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Guidance in a Nutshell

Steps to exporting cosmetic products to China

In this document, companies and individuals in charge of exporting cosmetic products into China will find a comprehensive and detailed overview of the regulatory procedures, rules and checkpoints mandated for premarket approval, importation inspection and market surveillance of cosmetics by the CFDA and AQSIQ.

Legal Disclaimer

This Guidance provides an overview of the regulatory requirements on imported cosmetic products and advice on how to comply with regulations. However, users are reminded that official government regulation “Regulation concerning Hygiene Supervision over Cosmetics” and related official documents are the only authentic legal reference. The information in this document does not constitute legal advice. NPAFInc Consulting Group does not accept any liability with regard to the contents of this document.

If you have questions or comments in relation to this document please do not hesitate to contact us.

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China established the current cosmetic regulatory system by enacting the "Regulation concerning the Hygienic Supervision of Cosmetic Products" in 1990, which was regulated under the auspices of the Ministry of Health (MoH).Regulatory responsibility was transferred to China's Food and Drug Administration (CFDA, formerly SFDA) in 2008 which was primarily tasked with pre-market evaluation of products whilst first stage assessment of imported shipments of cosmetic products was designated to the China Inspection and Quarantine Bureau (CIQ). This Guidance provides an overview of the regulatory requirements on imported cosmetic products along with practical advice on how to comply with regulations.

Steps to exporting cosmetic products to China

1. Determine if your product is defined as a cosmetic in China

Article 2 of China's cosmetic regulation defines cosmetic product as industrially produced chemical product subject to daily use, which are intended to be placed in contact with any external parts of human body (skin, hair system, nails, lips and oral cavity) by spreading, rubbing, spraying, sprinkling etc., with the purpose of cleansing, correcting body odors, protecting, maintain function or changing their appearance.

This definition is important for products which are at the borderline between cosmetics and other product types, such as wet wipe. The arbitrary defining criteria delineatingcosmetic and hygienicproducts can be difficult to ascertain, however the distinction is extremely important as the regulatory requirements vary quite considerably. (See Guidance in a Nutshell regarding the Chinese regulatory requirements of wet wipes for more detailed explanation.)

2. Check whether ingredients are permissible or banned

China regulated the cosmetic ingredients based on the Hygienic Standards of Cosmetics issued in 1987 prior to the enactment of cosmetic regulation, which covered the regulated ingredients of prohibited substances (359 entries), restricted substances (57 entries), preservatives (66 entries), UV Filters (36 entries) and Skin Colorants (67 entries).

China primarily regulates the market by compiling lists of permissible or restricted inventories. Reference to these inventories is the foundation upon which regulatory compliance is built. Promulgating standards and regulations leads to constant amendments and updates to these lists of regulated ingredients. In addition to this the influence of foreign regulatory frameworks is also evidenced by the inclusion of banned and restricted substances which both model and derive inspiration from international regulatory trends (e.g.2003 amendments on EU Cosmetic Directive, which instigated the inclusion of numerous substances to the restricted inventory)

The table below outlines the nine inventories encompassing regulated ingredients (hereafter referred as 9-Regulated Lists), and the table below shows the related name and date of

publication.

For more information, you can refer to the document regarding the introduction of the lists of regulated cosmetic ingredients in China, which details the entries of each list and the accompanying regulatory requirements along with the implications for enterprise.

List Name	First Publication	Current Version
Inventory of Existing Cosmetic Ingredients in China	2003	2013
List of Standardized Chinese INCI Name	2007	2010
List of Substances Prohibited in Cosmetic Products	1987	2007
List of Substances Restricted in Cosmetic Products	1987	2007
List of Colorants Allowed in Cosmetic Products	1987	2007
List of Preservatives Allowed in Cosmetic Products	1987	2007
List of UV Filters Allowed in Cosmetic Products	1987	2007
List of Hair Colorants Allowed in Cosmetic Products	2007	2007
List of Approved New Cosmetic Ingredients	2004	2012

3. Prepare the pre-market application dossier

A pre-market application dossier must be compiled for each imported cosmetic product and submitted to CFDA for evaluation on the quality, safety andlabeling. The application dossier consists of all the evidence of conformity and consisted of XX parts present as below.

No.	Items	Remarks
1.	Application form	Must be signed and stamped
2.	Product naming statement	The Chinese naming requirements must be complied and clarify any specific items, such as for particular population
3.	Quality control specification	The original QC specification and other supportive material should be provided, if necessary
4.	Manufacturing description	All the ingredients must be involved in the production description, plus primary process parameters and chart
5.	Formulation	All the ingredients must be listed and identified, and the certificate of analysis will be necessary sometime
6.	Package	The original package must be included and the newly designed for China market need to be submitted as well, furthermore, Chinese compliant label must be provided
7.	Testing reports	Cosmetic type-dependent safety testing must be carried out by CFDA approved institutes in China, except the sun protection factor determination
8.	Safety evaluation on the risk concern substance(1)	Information on the identities, analytical outcome and risk assessment regarding the potential risk concern substance should be provided
9.	Functional ingredients	The functional ingredients of special cosmetics(2) must be identified and supporting material be provide as well

10.	Authorization letter	The evidence of the assignment of local responsible agent
11.	Certificate of free sale or other equivalent	The document must be provided by the authority or industry association of the country of origin
12.	Safety commitmenton ingredients from mad cowinfectious area	This comes from the outbreak of EU mad cow disease in 2001, and safety commitment is required, instead of officialcosmetic quarantine certificate in 2007
13.	Technical requirements	Focusing on the quality requirement besides QC specification, including QC methods, usage instruction, storage condition and shelf time.
14.	Original product	One product for Chinese marketing should be provided

(1) Risk concern substances refer to any harmful chemicals, typically the prohibited substances (egdioxin from PEG-derivatives), generating from impurities of synthetic or natural ingredients or the manufacturing process

(2) Special cosmetics refer to the products with special function, including hair growth products, hair dye, products for waving or straightening hair, hair removal products, beauty breast products, products for body fitness (eg. slimming cream), deodorants, products for anti-spot or UV protection.

4. Appoint a Responsible Agent

A fundamental requirement for Cosmetic importers wishing to enter the Chinese Market is the appointment of a Chinese legal entity or Responsible Agent (RA) to represent their company during the application procedure. China requests that both the oversea manufacture and local RA ensure the product comply with Chinese national standards however there are no clearly defined regulations underpinning this requirement. RA's can bea Chinese subsidiary company, importer or other independent agent business, such as REACH24H.

(Please be aware that, only the oversea manufacture or the consignor in case of OEM, is qualified to be the applicant to assign the RA for application, and its name will be listed in the approval acknowledgement document, distributors or wholesalers do not qualify as a valid RA.)

5. Label your product according to China rules

CFDA provide two options for labeling imported cosmetics 1)The original upon with Chinese translation 2) Confirm with national labeling standards and use a Chinese commercial label and package,(hereafter know as Chinese label). Labeling refers to the combination of words, numbers, figures or instructions which appear on the container or packing .

The following information must be included in the Chinese label,

- ***Product name*** – the Chinese product name generated according to the Cosmetic Naming Rule
- ***Address of producer***– the name and address of the oversea manufacture
- ***Country of origin*** – the country of origin must be indicated on the Chinese label
- ***Approval ID number***– the ID number on the approval acknowledgement, such as '国妆备进

字 J20130000', representing the product type, approved date and sequence number

- ***List of ingredients***– all the ingredientswith concentration over 1.0% must be identified with Chinese INCI name
- ***Date of production and durability***–combination of production date and period after manufacturing (such as 6 months), or the batch number and date of minimum durability (such as 2013-12-31)
- ***Particular precautions for use***– warning and condition of use for products containing restricted substance (eg. Dichloromethane, which should be indicated, while the max concentration is less than 0.5%) or special cosmetics (eg. hair dye)
- ***Storage condition and use instruction***– should be provided if necessary for safety assurance
- ***Other***– the local distributor or wholesaler can be identified as well

Other notes on labeling

- ***Language***– original label can be remained by attaching the Chinese label, and the simplified Chinese is official required, plus necessary traditional Chinese or other language characters
- ***Small packaging –***as to the product with nominal content less than 15 g or 15 mL, where it is not practical to print warning, ingredients and product use information on the packing or container itself, a leaflet, label or card should be provided containing the related information, and making reference through necessary words on the label, such as 'find the ingredients on the leaflet inside'.
- ***Labeling namomaterials–*** this new obligation under EU cosmetic regulation is not required in China, however, the application dossier should specify the nano property for some ingredients, such as ZnO for baby products
- ***Labeling inspection–*** CFDA responsible for the labeling review prior to marking, China Inspection and Quarantine Bureau (CIQ) charged with the labeling assessment prior to custom clearance, and Administration of Quality Supervision (AQS) inspecting the labels of in-market products.
- ***CIQ Label –***all the imported cosmetic must be attached the CIQ label and this requirement has been declined for imported cosmetics after 1-Feb-2012

6. Check your product claim

CFDA promulgated special rules and guidelines on the product claimand name on the Chinese label. Medicinal or therapeutic function claims are prohibited along with inclusion of misleading information. The general principle is that industry can't claim the functions or features which the products do not possess. Local expertise will be necessary for balancing compliance with Chinese claim requirements and the addressing the interests of manufacturers who rely on the added value derived from inclusion of certain claims in their marketing strategies.

7. Submit the application dossier for review

Submission of a hardcopy paper dossier is still required; e-submission is only applicable for parts

of the dossier, including the information on the formulation (part 5) and technical requirement (part 13).The pre-market evaluation process consists of the dossier completeness check (Administrative Processing Center of CFDA), compliance review (Center for Cosmetic Evaluation of CFDA) and disclosure of outcome on CFDA website, and typically the period of review process will be around 60-70 working days.

8. Pre-market approval

All the imported cosmetic products are subject to the pre-market evaluation carried out by the CFDA. Acknowledgement of approval marks the first successful step for exporting. The following information will be present on the approval document,

- ***ID number***– indicating the product type, special or ordinary, approval year and sequence number
- ***Product and producer name***– both the Chinese and original name
- ***Product type*** – indicate the type of special cosmetics, such as anti-spot cosmetics
- ***Country of origin***– country name and producer address
- ***Responsible agent***– the name and address of RA
- ***Approval date***– marks the starting point of 4-year valid period of approval acknowledgement and refresh application should be submitted in 4 months prior to the expired date

9. CIQ Inspection

For each shipment of cosmetic product, the local importer or its agent should apply for the CIQ inspection carried out by the local offices, such as Shanghai CIQ. The inspection process includes on-site examination of the label or package, sampling or testing based on the outcome of on-site examination and other findings, and finally the issuance of the CIQ Certificate, which is the ultimate requirement for custom clearance.

10. In-Market Surveillance

CFDA and AQSIQ will carry out the in-market surveillance under their own authorities, such as the plant on-site inspection for hygienic condition and good quality management system, product contamination investigation and sampling from the supermarket or cosmetic stores as well, furthermore, the State Administration for Industry and Commerce (SAIC) will monitor the advertising activities of commercial cosmetic product.