Guideline

Central Administration of Pharmaceutical Products
General Administration for Cosmetic Registeration

Claims Guide for Cosmetics Notification for the Year 2025

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1. Introduction

This guide concerns some rules and instructions for the technical evaluation of cosmetics.

2. Unacceptable claims

1-Slimming.

2-Skin Tightening, Body Contouring, Body Shaping, Redefine Body, Body Sculptor.

3- Prickly Heat.

4- Anti-callus.

5- Anti-inflammatory.

6- Anti- hyperhidrosis (Products for excessive sweating).

7- Anti Pimple*, Anti Acne.

8- Anti-Cellulite, Skin Sagging.

9- Prevent Stretch Marks.

- The European Union rules regarding unacceptable claims for cosmetics, shall be adhered.

3. Massage products

Massage products shall have an approval for registration according to the following procedures and conditions:

1. **The composition form shall not contain any substance (or its derivatives) that has a therapeutic effect, as follows: (This list is not exclusive)**
   - **a)** Willow bark extract
   - **b)** MSM (Methyl Sulfonyl methane)
   - **c)** Hyaluronic acid
   - **d)** Capsicum

e) Methyl salicylate

f) Dimethyl sulfone

g) Cetyl myristoleate

h) Arnica extract

i) Glucosamine

j) Chondroitin

k) Collagen

l) Elastin

m) Diosmin

n) Hesperidin

o) Cannabis

p) Winter Green/ Glutheria extract

q) Heparin

r) Gelatin

2. **"Fast or rapid action"** phrases shall not be written.
3. Any medical claim, suggestion or number of uses are not allowed to be written on the package.
4. It is not permitted to attach a leaflet with the product.

4. Scar Improvement Products

The products that have the purpose of **Emollient for Scar Improvement** as a primary purpose shall be registered as a cosmetic product in case of containing > 90% **Silicone** or containing **Onion Extract ≥ 10%,** provided that the company shall be committed to that the product name shall not contain **"Scar"** or **"Anti-scar"** (**in case of violation of one of these conditions, the product cannot be notified as a cosmetic product**).

5. Ingredients Prohibited to be Used in Cosmetics

- The therapeutic substances such as: **Troxerutin, Escin, Permethrin, Ibuprofen, Naproxen** and similar substances, shall be prohibited to be registered.
- **Silver / Nano Silver** substance is not permitted to be used in the products registered for the purpose of Skin Moisturizing / Soothing.
- **Methanol** is not permitted to be used in cosmetics.
- **Miconazole Nitrate** is not permitted to be used in cosmetics except for Hair-Care Products.

6. General Requirements

1. Any amendment to the composition form on imported products during the notification process, shall be prohibited.
2. Cosmetics (except hair care products) shall not be diluted by the consumer and it shall be used as is.
3. The two substances **Beta-sitosterol and Sesame extract**, shall not be combined in one skin care product.
4. According to the decision of the Technical Committee of cosmetics Registration, the reference countries for the registration of cosmetic products are as follows:

   European Union countries, the United Kingdom, the United States of America, Canada, Australia, Japan, and Switzerland.

7. General Rules for Using the Electronic Platform

❖ Any variation shall be carried out to the product before applying for re-notification, as it is not permitted to make any change during the re-notification. If any change is made during the re-notification, the request will be rejected and the product shall be submitted to the Variations department. A re-notification request shall be resubmitted after *paying new fees.*

- The **short name** shall be a part of the **long name**. The short name shall be written in the platform in the part designated for the short name.
- In case of products' ownership transfer to another company, none of the companies is allowed to perform **line extension** unless the ownership transfer of the **whole brand** is completed.
- In the case of **kit** notification, each product in the kit shall be notified separately, and then a request shall be submitted to notify the **kit** on the company's request.
- The type of product and the type of registration shall be checked. If the company commits an error during submission in the **Registration Type** (imported reference, imported non-reference, locally manufactured or toll manufactured), in the **product type** (ordinary product, dye, or kit), or in the **request type** (fast or normal), the request shall be rejected and resubmitted after *paying new fees*.
- It is not permitted to submit an appeal to amend the composition form for the **imported products**. The appeal shall be rejected in case of submission.
- It must be ensured that the factory license contains a **production line** before applying for notification. In case there is no production line, the product shall be rejected and the company shall be obligated to change the manufacturing site.
- In case of rejecting the request, the company has the right to submit two appeals for each notification request, after which the request shall be obsolete and a new request shall be submitted after *paying new fees*.
- It is not permitted to carry out more than one procedure on the product at the same time.
- In the case of the flagged products "**approve with comment**"(Flag), no procedure will be performed on it except after fulfilling the requirements (unflag).

- **The product's re-notification** request shall be submitted **3 months** before the expiration of the notification validity so that the company can submit 2 appeals for the product when necessary, as it is not permitted to carry out any procedure on the product in case of expiring the validity of the re-notification.
- The specified **timeframe for any appeal** submitted by the company to the Authority during the notification is **30 days**. Upon expiring this period, the request shall be obsolete, the procedures of its completion shall be stopped and a new request shall be submitted for the product as a new product.
- In the event of arbitrating the circulation reference, a **free sale certificate** legalized by the **Egyptian embassy** shall be mandatory.
- In the event of arbitrating the manufacturing reference, the **manufacturing list** legalized by the **Chamber of Commerce** shall be mandated.
- In the case of registering **hair dye products or hair colorant kit**, the group name shall be added alongside the product name in long & short name places.
- In the case of **rejection of a variation request**, the period for fulfilling the comments shall be 15 days in the case of first rejection and an additional 15 days are granted for the second rejection. In the case of a third rejection, the company shall be prohibited to submit an appeal and a new request shall be submitted after *paying new fees*.
- In case of notifying a product with **multiple colors, fragrances, flavors, or all of them**, the service fee for each category shall be added to the notification fees that shown in the **Estimated Value** according to the list of the prescribed services fees.
- The Notification request shall be reviewed and the comments shall be sent to the company, without fees for once regarding the notification requirements in accordance with the regulatory guide for cosmetics notification (checklist). The company shall fulfill the requirements within 15 days then the request shall be technically reviewed, afterwards the final decision shall be issued, either approving and issuing the notification number or rejection. In case of

rejection, the company has the right to submit an appeal twice for each request.

- The **services fees** must be paid and the original payment receipt must be submitted to the relevant administrator before submitting the notification request.
- The company shall submit the **original and legalized documents** to the pharmacists working in the administration to review the original documents before uploading them to the platform.

8. Important Websites

1- Sun Screen Products

https://eur-lex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32006H0647

2- Guideline of Pharmaceutical Formulations Reference of Cosmetics "Frame Formulation"

https://pdfcoffee.com/cosmetic-frame-formulations-pdf-free.html

* It is evaluated on a case-by-case basis according to the reference of the product.

Table of Changes

Versions	Issue Date	Subjects of Change
Version: 4	December 24th, 2023	……
Version: 5	April 14th, 2025	• Updating the list of substances not allowed to be used in **Massage Products** by adding Heparin and Gelatin. • Revising Silicone Concentration to be more than 90% in **Scar Improvement Products.** • Adding Miconazole Nitrate to the list of **Prohibited Ingredients in Cosmetics**, except for Hair-Care Products. • Updating the **General Requirements** to include Reference Countries for The Registration of Cosmetic Products.