REGISTRATION OF IMPORTED COSMETICS IN CHINA

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OVERVIEW

Foreign manufacturers of cosmetics interested in entering Chinese cosmetic market without a local subsidiary need to assign a Chinese Responsible Person (RP)*. The RP will be responsible for filing products, the import, management, and the product quality and safety of that product in the territory of China.

RELEVANT HEALTH AUTHORITY:

- **National Medical Products Administration (NMPA)**: Responsible for supervising the production, declaration and post-marketing supervision of cosmetics.
- **Provincial Food and Drug Administration (MPA)**: Responsible for non-special cosmetics filing approval and post-marketing supervision.

DEFINITION AND CLASSIFICATION OF COSMETICS

In China, cosmetics are defined as: "*Products that can be spread on the outer surface of human body (e.g. skin, hairs, nails. lips etc.), the teeth and oral mucosa for the purpose of cleaning, protecting, beautifying, deodorizing and keeping in good condition, by way of smearing, spraying or other similar means*".

The Administrative license approval (for special cosmetics) or filing certificate (for non-special cosmetics) must be obtained prior to cosmetics' importation and commercialization in China.

Note: Multiple domestic responsible people cannot be authorized for the same product.

Cosmetics are classified in 2 categories, Special Cosmetics and Non-Special Cosmetics, based on their purpose and risks as shown below:

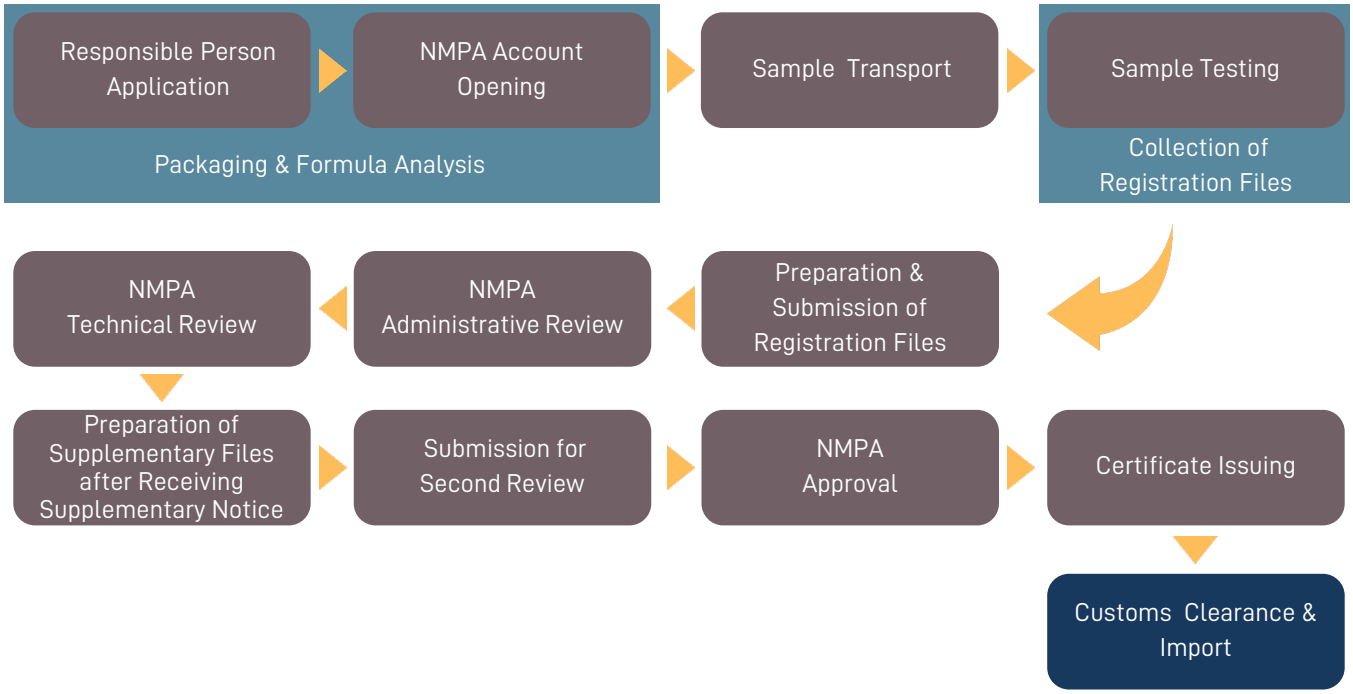
NON SPECIAL COSMETICS

Non-Special category covers 5 categories

SPECIAL COSMETICS

Special category covers 9 categories:

REGISTRATION PROCESS
(SPECIAL PURPOSE COSMETICS)



CONTENT OF NOTIFICATION DOSSIER

The following materials should be submitted for imported special-purpose cosmetics :

(1) Application form for imported special-purpose cosmetics;

(2) Product formula;

(3) List of functional ingredients should be submitted and their primary purpose of use

(4) Brief description and diagrams of the production process;

(5) Product quality standards;

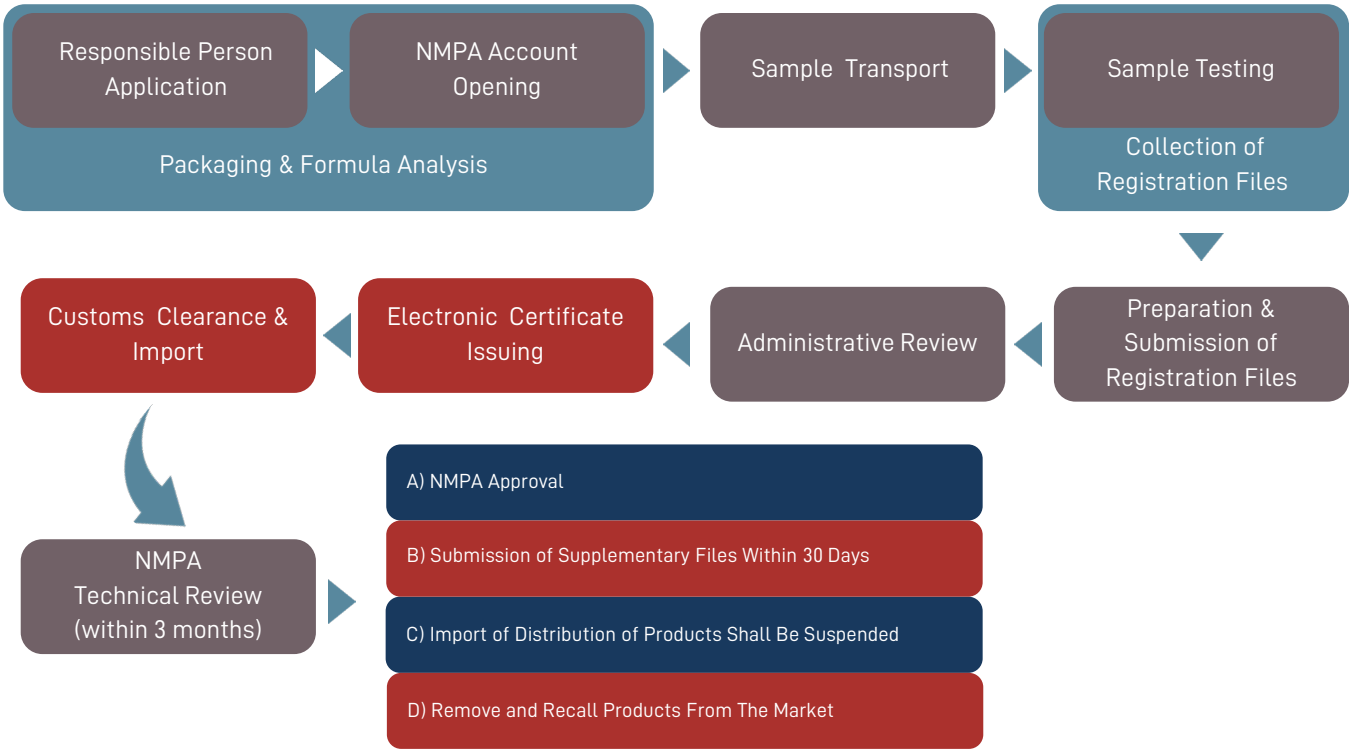
(6) Inspection reports and related materials issued by the inspection agency recognized by NMPA

(7) The original packaging and labeling of the product Intended exclusively for the Chinese market

(8) Business License of Local Representative

Note: *At present, the SFDA Food and Cosmetics Approval Office requires companies to submit an original of the application material.*

FILING PROCESS
(NON-SPECIAL PURPOSE COSMETICS)



CONTENT OF NOTIFICATION DOSSIER

The following materials shall be submitted for the record of imported non-special use cosmetics:

(1) Application form for the record of imported non-special use cosmetics;

(2) Product formula;

(3) Product quality standards;

(4) Inspection reports issued by an inspection agency recognized by NMPA

(5) The packaging and label of the product Intended exclusively for the Chinese market

Note: *At present, the SFDA Food and Cosmetics Approval Office requires companies to submit an original of the application documents.*

SAFETY ASSESSMENT AND LOCAL TESTING OF COSMETICS

Local testing for Cosmetics is required for cosmetic registration in China and is carried out in the three main disease control centers designated by the NMPA and are located in Beijing, Shanghai, and Guangzhou. Generally, cosmetics are subject to *the following tests*:

- **Microbiology testing**
- **Hygienic chemical and PH measurement testing**
- **Toxicology and safety testing**
- **Human Safety and efficacy functional testing (special cosmetics)**

TIMELINES

Product Testing Phase	
Product Testing (General Cosmetics)	1-3 months
Product Testing (Special Cosmetics)	6-8months
Registration/Filling Phase	
Acceptance Review	5 Days
Technical Review	90 Days
Administrative Review	20 Days

GRP COMPLETE MARKET ACCESS INTO CHINA'S COSMETIC MARKET

Cosmetic Compliance Services

- Formula and Packaging Review
- Product Classification

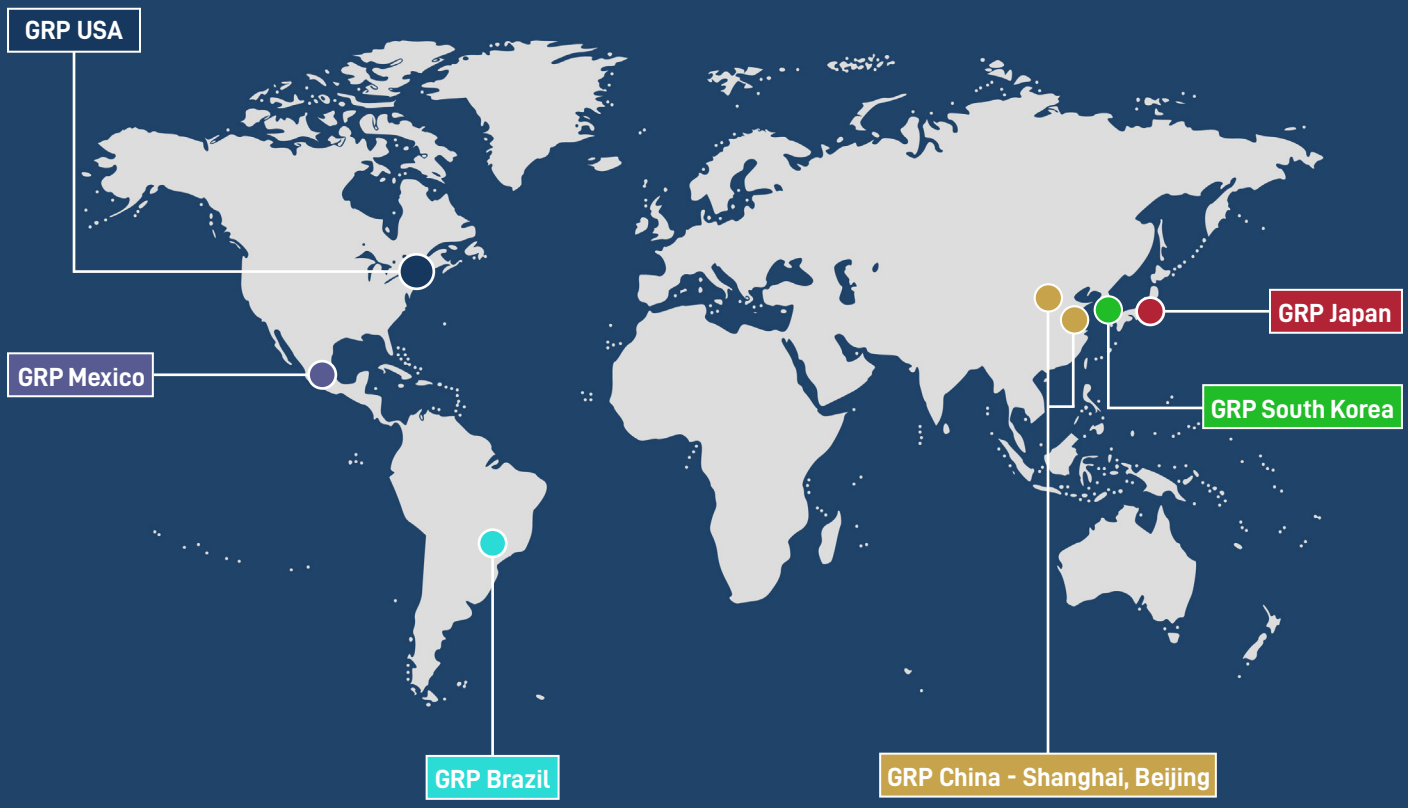
GRP as China Responsible Person (RP)

- Notification/Registration of Product
- Importation of Product
- Testing Facility Management
- Overall Product management
- Annual Report Obligation
- Adverse Reaction Monitoring (Liable for product quality and safety in territory of China)

GRP Distribution Network

- GRP will introduce Cosmetic Manufacturer to its trusted distribution network for product commercialization

GRP LOCAL BRANCHES



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ABOUT
GLOBAL REGULATORY PARTNERS, INC

Global Regulatory Partners Inc, (GRP) provides regulatory affairs, clinical, quality and safety services to medical devices and pharmaceutical companies globally. As a qualified and licensed legal representative with offices in USA, China, Japan, Brazil, Mexico, and South Korea the company can represent life science companies in those countries and help them register their products in compliance with local regulations and in record time.

CORPORATE OFFICE

Address:
550 Cochituate St, East Wing, Suite 25,
Framingham, 01701, MA, USA

Email:
info@globalregulatorypartners.com

Website:
www.globalregulatorypartners.com

Telephone:
(+1) 781.672.4200