Implementing Regulation of Cosmetic Products Law

Issued by Royal Decree
M/49 on 18/6/1436 AH.

This document is a draft, therefore, it is subjected to alteration and modification.

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Issued a decision by the Board Directors of Saudi Food and Drug Authority No. (11-13-1436 AH.) at its Thirteen meeting on 16/1/1437 AH. by approving its Implementing Regulation of the Cosmetic Products Law as the form attached.

Article One

The following words and expressions- as they appear in this Guideline- meaning as stated, unless the context otherwise requires:

1. **Law:** The Cosmetic Products Law
2. **Regulation:** Implementing Regulation of the Law
3. **Authority:** Saudi Food and Drug Authority
4. **Board:** The Board Directors of the Authority
5. **Chief Executive:** The Chief Executive of the Authority
6. **Cosmetic Product:** Any cosmetic product that contains one or more substances prepared for external usage to the human body parts including skin, hair, nails and lips or on the external parts of genitals , teeth or fused membranes of the oral cavity for cleaning, perfuming, protection, to keep it in a good shape, change its appearance, improve it or change the body odour.
7. **Listing:** Documenting cosmetic products in the cosmetic products record after it is approved by the Authority.
8. **Lister:** A person of natural or moral character who documenting cosmetic products by his name in the Authority
9. **Manufacturer:** The local establishment where the cosmetic product is manufactured.
10. **Good Manufacturing** Practice (GMP): A part of the quality is that cosmetic product is manufactured properly with quality and according to the standards that suitable to the purpose of its use.
11. **Warehouse:** A place that is licensed by the Authority for storing, distributing and trading cosmetic product.
12. **Laboratory:** The laboratory that is used by the Authority to analyze and examine cosmetic products.

13. **Trading:** The stages that cosmetic product goes through until it reaches the consumer, including import, export, manufacture, preparation, installation, processing, packaging, processing, storage, transport, possession, marketing, distribution, supply for sale, sale and distribution free of charge.
14. **Withdrawal:** Procedures or measures by the Authority to withdraw the cosmetic product from the markets.
15. **Recalls:** Procedures or measures taken by the lister voluntarily or upon request by the Authority to restore the acquisition of the unsafe cosmetic product for the consumer or contrary to this Law and forbidding its circulation.
16. **Adulterated Product:** A cosmetic product whose content, identity or source has deliberately changed whether it contains the same components, faulty ingredients, contaminated substances or without components.
17. **Defective Product**: A cosmetic product which its physical, chemical properties or microbial content changed.
18. **Advertisement:** Any statement, whether it is written, heard, visible or any other means that aims to promote, sell or market cosmetic products directly or indirectly.
19. **Manufacturing company:** The company which manufacture, marketing, distribute the product or contracting with other establishment to manufacture it.
20. **Establishment:** Any place that conduct one or more of phases of the manufacturing product.

Article Two

The provisions of this Law shall apply to cosmetic products, its factories, warehouses and to their trading and using.

Article Three

The Authority shall issue the Technical Regulations and the standard specifications for cosmetic products, its factories and personnel requirements

Circular No. 3-1-L

If the Saudi Technical Regulations or the Saudi standard specifications are unavailable, the Authority shall apply any legislation, regulations or specifications relating to cosmetic products, its factories and personnel requirements until these regulations issued by technical regulations or standard specifications as the followings sequence:

1. Technical Regulations, legislation or Gulf specifications.
2. Technical Regulations, legislation, international specifications or documents issued by relevant international organizations, international agreements or relevant joint committees.
3. Legislation or specifications issued by competent regional bodies.
4. Technical Regulations, standard specifications or requirements approved in any other country.

Article Four

The Authority shall determine illegal and restricted use substances in cosmetic products and publish them on its website.

Circular No. 4-1-L

1. The Authority shall publish a list of illegal substances in cosmetic products
2. The Authority shall publish a list of restricted use substances in cosmetic products.
3. The Authority shall update the lists periodically or whenever the need arises and publish them on its website.

Article Five

The Authority shall check the conformity of cosmetic products with the Technical Regulation, standard specifications and the conditions approved and may use specialized companies to verify it.

Circular No. 5-1-L

The Authority may use specialized companies to verify the conformity of cosmetic products with Technical Regulation and standard specifications and conditions approved by it as a third party with the continued responsibility of the Authority for those tasks.

Circular No. 5-2-L

The Authority shall create the conditions to be applied in the companies that may be engaged without prejudice to the conditions of other government bodies.

Circular No. 5-3-L

Tasks of the Verifying Company:

A. Ensure the conformity of cosmetic product to the Technical Regulations, standard specifications and conditions approved by the Authority.
B. Examination of the technical documents submitted for listing.
C. Any tasks consistent with its capabilities that the Authority considers to be assigned to it.

Circular No. 5-4-L

The Authority shall monitor the performance of the tasks assigned to the verifying companies.

Article Six

The cosmetic product will not be imported or traded in Saudi Arabia until it is listed by the Authority and obtained a listing certificate in accordance with the regulations and conditions established by the Regulation.

Circular No. 6-1-L

The Authority shall issue the listing certificate after ensuring that listing application has met its requirements and the certificate shall be valid for 5 years from the date of its issuance.

Circular No. 6-2-L

The listing certificate shall be renewable for a period of one year or similar period (5 years) and the applicant shall apply 90 days before the certificate is expired. The period of a renewed certificate shall be valid from the date of expiration of the previous certificate.

Circular No. 6-3-L

Listing will considered invalid when the certificate expires without renewal. In addition, the product should be re-listed if the product is intended to be re-imported or re-traded.

Circular No. 6-4-L

The expiration of the certificate shall not prevent trading the product at markets and warehouses until the expiration of the product.

Circular No. 6-5-L

The listed product shall not be exempt from the listing obligations and responsibilities after the cancellation of listing the product.

Article Seven

The manufacturer or the manufacturing company of the cosmetic product or their authorizers shall apply for listing in accordance with the Regulation's procedures and conditions.

Circular No. 7-1-L

The product shall be listed in accordance with the following procedures and conditions:

a) Submit the listing application attached with the listing required documents which determined by the Authority.
b) The product to be listed shall be corresponds to the Technical Regulations and conditions approved by the Authority.

Circular No. 7-2-L

The manufacturer or the manufacturing company shall authorize whoever is required to represent them in the Authority by a certified letter of authorization from a trusted body according to the procedures approved by the authority

Circular No. 7-3-L

If needed, the Authority shall verify the manufacturing practices of the external manufacturer of the listed product.

Article Eight

The Authority shall decide on the listing application within 15 days of the completion of its requirements and issue a listing certificate. If the application rejected or no decision has been made regarding it, the Authority shall indicate the reasons.

Article Nine

The Lister shall be responsible to the followings:

1. Safety of the Cosmetic Product

2. The product shall not cause any harm to the consumer under the normal ccircumstances of use in accordance with the guidance for use and disposal shown in the product label data

Circular No. 9-1-L

The cosmetic product is unsafe in the following cases:

1. If it contains banned or restricted substance in contravention of the condition for its restriction.
2. If the necessary warnings are not mentioned on the product's package.
3. If the full components are not mentioned in the package
4. If transferring or storageing product was unsuitable
5. Any other case considered by the Authority

Article Ten

The Lister shall be committed to the followings:

1. Reporting the Authority if there is damage caused by the cosmetic product, manufacturing defect or recalling reports it in any country.
2. Maintain the cosmetic product information file and submit it to the Authority upon request.
3. Report any adjustments to the cosmetic product.
4. The document of selling cosmetic product as wholesale.
5. Report any misuse of the cosmetic product to the Authority.

Circular No. 10-1-L

The lister commitment shall report the cases provided in Article Ten, paragraphs (1), (2) and (3) of the Law as soon as it is aware of them.

Article Eleven

Each cosmetic product shall contain data or label as specified in the Regulation.

Circular No. 11-1-L

Each cosmetic product shall contain the followings:

- The product name, the product trade name, the factory, the manufacturer company and their addresses.
- Product's validity.
- Any special warnings or alerts to be observed when using the product and any special caution information on in for professional use.
- The function of the product and how it used unless it is not clear from the method of submission.
- Product components list.
- Production date and batch number or one of them.
- Size or net product weight.
- Country of origin.
- Product storage instructions.
- Any other data determined by the Authority.

Circular No. 11-2-L

The Authority shall specify the data to be written in Arabic Language on the product.

Article Twelve

The Authority shall publish on its website a list of the cosmetic products that listed in the cosmetic products record.

Circular No. 12-1-L

The Authority shall publish in its website a list of the cosmetic products that listed in the cosmetic products record. In addition, the authority will periodically reviews the list by adding new products and updating the status of listed products.

Article Thirteen

A technical manufacturer license shall be obtained by submitting the license application with the requirements and conditions established by the Regulation.

Circular No. 13-1-L

In order to obtain a technical manufacturer license, it is required to fill a license application with the required documents in accordance with the Guidelines of Licensing Cosmetic Products Factories

Article Fourteen

The technical manufacturer license shall be obtained in accordance with the following procedures:

1. An application shall be submitted to the Authority in accordance with the requirements and conditions established by the Regulation, and the Authority shall decide on the application within a period not exceeding 30 days of completion of licensing requirements. If the application is approved, the Authority shall issue a document stating initial approval and if the request is rejected, reasons shall be explained.
2. The Authority shall issue the license for the manufacturer after the applicant has obtained the necessary approvals by the competent bodies and ensure that the manufacturer applies the good manufacturing practice (GMP) for cosmetics products, which is approved by the Authority.

Circular No. 14-1-L

The application shall be submitted in accordance to the form of the license application along with the necessary documentation.

Circular No. 14-2-L

The Authority shall examine the application after completing all the requirements and conditions and issue its decision for a period not exceeding 30 days.

Circular No. 14-3-L

If the Authority approves the application, the Authority shall issue a document of initial approval for the applicant to get the necessary approvals from other bodies.

Circular No. 14-4-L

The initial approval document is valid for 2 years from the date of its issuance. The applicant shall submit the requirements of other bodies.

Circular No. 14-5-L

If the application is rejected, the authority shall inform the applicant and explain the reasons for the refusal.

Circular No. 14-6-L

Once the license applicant has completed the necessary approvals from the other sectors, the Authority shall ensure the commitment of the applicant to the good manufacturer manufacturing practice (GMP) of the manufacturer in terms of buildings and equipment. The technical manufacturer license shall be issued, and the good manufacturing practice (GMP) to be verified in the production operations after the manufacturer obtained the license and is active.

Article Fifteen

The manufacturer must have a full - time Saudi technical director as specified in the regulation.

Circular No. 15-1-L

The manufacturer shall appoint a technical director before the beginning of production process with the following conditions:

a) Holding at least a bachelor degree in one of the majors (pharmacist, chemist, industrial engineering, chemical engineering, microbiology, biochemistry, biomedical engineering) or any other speciality or qualification accepted by the Authority.
b) Having appropriate manufacturing expertise accepted by the Authority

Article Sixteen

The manufacturer shall be under an obligation to report to the Authority any change in it, its products or the information provided, and the manufacturer may not be operated without its authorization.

Circular No. 16-1-L

The manufacturer shall inform the Authority about any changes in the following:

1. The technical director of the manufacturer.
2. Manufacturer address.
3. Production lines.
4. The factory name.
5. Ownership of the factory.
6. Data submitted for the licence application.
7. Factory products.

Article Seventeen

The manufacturing company may not start marketing the cosmetic product before it is approved for listing.

Article Eighteen

The manufacturer shall be obliged to apply the good manufacturing practice (GMP), and the Authority shall verify that whenever necessary in accordance with the procedures created by the regulation.

Circular No. 18-1-L

In order to ensure that the manufacturer applies the good manufacturing practice (GMP), if needed, the authority can conduct and request one or more of the following procedures:

1. Inspection visits to the manufacturing facility (factory).
2. Request technical reports on the application of the manufacturer to good manufacturing practice (GMP).
3. Request information on the technical director of the factory and its employees.
4. Access to records and private information on compliance with the good manufacturing practice (GMP).

Article Nineteen

A license for the warehouse shall be obtained by the Authority in accordance with the requirements and conditions established by the Regulation.

Circular No. 19-1-L

In order to obtain a license, applicant must provide the followings:

1. Filing the license application form attached with the documents by the Authority.
2. Meeting the technical conditions that required by the Authority.

Article Twenty

The license period for the manufacturer or warehouse is 5 years and it is renewable.

Circular No. 20-1-L

The license shall be renewable for a certain period and the applicant shall apply at least 90 days before the expiration of the license, keeping in mind that the application must be subjected to the conditions of articles Thirteen, Fourteen and Nineteen of the Law. The period of the license shall be valid after renewal from the date of expiration of the previous license.

Article Twenty-One

Cosmetic products may not be advertised or promoted prior to their listing, and advertising shall be subject to the controls and conditions established by the Regulation.

Circular No. 21-1-L

Advertising any cosmetic product - by whatever means - shall be subject to the following controls and conditions:

1. Advertisement shall not contain anything contrary to Islamic Law and public morals.
2. The product to be advertised shall be listed in the Authority and compatible to the Technical Regulations and circular issued or any regulation acknowledged in this regard by the Authority.
3. The advertisement that directed to children shall not contain aggressive, violent or dangerous scenes.
4. The advertisement's information shall be reliable, accurate, honest and can be proved.
5. The advertisement shall not carry an allegation that is contrary to the technical regulations or circular issued by the Authority.
6. The advertisement shall not carry written information, images, scenes or any other form that would mislead the consumer, including claim that it contains components that are not in its composition.

7. The name or logo of the Authority shall not be used directly or indirectly in the content of the advertisement or in any name or logo of another internal or external regulatory authority.
8. The product's image and data, which are used in the advertisement, shall be identical to the image and actual data of the product listed by the Authority.
9. Shall not offend any other product directly or indirectly.
10. Arabic language shall be the language used in the advertisement. Other languages could be used on condition of conformity with Arabic content.

Circular No. 21-2-L

It is not allowed to promote the cosmetic product without the authority permission, if the authority decides to cancel the listing, banned, withdraw, claim or suspend trading of cosmetic product.

Article Twenty-Two

Without prejudicing the Ministry of Health tasks which are provided in the Private Health Institutions Law and the Pharmaceutical Products and Establishments Law, the Authority shall monitor and inspect factories, warehouses, shops, dispatches and shipments of cosmetic products.

Article Twenty-Three

If the Authority considers that the cosmetic product affects public health, it shall rise the caution about it by using appropriate methods.

Article Twenty-Four

If the Authority proves that the cosmetic product is unsafe, unhealthy or not listed, it shall take the following procedures:

1. Cancel its listing.
2. Ban its trading.
3. Withdraw or recall it.
4. Suspend its trading for a period which determined by the Authority.

Circular No. 24-1-L

The decision of the Authority includes the withdrawal or recall the cosmetic product, the procedures provided in Article Twenty-six shall be taken

Article Twenty-Five

If the Authority suspects that the cosmetic product may be contrary to the provisions of this Law or its regulation, it may suspend its trading for a period to be determined by the Authority.

Circular No. 25-1-L

If the authority has reason to suspect a violation of the Law provisions or its Regulation, the Authority shall suspend the trading of the product and take one or more of the following procedures:

1. Determine the suspected products and identify the location of their trading.
2. Withdraw samples of it for analysis when needed.
3. Request any information or documents about the product.

Circular No. 25-2-L

If the Authority proves that the cosmetic product is contrary to the Law provisions or the Regulation, it shall be dealt with in accordance with the provisions of article Thirty- two of the Law.

Circular No. 25-3-L

If the violation of Law provisions or its Regulation is not proved, the suspension of product's listing shall be lifted.

Article Twenty-Six

If the Authority decides to withdraw or recall the cosmetic product, the lister is obligate to do so and if the lister did not comply within the period specified by the Authority, lister shall withdraw and destroy it, according to the status, at the lister expense in accordance with the procedures established by the Regulation.

Circular No. 26-1-L

1. The Authority shall issue a decision to withdraw or recall the cosmetic product explaining the reasons for such decision.
2. The lister shall be required to recall the cosmetic product within the period specified by Authority in its decision.

3. If the lister did not comply with the recall period specified by the Authority, Authority shall withdraw the product at the expense of the lister.
4. The Authority shall take any of the following procedures after the product withdrawal or recall:
A. Lister shall destroy the product at his/her expense.
B. Allowing the product to be traded after resolving the issue by the lister within the determined period.
C. Allowing re-exporting the imported product to its source (the country where the product is imported from) in cases where the Authority considers appropriate.

Circular No. 26-2-L

The lister is obligated to submit a statement containing the components of withdrawn or recalled products.

Article Twenty-Seven

A cosmetic product will not be traded when it is been cancelled, banned, withdrawn, recalled or suspended by the Authority.

Circular No. 27-1-L

The cosmetic product will not be allowed for re-trading without Authority's permission, if it decides to cancel the listing of a cosmetic product, banned, withdrawn, recall or suspended its trading.

Article Twenty-Eight

Inspectors may take samples of the cosmetic products for examination and analysis in accordance with controls and conditions established by the Regulation.

Circular No. 28-1-L

In order to verify the conformity of cosmetic products with the provisions of this Law and its Regulation, the inspectors of the Authority may take samples of cosmetic products for examination and analysis purposes at the Authority's laboratories or at accredited laboratories, which are certified by the Authority. This shall be done in accordance with the following procedures:

1. Proofing the withdraw procedure with a record signed by the inspector and the establishment responsible personal or, any person representing him/her. Refusing to sign or the personal absence will be documented in the report.
2. The samples shall be withdrawn according to the procedures approved by the Authority and the quantity of these samples shall be within the limits of the analysis needs and exclude them from any charge.
3. The sample shall be referred for examination and analysis in the laboratories of the Authority or at accredited laboratories that are approved by Authority, whether within or outside the Saudi Arabia, if necessary.

Article Twenty-Nine

Staff members, designated by decision of the Chief Executive Officer, control violations of the provisions of this Law and Regulation and they have the access and authority to perform criminal seizure.

Circular No. 29-1-L

Staff members designated by the Chief Executive Officer decision shall, jointly or individually, monitor, inspect and control violations of provisions of this Law and Regulation.

Circular No .29-2-L

The inspector, after shown his/her card that shows his/her authority, has access to the cosmetic products factories, its warehouses, places of sale and trading for inspection, access to the documents and records and keep a copy, if necessary, and may withdraw samples of products for analysis. The factories, warehouses, places of sale and trading of cosmetic products shall enable the inspector to perform his/her tasks without any obstructions.

Circular No. 29-3-L

The inspector shall reserve the unsafe product and other products that violate the provisions of this Law and the Regulation, in accordance with the following conditions:

1. A record of a seizure showing the type of violation, the type and quantity of the product, signed by the inspector and the responsible for the cosmetic products manufacturer, its warehouses and places of sale, or by a person acting on his/her behalf. Refusing to sign or the personal absence will be documented in the report. A copy of the report shall hand over to the person in charge.
2. The responsible or a person acting on his/her behalf will be obligated to not to dispose of the reserved product during the reservation period.
3. Taking samples from the product for analysis if needed.

Circular No. 29-4-L

The Inspector may recommend taking one or more procedures of the following:

1. Close the manufacturer or the warehouse.
2. Destroy the violated products at the expense of the manufacturer, warehouse or places of sale.
3. Grant the violator time to resolve the infraction if possible.
4. Permission to re-export the violated imported products.
5. Any other recommendation seen by the Inspector.

Circular No. 29-5-L

If the violation proved the regulatory procedures would be taken against the violator, if not, the product will be removed from the restriction list.

Article Thirty

Officials and employees in places to be inspected shall enable inspectors to perform their work and not obstruct them and provide all required facilities, information, documents and required samples.

Article Thirty-One

Any person who commits or attempts to commit one or more of the following acts shall be considered to be contrary to the provisions of this Law as follows:

1. fraud or cheating in the cosmetic product.
2. Trading a discarded, defective or expired cosmetic product or in contravention of its listed data.
3. Using incorrect information to promote the cosmetic product by advertising or by adding such information to the product.

4. Entering packages or wrappers a particular cosmetic product to Saudi Arabia for the purpose of cheating
5. Making, printing, acquiring, selling or displaying packaging or packages for a particular cosmetic product for the purpose of cheating
6. Providing the Authority with incorrect information relating to the cosmetic product.
7. Importing, exporting, re-exporting, manufacturing, marketing, selling, storing or offering the cosmetic product for himself/herself or for others in contravention of the provisions of this Law or its Regulation.
8. If the inspectors of the Authority were prevented from performing their inspection and seizure functions, either by preventing them from entering the manufacturer, warehouse or cosmetic product store, or by preventing them from obtaining samples of the product.

Article Thirty-Two

When controlling any violation of the provisions of this Law or its Regulation, the controlled cosmetic products are dealt with as follows:

1. Seizing them and their relevant documents if necessary.
2. Take samples for analysis if necessary.
3. Destructing defective products.
4. Destruction of counterfeited products.
5. Destruction of unlisted products

Article Thirty-Three

The process of destruction shall be carried out by one or more committees formed for this purpose. The regulation shall specify how the commission shall be formed; the process of its operation and the violator shall bear the expenses of the destruction operation.

The destruction committees shall be formed by a decision of the chief executive officer or his delegate and destruction operation shall be carried out in accordance with the followings:

1. Destruction shall be in accordance with the procedures approved by the Authority.
2. A technical committee that established by the Authority for this purpose on a case-by-case basis, taking into account the followed Regulations of such proceedings shall supervise the process of destruction operation.
3. The commission shall prepare a record of the actions taken to complete the destruction operation, indicating the type, quantity and cause of the destruction.
4. The violator shall bear all expenses arising from the destruction operation.

Article Thirty-Four

Without prejudice to any heavier penalty provided in another Law, any person who violates any provisions of this Law or its regulation shall be liable to one or more of the following penalties:

1. A fine of not more than 5 million riyals
2. Closing the manufacturer or warehouse until the violation is resolved.
3. Revoking the license of the manufacturer or warehouse.
4. Imprisonment for a period that not exceeding 5 years.

The penalty may be doubled if the violation is repeated.

Article Thirty-Five

1. The Board shall issue a table which shall include a classification of the violations and their penalties.
2. The Authority shall examine administrative violations and impose the penalties provided in article Thirty-Four of this Law, except for imprisonment, in accordance with the controls and procedures established by the Board.
3. The Authority shall transmit offences constituting crimes as provided in article 31 of this Law to the Public Investigation and Prosecution Service; to investigate, prosecute and take legal action for transfer to the competent court.

4. During the period of investigation or trial, the Authority has the right to temporarily close the manufacturer or warehouse for a fixed period or until the termination of the period of correction of the violation.
5. The authority shall publish the decision of the penalty at the expense of the offender.

Article Thirty-Six

1. The Board shall constitute one or more committees with at least three members, including at least one regular adviser, to consider complaints against penal decisions issued by the Authority
2. The decision of the Authority may be appealed to the committee within 30 days from the date on which the decision of the Authority is communicated. The committee shall decide on the complaint within a period not exceeding 60 days.
3. If no decision by the Authority within the period specified in paragraph (2) or a decision not acceptable to the violator, he may appeal against the decision before the Office of the Ombudsman within 60 days of the date of the decision or the time limit for the decision of the complaint before the committee.
4. The Board shall determine the procedures for the work of committees and rewards its members.

Article Thirty-Seven

The Implementing Regulations of this Law shall be issued by the Board and shall be in force from the date of its operation.

Article Thirty-Eight

The Law shall operate after 180 days from its publication in the Official Gazette.