representative (Signature)

Date:

Letter of Undertaking

We, the undersigned, hereby declare that we understand the requirements set forth in the *Provisions for Acceptance of Applications for Administrative Licence for Cosmetics* concerning application for the administrative licence for cosmetics in accordance with applicable laws, regulations, standards and specifications of the State as well as the responsibility and legal liability for application materials. We have reviewed the content of the application and the materials attached and undertake that all application materials we submit are true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Chinese Agent (Stamp)

Legal Representative (Signature)

Date:

Note: In the case of application through a Chinese Agent, the letter of undertaking of the Chinese Agent shall be provided.

Itemized changes applied for:
Reasons for changes (please attach additional sheets if necessary):

Annex 6:

Application Form for Extension of Administrative Licence for Cosmetics

Chinese Name of Product_____

State Food and Drug Administration

Instructions

1. This application form is downloadable from the SFDA website at http://www.sfda.gov.cn.
2. This application form and all other application materials shall be printed.
3. This application form shall be filled out completely and legibly without any alteration.
4. Please carefully read the relevant laws and regulations and provisions governing the acceptance of applications prior to filling out this application form.
5. In the "Type of Product" section, please specify the type of the special-purpose cosmetics, such as sun protection or hair growth.
6. All items provided in the table are those set forth in the approval document for hygiene license issued by the State Food and Drug Administration or the Ministry of Health.
7. An electronic form containing the same data as provided in the paper form shall be submitted simultaneously.

Name of Product	Chinese name				
	Foreign name				
Type of product					
Manufacturer	Chinese name				
	Foreign name				
	Address		Country (or region) of origin		
	Phone number		Contact person		
Chinese Agent	Name				
	Address				
			Postal code		
	Fax number				

	Phone number		Contact person	
Hygiene Licence No. of Manufacturer			Expired on	Date/month/year
Original approval document no.			Expired on	Date/month/year

Letter of Undertaking

We, the undersigned, hereby undertake that the information contained in and attached to this application form is true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Manufacturer (Stamp)

Legal Representative (Signature):

Date:

Letter of Undertaking

We, the undersigned, hereby declare that we understand the requirements set forth in the *Provisions for Acceptance of Applications for Administrative Licence for Cosmetics* concerning application for the administrative licence for cosmetics in accordance with applicable laws, regulations, standards and specifications of the State as well as the responsibility and legal liability for application materials. We have reviewed the content of the application and the materials attached and undertake that all application materials we submit are true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

_____ _____

Chinese Agent (Stamp) Legal Representative (Signature)

Date:

Note: In the case of application through a Chinese Agent, the letter of undertaking of the Chinese Agent shall be provided.

Documents attached (Please mark "√" in the appropriate box)

- □ 1. Application form for extension of administrative licence for cosmetics
- □ 2. Original of the approval document (registration certificate) for the administrative license for cosmetics
- □ 3. Basis of nomenclature for the Chinese name of the product (unless it has been provided during initial application and the name remains unchanged)
- □ 4. Product formula
- □ 5. Requirements on product quality and safety control
- □ 6. Packaging of commercially available product (including product label and product specification); in the case of domestic product not commercially available, the designed product packaging (including product label and product specification) may be provided
- □ 7. In the case of domestic product, the opinion on manufacturing, commercial availability and supervision of product or the review opinion on commercial unavailability of product issued by the provincial food and drug administration authority where the applicant is located
- □ 8. In the case of application through a Chinese Agent, a copy of the registered power of attorney issued to the Chinese Agent and a copy of the business licence of the Chinese Agent under common seal
- □ 9. A sealed sample of commercially available product and other data that may help in application for administrative license

Others

Annex 7:

Application Form for Re-issuance of Approval Document (Registration Certificate) for Cosmetic Licence

Chinese Name of Product_____

State Food and Drug Administration

Instructions

1. This application form is downloadable from the SFDA website at http://www.sfda.gov.cn.
2. This application form and all other application materials shall be printed.
3. This application form shall be filled out completely and legibly without any alteration.
4. Please carefully read the relevant laws and regulations and requirements on application materials prior to filling out this application form.
5. All items provided in the table are those set forth in the approval document for hygiene license issued by the State Food and Drug Administration or the Ministry of Health.
6. An electronic form containing the same data as provided in the paper form shall be submitted simultaneously.

Name of Product				
Reason for re-issuance	□ Damaged □ Lost			
Manufacturer	Name			
	Address			
	Phone number		Contact person	
Chinese Agent	Name			
	Address			
	Fax number		Postal code	
	Phone number		Contact person	

Hygiene Licence No. of Manufacturer			Expired on	Date/month/year
Original approval document no.			Expired on	Date/month/year

Documents attached

- □ 1. Application form for re-issuance of approval document (registration certificate) for the administrative licence for cosmetics
- □ 2. Origin of the approval document (registration certificate) for the administrative license for cosmetics if it is damaged
- □ 3. Original of the declaration of loss published in newspapers of provincial or larger circulation if the approval document (registration certificate) is lost; the application for re-issuance due to loss shall be filed at least twenty days after publication of the declaration of loss
- □ 4. In the case of application through a Chinese Agent, a copy of the registered power of attorney issued to the Chinese Agent and a copy of the business licence of the Chinese Agent under common seal

Letter of Undertaking

We, the undersigned, hereby undertake that the information contained in and attached to this application form is true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

Manufacturer (Stamp)

Legal Representative (Signature):

Date:

Letter of Undertaking

We, the undersigned, hereby declare that we understand the requirements set forth in the *Provisions for Acceptance of Applications for Administrative Licence for Cosmetics* concerning application for the administrative licence for cosmetics in accordance with applicable laws, regulations, standards and specifications of the State as well as the responsibility and legal liability for application materials. We have reviewed the content of the application and the materials attached and undertake that all application materials we submit are true, lawful and consistent with the original, if applicable, and data provided in attachments hereto are derived from studies and tests on the product in compliance with the *Hygienic Standard for Cosmetics*. We are willing to assume any legal liability for and all consequences of any misrepresentation.

_____ _____

Chinese Agent (Stamp) Legal Representative (Signature)

Date:

Annex 8:

Application Form for Correction of Errors in Approval Document (Registration Certificate) for Administrative License for Cosmetics

<table>
<tr><td colspan="2">Original acceptance no.</td><td colspan="3"></td></tr>
<tr><td rowspan="2">Name of Product</td><td>Chinese</td><td colspan="3"></td></tr>
<tr><td>Foreign</td><td colspan="3"></td></tr>
<tr><td colspan="2">Approval (registration) no.</td><td colspan="3"></td></tr>
<tr><td colspan="2">Name of manufacturer or Chinese Agent</td><td colspan="3"></td></tr>
<tr><td colspan="2">Contact person</td><td></td><td>Telephone</td><td></td></tr>
<tr><td colspan="5">Errors in approval document (registration certificate):

Note: In the case of application through a Chinese Agent, the letter of undertaking of the Chinese Agent shall be provided.</td></tr>
</table>

Requested changes in approval document (registration certificate):

Chinese Agent (Stamp)

Legal Representative (Signature)

Date: