

Investor Guide to Obtain a License for Cosmetic Manufacturer

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Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

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1st chapter

Introduction:

The first article of the executive regulation of the cosmetic products law issued by Royal Decree No. M/ 49 dated 18/6/1436 AH established the cosmetic products manufacturer within the establishments that belong to the definition of (manufacturer) which is a local establishment in which the cosmetic product is manufactured. The function of the cosmetic manufacturer includes the export of listed cosmetic products and the import of raw materials used in the manufacturing of cosmetic products.

Investor definition:

An individual or a group of people (company) that desire to invest and establish a manufacturer in an industrial or economic city in the field of manufacturing cosmetic products. Whether it is Saudi, Gulf, or foreign.

2nd Chapter

Field and Applicability:

The guideline valid applies to investors who desire to obtain a license for cosmetic product manufacturer for industrial activities Activities (ISIC) under SFDA, after meeting all the documentations and special requirements of the following government agencies:

- Saudi Food and Drug Authority.
- Ministry of Commerce and Investment.
- Ministry of Industry and Mineral Recourses.
- Saudi Authority for Industrial Cities and Technology Zones.
- Economic Cities and Special Zones Authority.
- Royal Commission for Jubail and Yanbu.
- General Investment Authority.

ISIC activities that apply for this guideline
can be found on the SFDA website www.sfda.gov.sa

3rd Chapter

Mechanism for Obtaining a new License for Cosmetic Products Manufacturer:

1. Registration in the electronic system of SFDA (ELS) for the purpose of obtaining the license to practice the activity.
2. Issuing the financial compensation for the license if Executive Department of Inspection at the SFDA approved.
3. A visit to the manufacturer by SFDA inspectors.
4. Obtaining the license by SFDA and the manufacturer cannot practice the activity until obtaining a GMP certificate.
5. The establishment applies to issue a GMP certificate.
6. Conduct a field inspection.
7. Obtaining GMP certificate and activity practice certificate.
8. Listing cosmetic products in the electronic system.

• Estimated Time for Issuing a License for Cosmetic Products Manufacturer



A direct license will be issued for low-risk activities after examining the establishment request and issue the license shortly after paying the financial compensation. The site inspection will take place after issuing the license, the establishment can engage in activities afterward.



4th Chapter

Requirements and Documentations for Issuing a License

✓ **Requirement:**

1. The technical manger shall have the following :
 - Saudi and Free
 - A Bachelor's degree in Pharmacy, Chemistry, Industrial Engineering, Chemical Engineering, Microbiology, Biochemistry, Biomedical Engineering. Or any other specialty or qualification accepted by SFDA.
 - The appropriate expertise in the field of manufacturing accepted by SFDA.
 - Registered with the Saudi Commission for Health Specialties (Pharmacists).
2. The manufacturer shall set a responsible for the quality.
 1. Pay the financial compensation for the license which sent via email to the applicant. Including the bill number for the payment of the financial compensation for the license and the invoice amount (5000 Riyals) is paid through SADAD system. Informing that SFDA code on SADAD is (109)

<https://www.sadad.com/ar/Pages/home.html>

Apply the GMP requirements for cosmetic products manufacturer.

✓ **Documents:**

1. **A copy for the following documents for the manufacturer Technical Manger:**
 - A copy of the national ID of the manufacturer Technical manger.
 - A verficated copy of the Technical manger certificate.
 - A copy of notarized experience certificates.
 - A copy of the professional registration card (for pharmacists).
 - Commitment by the manufacturer Technical Director, certified by the Chamber of Commerce.
2. **Applying GMP requirements for cosmetic products manufacturer. Besides, the manufacturer implementation of these requirements is confirmed by the Inspection**

Department during the manufacturer visit. Inspection can be found on the following website:

https://www.sfda.gov.sa/ar/cosmetic/Technical%20regulations%20and%20manuals/Good_Manufacturing_Practice_cGMP_for_Cosmetic_Products.pdf

5th Chapter

- **Application Mechanism for Issuing a License to practice an activity through the SFDA electronic system.**
 1. After the manufacturer is technically ready and after obtaining the regulatory licenses from government agencies, enter the electronic system through the following link:
<https://ecosma.sfda.gov.sa/home.aspx>
 2. Choose the active initial approval from the (My Establishments) list.
 3. Choose (Create License Application).
 4. Pay the financial compensation for the license which sent via email to the applicant. Including the bill number for the payment of the financial compensation for the license and the invoice amount (5000 Riyals) is paid through SADAD system. Informing that SFDA code on SADAD is (109).
 5. Achieve the conditions and attach the necessary documents in Chapter Four.

6th Chapter

Guide to Renewal a License

1. The establishment shall apply for renewal of the license 6 months before the expiration date of the valid license.
2. The renewal request is applied by entering the electronic system via the following link: <https://ecosma.sfda.gov.sa/home.aspx> and following the steps below:
 - Select (my establishment).
 - Click on the license to be renewed.
 - After entering the license details, click on the (license renewal) icon.
 - Pay the financial compensation for the license which sent via email to the applicant. Including the bill number for the payment of the financial compensation for the license and the invoice amount (5000 Riyals) is paid through SADAD system. Informing that SFDA code on SADAD is (109).
 - Update the documents attached to the application to establish an invalid license as the commercial record and the final industrial license.
3. Visit the establishment by SFDA inspectors to ensure that the establishment applies the technical requirements, the Technical Regulations and specifications.
4. Obtaining a license to practice the activity by SFDA.

7th chapter

License Duration and Financial Compensation

License Duration:

5 years

Financial Compensation:

The Authority receives the financial compensation (5000 Riyals) for the service that will receive and inspect cosmetics product manufacturer.

8th chapter

Violations and Penalties:

Article Thirty-Four of the Executive Regulations for the Cosmetic Products Law issued by Royal Decree, No. M / 49 dated 18/06 /1436 AH, stated that “Whoever violates any of the provisions of this Law or its regulations shall be punished with one or more of the following penalties:

1. A fine not exceeding up to five million Riyals.
2. Closing the manufacturer or warehouse until the violation is corrected.
3. Canceling the license of the manufacturer or warehouse.
4. Imprisonment for a period not exceeding five years.

The penalty may be doubled when the violation is repeated.

*The Executive Regulations issued by Royal Decree No. M / 49 dated 06/18/1436 AH, cosmetic products manufacturer, can be found on the following link:

التنفيذية 20% ولائحته 20% التجميل 20% منتجات 0.pdf
نظام/https://www.sfda.gov.sa/ar/cosmetic/Technical%20regulations%20and%20manuals

9th Chapter

FAQ

Q / Why is registration in licenses for the electronic cosmetic establishments important?

Registration in the electronic establishment licensing system for cosmetic establishments is an important matter for several reasons:

1. Issuing a license to practice activity for a cosmetic establishment.
2. Building a database for all cosmetic establishments and their products in the Kingdom of Saudi Arabia.
3. Improving communication means between SFDA and cosmetic establishments.
4. Enabling cosmetic establishments to update their data continuously, besides facilitating the process of communicating with the SFDA as a supervisory Agency over these establishments.
5. 5. Obtaining a certificate of listing cosmetic products

Q/ Who does register in the electronic establishment licensing system?

A person responsible and authorized by the establishment and has sufficient technical information to complete the technical and administrative registration steps.

Q / When is the application for a license to practice the activity with the Authority to be submitted?

The license to practice the activity is submitted via the electronic system as soon as the industrial license is extracted, and the factory is 100% prepared.

Q / When does the manufacturer have the right to practice the activity?

The establishment has the right to practice the activity if a license by SFDA obtained and apply the code of GMP principal for cosmetic products manufacturer. Then, list cosmetic products in the manufacturer. Practice the activity before that is forbidden, and the penalties prescribed according to the Executive Regulations of the cosmetic products system are applied against the violator.

Q / How long is the license to practice activity issued by SFDA for practicing cosmetic activity?

5 years.

Q / When shall the investor make a request to renew the license for practicing the activity?

The establishment shall request the renewal of the license 6 months before the expiration date of the valid license.

Q / If the investor has more than one cosmetic establishment (manufacturer), is it registered as one in SFDA registration and licensing system?

The investor shall register each cosmetic establishment separately (two independent applications).

Q / Is it necessary to update the registered file establishment?

Yes, the data shall be updated when needed as the commercial record, industrial license, or contact information through the system.

Q / What are the contact addresses that I can call in case I need help?

If they need help, applicants can call the standard number 19999 or send an email to Est-license.drug@sfd.gov.sa .

Contact Information

Contact Information	
Standard number	19999
Email	Est-license.drug@sfda.gov.sa