Guidance of filing management for first import non-special use cosmetics through Shanghai Pudong

进口非特殊用途化妆品备案办事指南

Shanghai FDA

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I Scope of Application

This Guidance is applicable to the application for and handling of relevant service concerning the filing management of imported non-special use cosmetics in Pudong New Area of Shanghai.

II Name of Items

Filing management of imported non-special use cosmetics

Name of sub-items: Initial filing, change of filing, cancellation of filing

III Basis for Handling

Reply of the State Council about the Overall Plan on Carrying out the Pilot Reform of "Separating Certificates from Business License" in Shanghai (Letter No.222 (2015) of the State Council)

Decision of the State Council about Temporarily Adjusting Administrative Approval and Other Matters Stipulated in Relevant Administrative Laws & Regulations and Documents of the State Council in Pudong New Area of Shanghai (No.24 (2016) of the State Council)

Announcement of State Food and Drug Administration and General Administration of Quality Supervision, Inspection and Quarantine about Related Matter Concerning Experimentally Implementing the Filing Management of Imported Non-special Use Cosmetics in Pudong New Area of Shanghai (No.7 (2017))

Announcement of China Food and Drug Administration about Releasing the Working Procedures for the Filing Management of Imported Non-Special Use Cosmetics in Pudong New Area of Shanghai (Interim) (No.10 (2017)).

IV Handling Agency

(I) Name and authority of the handling agency

Shanghai Food and Drug Administration Filing management

(II) Contents of review

Whether or not the products applying for filing management are covered by the scope of filing; whether or not all the documents for filing are complete and are provided in the prescribed forms, etc.

(III) Legal force

In case that the filing requirements are met, the filing of products shall be granted. The domestic responsible person can go through the relevant import formalities in accordance with the relevant provisions at Shanghai entry-exit inspection and quarantine department by holding the filing information certificate generated by the filing system of the China Food and Drug Administration

and the document receipt sheet issued by Shanghai Food and Drug Administration. The product filing information shall be publicized on the filing information system for imported non-special use cosmetics of the China Food and Drug Administration (www.cfda.gov.cn).

The Shanghai Food and Drug Administration shall organize the supervision and examination of the documents for filing within 3 months after the products are filed.

(IV) Object of filing

The non-special use cosmetics imported for the first time through the port of Pudong New Area of Shanghai, of which the applicant as the domestic responsible person of the overseas manufacturing enterprise is registered in Pudong New Area of Shanghai

Before the legal person of the enterprise registered in Pudong New Area of Shanghai, applies for product filing as the domestic responsible person authorized by the overseas cosmetics manufacturing enterprise, it shall register a username and get the password through the filing system in advance.

V Filing Conditions

(I) Initial filing

1 The products are covered by the scope of filing;

2 The documents for filing are complete;

3 The documents for filing are provided in the prescribed forms;

4 The electronic version of the documents for filing is consistent with the paper version.

(II) Change of product

Handling of the change of related information for the imported non-special use cosmetics that have obtained the filing information certificate.

(III) Cancellation of filing

The products that have been filed are not imported from Pudong New Area any more.

VI Number of Filings

No quantitative restrictions on filing

VII Application Materials

(I) Catalogue and requirements of the application materials for filing

No. Name of the materials submitted Requirements

1 Application form for filing of imported non-special use cosmetics. After the application form is filled out online, the paper application form shall be printed and then signed and stamped with seal as required. The contents shall be complete and clear and shall not be altered.

2 Basis on which the Chinese name of products is named The Chinese name of products

shall meet the requirements of the Regulations on Naming of Cosmetics and the Guide on Naming of Cosmetics.

- 1) Interpretations on the specific meaning of the trade name, generic name (including the intended use and the body parts intended for use onto) and attribute name of the products applying for filing shall be provided in the basis for naming. For any conventional or habitually-used cosmetic name, the generic name and attribute name can be omitted.

2) Explanation shall be given if any content indicating the physical character or appearance as well as the color, color number, odour, suitable hair quality, skin type or specific crowds, etc., of the products is contained in the Chinese name of the products.

3) Explanation shall be given in case that the name of any specific raw material or any word(s) indicating the category of the raw material is/are used in the Chinese name of the product.

4) Explanation shall be given in case that there are modifiers and adjectives, or foreign letters, symbols, etc. must be used in the Chinese name of the product.

5) The Chinese Pinyin name of the product Chinese name shall be marked.

3 Product formula For requirements on product formula, refer to Article 14 and Article 26 in the Requirements on Application Materials for Administrative Licensing of Cosmetics as the attachment of the Notice about Printing and Distributing the Regulations on Application and Acceptance of Administrative Licensing of Cosmetics (No.856 (2009) of CFDA).

4 Requirements for control of product quality and safety The requirements for control of product quality and safety that are implemented in the country of origin (both the foreign language edition and translated Chinese text) and the commitment to compliance of products with the requirements of Technical Specification for Safety of Cosmetics (2015 edition) shall be included.

5 Pictures of product packages The pictures of product original packages (including product labels and product instructions); In case of packages intended to be specially designed for the Chinese market, the designed product packages (including product labels and product instructions) shall be submitted at the same time.

6 Brief description of product production process The brief description of the production process provided shall include the process flow diagram. The process description shall be able to succinctly reflect the actual manufacturing process of products, including operation steps and raw materials involved in each step, etc. All raw materials in the product formula shall be listed in the production process. The name of the raw materials shall be consistent with those stated in the product formula. The process description shall be consistent with the process diagram.

7 Technical requirements for products It shall be prepared by reference to Notice about

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