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## Provisions for Management of Cosmetic Registration and Notification Dossiers

#### **Chapter I General Provisions**

**Article 1** For the purpose of standardizing the administration of cosmetics registration and notification, ensuring the standardized submission of various documents for cosmetics registration and notification, these Provisions are formulated in accordance with the requirements of "Cosmetic Supervision and Administration Regulations (CSAR)", "Administrative Measures on Cosmetics Registration and Notification" and other relevant laws and regulations.

**Article 2** When applying for cosmetics registration or handling notification within the territory of the People's Republic of China, documents shall be submitted in accordance with the requirements of these Provisions.

**Article 3** The cosmetics registration applicant and notification applicant shall follow the principles of risk administration, based on scientific research, be responsible for the legality, authenticity, accuracy, completeness and traceability of the submitted registration and notification documents, and bear corresponding legal responsibilities. The overseas cosmetics registration applicant and notification applicant shall supervise the registration and notification of domestic responsible persons.

**Article 4** The cosmetics registration and notification documents shall use standardized Chinese characters published by the State. Except for registered trademarks, website addresses, patent names, names and addresses of overseas companies, *etc.*, which must use other languages, or conventional terminologies (such as SPF, PFA, PA, UVA, UVB, vitamin C, *etc.*), all other texts shall be fully and normatively translated into Chinese, and the original text shall be attached following the corresponding translation.

**Article 5** The cosmetics registration and notification documents shall comply with the relevant national provisions on the use of seals, be with complete signatures and seals, and have legal effect. If overseas enterprises and other organizations do not use official seals, the documents shall be signed by the legal representative or the person in charge of the enterprise (other organization). In addition to user information related documents, if the overseas cosmetics registration applicant or notification applicant's signature is required by the product registration and notification documents, the legal representative or person in charge may authorize the signatory of the registration applicant, notification applicant or domestic responsible person to sign. In case of authorized signature, the original authorization letter and the original notarial certificate shall be submitted. The authorization letter shall specify the matters and scope of the authorized signature.

Except for the document originals issued by the competent government departments or relevant institutions, registration and notification testing institutions, notary publics, *etc.*, the cosmetics registration and notification documents shall be stamped with the official seal page by page by the domestic registration applicant, notification applicant or domestic responsible person. The user who uses the official seal with the electronic encryption certificate can directly stamp the electronic official seal on the electronic documents.

Article 6 China's legal measurement unit shall be used in the cosmetics registration and notification documents. If other measurement units are used, they shall be converted into China's legal measurement unit; references shall be quoted accurately with the source indicated to ensure valid traceability; the use of punctuation marks, diagrams, terminology, *etc.* shall be standardized to ensure that the content of the documents is accurate and standardized.

**Article 7** The contents of the same item in the cosmetics registration and notification documents shall be consistent; if there are relevant supporting documents, the items shall be accordant with the content included in the supporting documents.

**Article 8** The main text in the cosmetics registration and notification documents shall be black, and the contents shall be easy to identify. Appropriate line spacing and page margins shall be set to ensure that no text information is lost during printing or binding.

**Article 9** The paper documents for cosmetics registration and notification shall use the international standard A4 size paper with complete and clear contents, which shall not be altered. If larger size paper is needed for the unfolding pictures of cosmetics packaging, other specifications of paper can be used to ensure that it is properly placed in the A4 size documents. The carrier and writing materials of paper documents shall meet the durability requirements.

#### **Chapter II Requirements for User Information Related Documents**

#### **Section I Document Items and Requirements**

**Article 10** When applying for registration of special cosmetics or notification of general cosmetics for the first time, the domestic registration applicant, notification applicant and domestic responsible person shall submit the following user information related documents:

(I) Registration applicant and Notification applicant Information Form (Annex 1) and the resume of the person in charge of quality and safety;

(II) Quality Management System Overview of Registration applicants and Notification applicants (Annex 2);

(III) Adverse Reaction Monitoring and Evaluation System Overview Form of Registration applicants and Notification applicants (Annex 3);

(IV) Overseas registration applicants and notification applicants shall submit a Domestic Responsible Person Information Form (Annex 4);

(V) The original of the authorization letter of the domestic responsible person (see Annex 5 for the template) and its original notarial certificate;

(VI) If the registration applicant and notification applicant have self-production or entrust overseas production enterprises to produce, they shall submit the Production Enterprise Information Form (Annex 6) and the information of the person in charge of quality and safety, and fill in the existing production enterprises and their information at one time. If the production enterprise is overseas, the original certification documents of overseas manufacturing practices shall be submitted.

**Article 11** Enterprises that only engage in entrusted production in China shall submit the Production Enterprise Information Form in Item (VI) of Article 10 in order to associate and confirm the entrusted production relationship.

**Article 12** If the applicant has multiple identities such as domestic registration applicant or notification applicant, domestic responsible person, production enterprise, or if the same domestic responsible person corresponds to multiple overseas registration applicants and notification applicants, he/she may submit all relevant documents at once, and obtain the corresponding user permissions. Existing users can supplement relevant documents according to the situation and increase user permission.

## Annex 4

## Domestic Responsible Person Information Form

	Enterprise name				
<b>Basic information</b> (General review maintenance)	Unified social credit code				
	Address of residence				
	Location	Province	City	District	
	Legal representative				
Legal representative information (Self-maintenance)	Type of legal representative certificate				
	Certificate number of legal representative				
	Contact person				
Contact information (Self-maintenance)	Contact number (mobile phone)				
	Contact number (landline phone)				
	E-mail address				
	Fax number				
	Actual office				

address	
Postal code	

### **Commitment Letter**

1.As the domestic responsible person, this enterprise handles matters related to the registration and notification of cosmetics or new ingredients in the name of the overseas registration applicant/notification applicant within the scope of authorization.

2. This enterprise will conscientiously fulfill the responsibilities of domestic responsible person, assist in the monitoring of cosmetic adverse reactions and product recalls, truthfully submit all registration and notification documents as well as bear corresponding legal responsibilities.

3. The enterprise will properly keep the user's password. The relevant registration and notification behaviors by the user represents the enterprise's behavior, and the loss caused by lost or compromised password will be borne by the enterprise itself.

(Seal of domestic responsible person)

MM/DD/YY

#### Annex 5

## Authorization Letter to Domestic Responsible Person for Cosmetics Registration and Notification

### (Template)

After consensus reached by both parties, the relevant matters concerning the authorization and commitment of the domestic responsible person for cosmetics registration and notification are hereby specified as follows:

Authorizing party:

Authorized party:

Authorization scope:\_\_\_\_\_

Authorization period: <u>MM/DD/YY</u>

MM/DD/YY	MM/DD/YY
Contact information:	Contact information:
Legal representative (signature):	Legal representative (signature):
Authorizing party (seal):	Authorized party (seal):

### Annex 6

# Production Enterprise Information Form (Domestic Registration applicant/Notification applicant Self-production)

	Name
	(Associated with the
Basic information	"Registration
	applicant/Notification
(General review	applicant
maintenance)	Information Form")
	Production license
	number
	Actual production
Production site	site 1
information	
(Production site	Actual production
review	site 2
maintenance)	
	Contact person
	Contact number
	(mobile phone)
Contact	
information	Contact number
	(landline phone)
(Self-maintenance)	E-mail address
	Fax number
	Postal code

(Seal of registration applicant/notification applicant)

MM/DD/YY

# Production Enterprise Information Form (Overseas Registration applicant/Notification applicant Self-production)

Basic information	Name (Chinese)		
(Associated with "Registration applicant/Notification applicant Information Form")	Name (foreign Ianguage)		
	Actual production site 1		
<b>Production site</b> <b>information</b> (Production site review maintenance)		Certification types of manufacturing practices	<ul> <li>Issued by the competent government department of the country (region)</li> <li>Issued or approved by a certification institution or a third party</li> </ul>
	Actual production site 2		
		Certification types of manufacturing practices	<ul> <li>Issued by the competent government department of the country (region)</li> <li>Issued or approved by a certification institution or a third party</li> </ul>
Contact	Contact person		

information (Self-maintenance)	Contact number (mobile phone)	
	Contact number (landline phone)	
	E-mail address	
	Fax number	
	Postal code	
	(Seal of reg	gistration applicant/notification applicant)

## Production Enterprise Information Form (Entrusted Overseas Production)

Production	Enterprise name		
enterprise basic information (General review	Address of residence		
maintenance)	Country/Region		
Legal	Name		
representative information	Certificate type		
(Self-maintenance)	Certificate number		
<b>Production site</b> <b>information</b> (Production site review maintenance)	Actual production site 1		
		Certification types of manufacturing practices	<ul> <li>Issued by the competent government department of the country (region)</li> <li>Issued or approved by a certification institution or a third party</li> </ul>
	Actual production site 2		
		Certification types of manufacturing practices	<ul> <li>Issued by the competent government department of the country (region)</li> <li>Issued or approved by a certification institution or a third party</li> </ul>

Information of	Name			
person in charge of quality and	Certificate type			
safety (Self-maintenance)	Certificate number			
	Contact person			
Contact information (Self-maintenance)	Contact number (mobile phone)			
	Contact number (landline phone)			
	E-mail address			
	Fax number			
	Postal code			
(Seal of registration applicant/notification applicant) MM/DD/YY				



# Production Enterprise Information Form (Domestic Enterprises Only Engaged in Entrusted Production)

	Name				
<b>Basic information</b> (General review maintenance)	Unified social credit code				
	Address of residence				
maintenance)	Location	Province	City	District	
	Production license number				
Legal representative information (Self-maintenance)	Name				
	Certificate type of legal representative				
	Certificate number of legal representative				
Person in charge	Name				
of quality and safety information (Self-maintenance)	Certificate type				
	Certificate number				
Production site information	Actual production site 1				



(Production site review maintenance)	Actual production site 2	
	Contact person	
Contact information (Self-maintenance)	Contact number (mobile phone)	
	Contact number (landline phone)	
	E-mail address	
	Fax number	
	Postal code	
		(Seal of production enterprise)
		MM/DD/YY