

Guidance of

Regulations and Requirements for Cosmetic Products Notification

Version No. 4

Version	Publication Date	Publisher	Notes	Updates
1		**Drug and Cosmetic Products Registration Department	Final	-
2	August 20, 2020	**Drug and Cosmetic Products Registration Department	Update	-
3	October 10, 2022	Drug and Cosmetic Products Registration Department	Update	 Add a link to the Lists of prohibited and restricted cosmetic ingredients colorants preservatives and UV filters on the website. Add a link to the application form for a cosmetic products warehouse license. Add the latest edition of the guide for the clearance of cosmetic products, including the conditions for clearing cosmetic products and the raw materials used in their manufacture. Add the latest edition of the product classification guide. Add Appendix (2) to understand the steps for renewing product notification.
4	May 28, 2024	Drug and Cosmetic Products Registration Department	Update	Update what's related to the previous electronic system (ECOSMA) due to the transition to the unified electronic system (Ghad).



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Definitions

The following words and phrases, as they appear in this Guideline, shall have the meanings set forth below:

Cosmetic Product:

Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

Unified Electronic System (GHAD):

An electronic platform that includes several services that facilitate users in submitting and tracking their requests through a single system and paying the required fees without referring to the Authority's branches.

Notification:

The process of listing a cosmetic product in the cosmetic products records after it has been approved by the Authority.

Notifier:

The individual, whether a natural or legal person, who lists the cosmetic product in their name with the Authority.

Manufacturer:

The local establishment where the cosmetic product is manufactured.

Warehouse:

A location licensed by the Authority for the storage, distribution, and trade of the cosmetic product.

Recall:

The action or measure taken by the Notifier, either voluntarily or upon request by the Authority, to retrieve a cosmetic product that is unsafe for consumers or in violation of this system, and to prevent its distribution.

Advertising:

Any statement—whether written, audio, visual, or otherwise—that aims to promote, sell, or market cosmetic products, directly or indirectly.

Introduction

Based on the Cosmetics Products Law issued by Royal Decree No. M/49 dated 18/06/1436 AH and its executive regulations issued by the Board of Directors of the Saudi Food and Drug Authority, which include the issuance of regulations and requirements for Cosmetic Products Notification to clarify and explain the provisions of the law and its executive regulations related to the Notification of cosmetic products in the Unified Electronic System (GHAD).

In accordance with Article 6 of the law, the cosmetic product should not be imported or traded in the Kingdom unless it is listed in the Unified Electronic System (GHAD) for Cosmetic Products Notification. The objective of Notification is to regulate the importation, trading, and marketing of cosmetic products in the Kingdom, and to provide a comprehensive database containing all cosmetic products available in the market, in addition to information about their importers, manufacturers, and local producers.

Notification of Cosmetic Products in the Kingdom

Cosmetic products notification in the Authority records is processed directly once the notification request is submitted. This assumes that the notifier has fulfilled responsibilities, provided accurate and correct information and ensured the product compliance with all requirements specified in the technical regulations and standard specifications approved by the Authority through commitments made during the notification process in the Unified Electronic System (GHAD).

The goal of this process is to establish a comprehensive database for locally manufactured and imported cosmetic products, and to record them in the Saudi Food and Drug Authority's registry, with the notifier ensuring the accuracy of the submitted information and the safety and efficacy of the products.

The Saudi Food and Drug Authority also implements precautionary measures to verify the safety of cosmetic products. This includes verifying product data post- marketing, sampling, and conducting tests. In case of violations, the Authority will take appropriate legal actions against the Notifier.

For more information on how to use the Unified Electronic System (GHAD), please refer to the "GHAD" System User Guide for Licensing Cosmetic Facilities and Product Notification by clicking or scanning the following barcode:

2. Requirements of cosmetic products notification:

2.1. Labeling

It is mandatory to attach one or more clear picture (artwork) of the product label, as well as a picture suitable for publication on the Saudi Food and Drug Authority's website. The product's picture must clearly display its identity and ingredients. This includes both the internal and external labels of the product, and any internal leaflet, which can be submitted in one of the following formats: JPEG, JPG, PDF, or PNG.

The product label must comply with the Cosmetics Products law and its executive regulations and the Safety Requirements of Cosmetics and Personal Care Products, SFDA.CO/GSO No. 1943. This document is available through the Saudi Food and Drug Authority's online standards store. For access, click or scan the following barcode:

The product label should not indicate its Notification with the Authority.

The label must contain a unique barcode, with the attention to provide a separate barcode for each size, color, or variation of the product.

Claim is a criteria that may disqualify a product from being classified as a cosmetic product. Claims encompass any statements made about the product on the internal or external packaging, any labels or leaflet, or in any form of advertising. These claims may be in the form of words, phrases, paragraphs, images, or suggestions. The Technical Regulation of cosmetic and personal care products claims - SFDA.CO/GSO No. 2528, is available through the Saudi Food and Drug Authority's online standards store. For access, click or scan the following barcode:

2.2. Ingredients:

Adding the product's ingredients in the electronic system is a key requirement for the notification process. This involves entering all active and inactive ingredients of the product with their correct concentrations, as well as the role of each ingredient. The notifier is fully responsible for the accuracy of the data entered and the safety of the ingredients. Whereas the Authority has published a list of substances that are prohibited and restricted for use in cosmetic products, as well as a list of allowed preservatives and colorants on its website, in accordance with Article 4 of the executive regulations of the Cosmetics Products Law. These lists can be accessed by clicking or scanning the following barcode:

The Authority also publishes circulars related to cosmetics on its website, which can be found under the "areas" tab, cosmetics, circulars. barcode

Currently, when submitting a product notification request, you can search for ingredients (by name) in the electronic system or attach them using the "Cosmetic Product Ingredients Template" in the Unified Electronic System (GHAD). Access this template by clicking or scanning the following barcode:

Adding an Ingredient to the Cosmetic Products Ingredients Database in the Unified Electronic System (GHAD):

In case you need adding a new ingredient that is unavailable in the Notification system database (GHAD), you must contact the Call Center at 19999. Provide the ingredient's name with its approved INCI nomenclature, role, and CAS number.

2.3. Required Documents

2.3.1. Documents Required to Create an Account in the Unified Electronic System (GHAD):

- A commercial registration record that includes one of the economic activities related to cosmetics according to ISIC4, with the appropriate domain and activity selected in the "Domains and Activities" field on the application. barcode
- A copy of the Ministry of Investment license (for foreign and mixed companies)
- A notarized authorization from the Chamber of Commerce for the person responsible for submitting and following up on requests in the Unified Electronic System (GHAD).

2.3.2. Required Documents for Cosmetic Products Notification:

- A notarized copy of the authorization letter from the manufacturer/ the entity where the products are imported from, or a contract manufacturing agreement between the local manufacturer and the producing establishment.
- A picture of the product label including all its information (Artwork).
- A picture of the product suitable for publication.
- A list of the product's ingredients with their concentrations and roles.

Requirements for the Marketing Authorization Letter:

- 1- Name, address and commercial registration number of the delegated establishment.
- 2- Name, address and commercial registration number of the authorizing establishment.
- 3- The agreement must be printed on the authorizing establishment's official letterhead, and stamped.
- 4- Name and signature of the responsible person from the authorizing establishment.
- 5- Notarization by the relevant authorities.

2.3.3. Required Documents for Cosmetic Products Clearance:

You can view the necessary documents for clearing cosmetic products through customs on the Authority's website by clicking or scanning the following barcode:

3. Responsibilities of the Notifier

The Notifier is responsible and obligated to:

- the safety of the cosmetic product.
- the cosmetic product does not cause harm to the user's health under normal usage conditions, in accordance to the usage and disposal instructions provided on the product's label.
- Inform the Authority immediately if any harm is caused by the cosmetic product, if there is a manufacturing error, or if a recall occurs in any country.
- Maintain a product information file for the cosmetic product and submit it to the Authority upon request. The specification for the product information file for cosmetics, SFDA.CO 6000:2020, can be obtained from the Saudi Food and Drug Authority's online specification store by clicking or scanning the following barcode:
- Report the Authority of any modifications made to the cosmetic product.
- Document the wholesale sale of the cosmetic product.
- Report any misuse of the cosmetic product to the Authority.
- Provide the Authority with test results proving that the cosmetic product complies with specifications upon request.
- comply with the technical regulations and circulars issued by the Authority.

- Monitor recalls or withdrawals of products from all sales points and distribution as necessary.
- Ensure the accuracy of the data provided to the Authority.
- Ensure the correct regulatory pathway for the product notification according to the cosmetic product definition and the product classification guide provided by the Saudi Food and Drug Authority. Access the guide by clicking or scanning the following barcode:

4. Procedure for Cosmetic Products Notification

4.1. Notifying a New Product or Selecting an Existing Product

- Log in to the Unified Electronic System (GHAD) and select the account for cosmetic products.
- From the product services, choose "Add New Product" and then request a cosmetic product notification (marketing notification).
- 3. Enter the core details of the product, such as brand name, product type, physical form, HS-code, and whether the product has variations.
- If selecting an already listed product, the system will automatically retrieve the product information, except for some details that need to be added.

4.2. Adding a New Manufacturer or Selecting an Existing Manufacturer

- 1. Select manufacturer location (My facilities\contractual) or oversea.
- Choose "Add Manufacturer" to add a new manufacturer or select an existing manufacturer.
- 3. You can modify or delete the selected manufacturer.
- 4. Attach the supporting documents (Authorization Letter Contract Manufacturing Agreement) by clicking on "Edit Details."

4.3. Entering Variant Information

- Choose "Add variant Product" to either add a new product or select an existing one.
- Enter the required information, such as the product name in both languages, manufacturing details, upload the product label (Artwork), and add a product picture for publication. Also, answer any product-related questions.
- 3. Select "Manage Ingredients" to enter the ingredients with their concentrations and roles as described in section 2.2.
- 4. Select "Manage Volume" to add product volumes and barcode numbers.
- 5. Acknowledge and confirm the details.

4.4. Notifying a Cosmetic Product Kit

- 1. Access the product services and select "Add New Product," then choose "Cosmetic Kit notification requests (marketing notification).
- 2. Complete the required information, including the kit name, kit barcode number, kit label (ARTWORK), kit picture, and packaging country.
- 3. Search for the product using search criteria, with the ability to delete or modify entries.
- 4. Acknowledge and confirm the details.

5. Notifier Privileges



5.1. Updating a Cosmetic Product:

The Unified Electronic System (GHAD) allows the Notifier to update a previously listed product, provided that the modification does not alter the product's characteristics or its basic form and composition. If the product's identity changes, the Notifier must re-notify the product and deactivate the previous notification.

The following table shows where updating or re-notifying the product may be necessary:

Modification	Product Update	New Product
Product Picture (Changing design or adding a logo)	V	
Brand Name		V
Product Name		V
Manufacturer		V
Ingredients (Adding a new ingredient - Changing the concentration of an ingredient - Removing an ingredient)		V
Product Volume	V	
Barcode Number	V	
Storage Conditions	V	
Precautions Instruction	V	
Purpose of Use		V

Updates to the product or re-notification that do not fall within the previous table will be evaluated according to the Authority's discretion.

5.2. Renewal of a Cosmetic Product Listing

According to Article 6 of the Executive Regulation of the Cosmetic Products Law, the Notifier must apply for the renewal of a listed product at least 90 days before the current listing expires.

5.3. Deactivating a Cosmetic Product Notification.

The Unified Electronic System (GHAD) allows the Notifier to deactivate a cosmetic product listing at any time as follows:

- 1. Log in to the account and select "Product Services."
- Choose "Cosmetic Products," then search for the product you need to deactivate.
- 3. Click on "Actions" and select "Deactivate."
- 4. Enter the reason for deactivation and click "Save."

5.4. Downloading the product Marketing Notification

This notification is provided solely to facilitate commercial transactions in the Kingdom and does not serve as proof that the product is a cosmetic, has been evaluated, studied, analyzed, or approved by the Authority.

- It is prohibited to be used for marketing, advertising, or promotional purposes in accordance with the Executive Regulation of the Cosmetic Products Law.
- Any modification or update to the product will invalidate the marketing notification.
- The notification becomes void if the product's notifying expires without renewal.
- The Notifier remains responsible for all obligations and responsibilities associated with the product notification.

