Regulatory Guideline for the Rules and Procedures Governing the Importation and Medical Customs Release of Cosmetic Products, Their Raw Materials, and Packaging Materials
2022

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1- Introduction:

Explain the rules and procedures for the process of importation and Customs medical release of cosmetic products, their raw materials & their packaging materials.

2- Definitions:

- **Importation approval:**

The Importation approval for cosmetics, raw materials and packaging materials - per single invoice - is valid for total shipment and has a validity of one year from the date of issuance.

- **Customs medical release:**

A release issued to allow the entry of cosmetics, their raw materials and packaging materials into the country in preparation for their final release through the inspectors of the Central Administration for Inspection of Pharmaceutical Institutions in accordance with the rules and procedures governing this matter.

- **Final customs medical release:**

A final release issued for the reference cosmetics, raw material and packaging materials, provided that the examination and conformity is carried out by representatives of the Egyptian Drug Authority at the different customs ports

- **Cosmetic Raw material imported from an external supplier:**

1. It is the cosmetic raw material that is imported from abroad by the manufacturer or the importing company according to the composition statement of the cosmetic product and is subject to import and release by the Egyptian Drug Authority.

2. It is the cosmetic raw material that is imported by importers of cosmetic raw materials registered in the registry of cosmetics Raw Material Importers and is subject to import and release by the Egyptian Drug Authority.

- Cosmetic Raw material imported from a foreign supplier for the purpose of export:

It is the cosmetic raw material that is imported from abroad by the manufacturer or the importing company for the purpose of exporting an unnotified cosmetic product that is not traded in the local market, and the imported material is subject to import and release rules by the Egyptian Drug Authority.

Cosmetic Raw material from an internal supplier: It is the material purchased by the manufacturer from an internal supplier according to the composition statement of the cosmetic product.

- Locally manufactured cosmetic raw material: Raw material supplied to the factory according to the composition statement of the cosmetic product.

- Imported Bulk cosmetic: (Bulk) are products that are imported in their entirety and are packaged only within the Arab Republic of Egypt.

3- Scope:

Allowing the importation of cosmetics, raw materials and packaging materials and releasing them as a sealed release or final release according to the company's request on the electronic platform of the Egyptian Drug Authority within the limits of the purpose for which they are imported according to the license granted and according to the cases of final release mentioned in the manual.

4- Procedures:

The data of the imported shipment is entered on the electronic platform of the Egyptian Drug Authority

A- Procedures followed to issue an Importation approval for cosmetics, raw materials and packaging materials:

First: Importation approval for finished cosmetics:

The Importation approval - for a single invoice valid for total shipment - is issued to cosmetics companies and agents who are registered in the cosmetics importers' register at the Egyptian Medicines Authority, after fulfilling the following requirements:

1- The invoice

2- A copy of the cosmetic importers' registry at the Egyptian Drug Authority.

Second: Importation approval for cosmetic raw materials and packaging materials:

The Importation approval is issued - for a single invoice valid for total shipment - for cosmetic raw materials and packaging materials for local companies and factories owning cosmetic products. An Importation approval for cosmetic raw materials is also issued to importers of cosmetic raw materials who have a cosmetic raw materials importers' registry, after fulfilling the following requirements:

1- The invoice

2- A copy of the Egyptian Drug Authority's Cosmetic Importers Register in the case of importers of cosmetic raw materials.

3- Material Safety Data Sheet

4- A letter from the external manufacturer stating the source of the material, and in the case of materials that require specific health requirements, the necessary certificates are fulfilled upon release.

5- In the case of colors or premix and processed raw materials, the color composition statement from the external factory shall be submitted and matched with the approved composition statement.

6- In the case of raw materials for the manufacture of cosmetics for export, a pledge is provided by the factory that the invoice is for the production of a product for export only and is not traded in the local market.

B- Procedures followed for the release of cosmetics, raw materials and packaging materials:

The sealed customs medical release letter is issued for incoming shipments within one working day - unless the company requests final release according to the cases mentioned in this guide - after fulfilling the following requirements:

- Commercial invoice and matching it with the import approval.
- Shipping policy
- Packing list
- In the case of importing from the free zone, the country of origin certificate and certificates of analysis shall be presented.

- In the case of raw materials that require specific health requirements, the necessary certificates are fulfilled.
- All requirements contained in the Importation approval are adhered to.

- A customs medical release letter and an invoice approved by the Egyptian Drug Authority and stamped with the seal of the Republic's shall be delivered to the company to release the

shipment from customs, provided that the contents of the shipment are not released finally except through the inspectors of the Central Administration for Inspection of Pharmaceutical Institutions of the Egyptian Drug Authority.
- The sealed customs medical release letter is granted - without the requirement to obtain prior Importation approval - for imported shipments of samples for finished cosmetics or cosmetic materials.

- In case of final release:

Companies must bring imported batch records, along with the necessary certificates of analysis.

In the case of tourist establishments importing finished cosmetics:

- The release is done through one of the companies registered in the registry of Cosmetic Importers at Egyptian Pharmaceutical Authority, It is allowed through the establishment with a six-month deadline from the date of release to authorize one of the companies registered in the Authority to import.

General Rules in case the company requests final release of imported shipments

- This is initiated as a first phase through Cairo Airport Port and then activated three months after the start of the first phase at the following customs ports (Alexandria Port - Borg El Arab Airport - Dekheila Port - 6th of October Port - Damietta Port - Port Said Port - Port Said Port - Sharq El Tafreea Port - Adabiya Port - Port Tawfiq Port - Badr Dry Port - Sokhna Port - Marsa Alam Airport - Safaga Port - Hadraba Land Port - Bernice Airport - Hurghada Airport - Hurghada Port - Suez Port - Port Said Airport).

- Final release of imported finished cosmetic products is allowed for shipments from reference countries only.

- Final release is allowed for imported shipments containing cosmetics only, without other goods that are not under the jurisdiction of the Egyptian Drug Authority to ensure the speed of examination and completion of the final release process.

- Before final release at customs ports, representatives of Egyptian drug authority are competent to check and match the composition statement, approved layout, expiration dates, the name of the importing company and the notification number on the packages according to the rules of the Central Administration for Inspection of Pharmaceutical Institutions and the Central Administration of Drug Control.

- The final release of the first imported shipment or a shipment with a variant (Tell & Do) is allowed for cases that do not require analysis, according to the cases mentioned in the guidelines for listing cosmetics issued by the Central Administration of Pharmaceutical products , and in cases that require analysis, the release is reserved.

- In the case of imported finished products, companies are allowed to perform processing to complete the data within the customs Authority or are released sealed if the data is not met.