Importing cosmetic products into China

Imported cosmetics need pre-market approval before entering China

All cosmetics imported into China are required to obtain pre-market approval or notification from the Chinese State Food and Drug Administration (SFDA). The approval is referred to as either the Administrative Approval or Administrative Notification.

Two main regulations lay the foundation of cosmetics regulation in China. The "*Regulation for the Hygiene Supervision of Cosmetics*" (1989), issued by Ministry of Health (MoH) stipulates that exporters, manufacturers and distributors of cosmetics selling finished products and new cosmetic ingredients in China are subject to licensing requirements from the SFDA. The "*Provisions for the Hygiene Licence application procedure*" (2009) details the procedures and documentation requirements for cosmetics Administrative Approval and Notification.

The SFDA is the responsible administration managing the cosmetics sector and has issued a number of regulations and technical standards covering labelling, hygiene requirements, as well as other technical guidelines.

Cosmetics products are currently classified into ordinary cosmetics and cosmetics for special use:

- **Ordinary cosmetics** are those which are used for hair care, skin care, fragrances, make-up and nail/toe cosmetics among others.
- **Cosmetics for specific use** include hair growing restoration, hair dyeing colorants, hair perming, depilatories, body slimming/breast enhancement, deodorants, spot removing, sun screen protection.

All ordinary cosmetics need notification to SFDA and special use cosmetics require Administrative Approval before market entry. In addition, cosmetics containing new ingredient not previously approved for the Chinese market require separate pre-approval from the SFDA before it can be introduced in cosmetic products destined for the Chinese market.

New cosmetic ingredients are any ingredient that is introduced on the Chinese market for the first time as introduced in article 9 of the *Regulation for the Hygiene Supervision of cosmetics*. The SFDA currently maintains an *Inventory of Existing Cosmetic Ingredients in China*, listing those allow in China.

In addition to the Administrative Approval or Notification, all cosmetics are subject to labelling requirements stipulated in the Chinese National Standards GB 5296.3 -2008.

The Administrative Approval is valid for 4 years and application for renewal should be submitted at least 4 months before its expiration.

If any amendments are made to the approved cosmetics, in terms of labelling information, changes to product name, etc. the amendments need to be notified to the SFDA and should follow the proper procedures stipulated by the SFDA.

In addition to the SFDA Registration and Notification Approval, all cosmetics products imported to China are subject to the Chinese Inspection and Quarantine authority (CIQ) verification and testing.

For cosmetics imported to China for the first time, Chinese importer needs to provide the following documents when applying for an inspection from CIQ:

- A self-declaration letter stating that the imported cosmetic product complies with relevant Chinese laws and the normal use of the product will not cause any harm to human health;
- Product formula;
- Hygiene licence or record-keeping certificate;
- For cosmetics exempted from hygiene licence or record-keeping requirement, the following documents are required:
    - Safety Evaluation Report issued by the qualified institutions for substances of potential safety risks; and
    - Documentation that permits the production and distribution of the imported cosmetics in the country of production or a Certificate of Country of Origin;
- Sample labels in Chinese, product labels in the original language and the translated text in Chinese;
- Information on the product name, volume/weight, specifications, country of origin, batch number, expiry date (production date and shelf life), target market, and information about packaging company;
- Other documentation required by AQSIQ (the General Administration of Quality Supervision, Inspection and Quarantine)

How to apply for SFDA administrative approval or administrative notification?

The application procedure for the *Hygiene Licence* can generally be divided into a 4-step process:

1. **Appointing an agent**: applicant must be a legal Chinese entity
2. **Standards and testing**: all cosmetics imported into China will need compliance testing at a designated laboratory
3. **Application**: preparation of application and supporting documentation for Administrative Approval or Notification including labelling
4. **Evaluation**: SFDA conducts a technical evaluation of information provided and approves application.

1. Appointing an agent

According to the *Cosmetics Administration Regulation*, application for Administrative Approval and Notification can only be carried out by a Chinese legal entity. Overseas cosmetics manufacturers without legal representation in China are thus required to apply for the licence through agent services. When using agent services the manufacturer is required to issue a power of attorney stipulating the relationship between the agent and the manufacturer.

Both the manufacturer and the agent bear the legal responsibility for the product.

2. Standards and testing

All imported cosmetics need product testing at a SFDA designated laboratory. All designated laboratories are located in China.

Currently, there are 17 national designated laboratories that can carry out the pre-approval testing. All have different testing capabilities designated for testing against specific conditions, such as microbiology, hygienic chemistry, or conducting safe-for–human-use trials. The designated laboratories are listed on the SFDA website with introductions to testing capabilities.

Product samples should be delivered in their original packaging to the designated laboratory for testing. The sample should be submitted together with the product formula and instructions for use – all translated into Chinese.

The designated laboratory will conduct testing based on a number of mandatory hygienic standards. These are Chinese national (GB) standards1 and namely refers to the GB 7916–1987; GB 7917–1987 1 to 4; GB7918 – 1 to 5, stipulating hygienic tests for ingredients such as Mercury, Arsenic, Lead, and Methanol, as well as other standards.

GB 7916-1987 and **GB 7919-1987** describe the hygienic standard for cosmetics and the Procedures and methods of safety evaluation for cosmetics.

Chinese Hygienic Standards are introduced and described in *Rules of Cosmetic Administrative Approval Testing, No.82* (2010) issued by the SFDA. The document set out the different requirements applying to both the testing laboratory and the applicant covering the process of the testing. The annex includes a detailed list of the different items that will be tested such as acute toxicity testing, sub-toxicity testing, etc.

The Chinese Ministry of Health has issued the *Hygienic Standard for Cosmetics* guiding document (2007) providing useful information on testing, standards, restricted ingredients, etc. however the document is only available in China language.

The designated test laboratory will conduct testing according to the specific product. Once testing is completed, the designated laboratory will issue a test report which needs to be submitted together with the other documentation requirements for the application.

3. Application

It is a pre-requirement for submitting the Administrative Approval or Notification Application that the product has a valid test report as described above. Once the manufacturer has obtained this documentation, the application can be submitted to the SFDA.

It is important that consistency is kept throughout the application – names should be matching with business registrations, product codes, etc. Any inconsistency will result in a delay in the application process. The application should be submitted in Chinese.

Depending on whether you are applying for a New Cosmetic Ingredient, Cosmetic for Specific Use or Ordinary Cosmetics, the application varies slightly. The following tables indicate the documentation that it should contain in each case:

[1] National **GB standards** are often harmonized with relevant international standards, however deviations occurs. The Standardisation Administration of China (SAC) provides a **national standards enquiry** service searchable by standard number, title, ICS code, etc.

http://220.194.5.109/stdlinfo/servlet/com.sac.sacQuery.GjbzcxServlet

New cosmetic ingredients	
1	**Application form** for hygiene licence for new cosmetic ingredient.
2	**A research & development report** consisting of the following information: - Background of research, R&D process and relevant technical files. - The source of ingredient, physio-chemical properties, molecular structure, molecular structure, molecular weight. - The purpose of using the ingredient, supporting proof, the range of concentration and limits on volume, announcements and warning words. - Statements on the use of the ingredient in cosmetics in other countries (areas).
3	Brief introduction to **manufacturing process and flow chart.**
4	Applying **product standards and codes for quality and safety control of ingredient** (including test method, specifications, potential safety risk substances and relevant measures of control).
5	**Toxicology safety assessment data** (including the assessment review, required toxicology experiments materials and safety assessment materials for potential safety risk substances). *Note: required toxicology experiments materials could be testing reports, scientific documentation and contents issued by official websites of domestic or overseas governments or international organisations.*
6	**Power of attorney** between manufacturer and agent - (the authorisation letter needs to be translated into Chinese and notarized by the native notary office and Chinese notarisation agent), copy of the agent's business licence.
10	Statement from manufacturer guaranteeing that materials used meet the requirements of **BSE free regions**.
11	Documents proving that the manufacturer is allowed to produce/ sell cosmetics in the country of origin. In addition, the certification of the manufacturer quality assurance system or Good Manufacturing Practice (GMP) inspection report should be also submitted (if applicable).
12	Other relevant information which can support the application.
13	Summary of application following SFDA announcement No.393 (2010) giving guidance to the documentation preparation.

	Specific use
1	**Application form** for the cosmetic product to be imported.
2	**Product ingredients** translated into Chinese.
3	**Product formula** provided in both Chinese and English.
4	Brief introduction to **manufacturing process and flow chart.**
5	Applying product **quality and safety standards** – Cosmetics manufacturer can list international standards. As a minimum the international standard must not have lower requirements than the applying Chinese standard. If using Chinese standards, list the specific standards used, including testing limits and methods.
6	Original product packaging including **labelling information** following requirement set out in GB 5296.3-2008.
7	Copy of approved **test report** from the designated laboratory.
8	For Special Use Cosmetics using functional components, such as sliming aids, hair nourishing, breast enhancements, etc. the manufacturer should provide the **clinical study**.
9	**Power of attorney** between manufacturer and agent - (the authorisation letter needs to be translated into Chinese and notarized by the native notary office and Chinese notarisation agent), copy of the agent's business licence.
10	Statement from manufacturer guaranteeing that materials used meet the requirements of **BSE free regions**.
11	Documents proving that the manufacturer is allowed to produce/ sell cosmetics in the country of origin. In addition, the certification of the manufacturer quality assurance system or Good Manufacturing Practice (GMP) inspection report should be also submitted (if applicable).
12	Other relevant information which can support the application.
13	Summary of application following SFDA announcement No.393 (2010) giving guidance to the documentation preparation.

Registration procedures for Ordinary cosmetics are slightly different as the mandatory testing is not required. In order to apply for the Notification Certificate applicants need to file an application together with the following supporting documentation:

	Ordinary cosmetics
1	**Application form** for the cosmetic product to be imported.
2	**Product ingredients** translated into Chinese.
3	**Product formula** provided in both Chinese and English.
4	Applying product **quality and safety standards** – Cosmetics manufacturer can list international standards. As a minimum the international standard must not have lower requirements than the applying Chinese standard.
5	**Product quality control** - including description of internal control mechanisms put in place by the manufacturer to guarantee quality of raw material, compliance with adopted standards, etc.
6	Original product packaging including **labelling information** following requirement set out in GB 5296.3-2008.
7	Copy of the approved **test report** from the designated laboratory.
8	**Power of attorney** between manufacturer and agent - (the authorisation letter needs to be translated into Chinese and notarized by a Chinese notarisation agent), copy of the agent's business licence.
9	Statement from manufacturer guaranteeing that materials used meet the requirements of **BSE free regions**.
10	Documents proving that the manufacturer is allowed to produce/ sell cosmetics in the country of origin. In addition, the certification of the manufacturer quality assurance system or Good Manufacturing Practice (GMP) inspection report should be also submitted (if applicable).
11	Other relevant information which can support the application.
12	Summary of application following SFDA announcement No.393 (2010) giving guidance to the documentation preparation.

4. Labelling of cosmetics

Cosmetic products imported into China must be labelled according to the mandatory National Standard **GB 5296.3-2008** - *Instruction for use of consumer products - general labelling for cosmetics*. The manufacturer is required to list the following information, in Chinese, on a label:

- Product name
- Name and address of the manufacturer
- Net content
- Product ingredients
- Shelf life
- Manufacturer licence, product standard or administrative approval code
- Safety marks and product literature

In case of imported cosmetics, the country of origin, the name and address of the distributor in China shall be identified on the label.

5. Evaluation

The applicant will be notified by the SFDA within 5 days confirming whether the application is accepted or not. If the application is not accepted, the SFDA will provide explanation of discrepancies or missing documentation allowing the application to be resubmitted.

After acceptance by the SFDA, the application agent or representative office is likely to be contacted for clarifications of any technical questions that may arise during the review.

The technical review meeting is generally carried every month. The timeframe for concluding the reviewing is 60 days.

Any changes made to the approved cosmetic product should be notified to the SFDA following the applying regulations. This applies both to changes in the labelling information and to changes in the product ingredients.

Application for renewal of SFDA approval should be applied for well in advance in order to avoid any disruptions.

List of important regulations:

Regulation for the Hygiene Supervision of Cosmetics [1989]

Provisions for the Hygiene Licence application procedure [2009]

Rules of Cosmetic Administrative Approval Testing, No.82 [2010]

Hygienic Standard for Cosmetics [2007]

The Administrative Measures on the Inspection, Quarantine and Supervision of Import and Export of Cosmetics - AQSIQ Order No. 143 [2011]

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Contact the Centre at:

Room 910, Sunflower Tower
37 Maizidian West Street
Chaoyang District
Beijing, 100125

T: +86 10 8527 5300
F: +86 10 8527 5093

www.eusmecentre.org.cn
enquiries@eusmecentre.org.cn

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