



## Cosmetic products in 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 the Ministry of Health (MoH) stipulates that exporters, manufacturers and distributors of cosmetics selling finished cosmetic 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 classified into ordinary cosmetics and cosmetics for special use:

- **Ordinary cosmetics** are those which are used for hair care, skin care, fragrances, nail/toe cosmetics among others.
- **Cosmetics for special use**, including 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 the SFDA and special use cosmetics require administrative approval before market entry. In addition, cosmetics containing a new cosmetic 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:** 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 the inventory of existing cosmetic ingredients in China, listing ingredients allowed in China.

In addition to the administrative approval or notification, all cosmetics are subject to labelling requirements stipulated in the Chinese national standard 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, both 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 cosmetic products imported into China are subject to verification and testing by the Chinese Inspection and Quarantine authority (CIQ). Imported cosmetic products will receive the CIQ label – printed on the product packaging – verifying that the product has been tested and approved. Application for a CIQ label requires additional documentation.

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### 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 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:** the SFDA conducts a technical evaluation of information provided and approves application.

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#### 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 trials for human use. 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) standards<sup>1</sup> and namely refers to 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 sets 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 guiding document “*hygienic standard for cosmetics*” (2007) providing useful information on testing, standards, restricted ingredients, etc. however the document is only available in Chinese 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.

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<sup>1</sup> National **GB standards** are often harmonised with relevant international standards, however deviations occur. 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>

The application should contain the following documentation:

Specific use & new cosmetic ingredients	
1	<b>Application form</b> for the cosmetic product to be imported.
2	<b>Product ingredients</b> translated into Chinese.
3	<b>Product formula</b> provided in both Chinese and English.
4	Brief introduction to <b>manufacturing process and flow chart</b> .
5	Applying product <b>quality and safety standards</b> – 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 <b>labelling information</b> following requirements set out in GB 5296.3-2008.
7	Copy of approved <b>test report</b> from the designated laboratory.
8	For special use cosmetics using functional components, such as slimming aids, hair nourishing, breast enhancements, etc. the manufacturer should provide the <b>clinical study</b> .
9	<b>Power of attorney</b> between manufacturer and agent - (the authorisation letter needs to be translated into Chinese and notarised by a Chinese notarisation agent), copy of the agent's business licence.
10	Statement from manufacturer guaranteeing that materials used meet the requirements of <b>BSE free regions</b> .
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	<b>Application form</b> for the cosmetic product to be imported
2	<b>Product ingredients</b> translated into Chinese
3	<b>Product formula</b> provided in both Chinese and English
4	Applying product <b>quality and safety standards</b> – cosmetics manufacturer can list international standards. As a minimum the international standard must not have lower requirements than the applying Chinese standard.
5	<b>Product quality control</b> - 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 <b>labelling information</b> following requirement set out in GB 5296.3-2008
7	Copy of the approved <b>test report</b> from the designated laboratory
8	<b>Power of attorney</b> between manufacturer and agent - (the authorization letter needs to be translated into Chinese and notarised by a Chinese notarization agent), copy of the agent's business license.
9	Statement from manufacturer guaranteeing that materials used meet the requirements of <b>BSE free regions</b> .
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.

## 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, country of origin and the name and address of the distributor in China shall be identified on the label. Besides, a **CIQ label** needs to be acquired from AQSIQ. An imported cosmetic with a CIQ label means it has already passed the examination of the China Entry-Exit Inspection and Quarantine Bureau and is allowed to be sold in China.

## 4. Evaluation

The applicant will be notified by the SFDA within 5 days confirming if 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 out 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 as well as product ingredients.

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

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### List of important regulations:

Regulation for the Hygiene Supervision of Cosmetics [1989]

Provisions for the Hygiene License application procedure [2009]

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

Hygienic Standard for Cosmetics [2007]



**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](http://www.eusmecentre.org.cn)  
[enquiries@eusmecentre.org.cn](mailto:enquiries@eusmecentre.org.cn)

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The Centre's range of free services cover:

- Business Development – provision of market information, business and marketing advice
- Legal – legal information, 'ask the expert' initial consultations and practical manuals
- Standards – standards and conformity requirements when exporting to China
- HR and Training – industry and horizontal training programmes
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