



**NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION  
AND CONTROL (NAFDAC)**

## **COSMETIC PRODUCTS REGISTRATION REGULATIONS, 2019**

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(ending 9<sup>th</sup> March, 2020).**

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# COSMETIC PRODUCTS REGISTRATION REGULATIONS, 2019

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Draft

## COSMETIC PRODUCTS REGISTRATION REGULATIONS, 2019

[ ] Commencement

In exercise of the powers conferred on it Sections 5 and 30 of the National Agency for Food and Drugs Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Honorable Minister of Health makes the following Regulations –

### 1. Scope of application

These Regulations shall apply to cosmetic products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

### 2. Prohibition

- (1) A cosmetic product shall not be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations.
- (2) Notwithstanding the provisions of Regulations 2 (1) of this Regulation, the National Agency for Food and Drug Administration and Control may grant a permit for the importation or manufacture of a sample of cosmetic product for the purpose of:
  - (a) registration
  - (b) global Listing of Supermarket Items (GLSIs) and the importation or manufacture shall be in accordance with the conditions specified in the permit.

### 3. Application for registration

- (1) Application for the registration of a cosmetic product shall be made by submitting a complete application form, accompanied by relevant documents as the Agency may, from time to time, prescribe and shall-
  - (a) contain the particulars and description of the cosmetic product in respect of which the application is made;
  - (b) be accompanied by such fee as the Agency may, from time to time, prescribe.
- (2) The cosmetic product particulars and description shall be detailed enough to consist of all administrative and technical information in sufficient details as may be required to allow the Agency make informed decision about the product.
- (3) The Agency, in considering an application:
  - (a) may ask the applicant to supply such other information as it may require to enable it reach a decision on the application;
  - (b) shall satisfy itself that there is need to have the cosmetic product registered in Nigeria.

- (c) May register the cosmetic product in accordance with the provisions of Food, Drug and Related Products (Registration etc.) Act Cap F33 LFN 2004.
- (4) The registration of a cosmetic product under these Regulations shall, unless cancelled earlier, be valid for a period of five years or as may be prescribed by the Agency and shall be renewed.
- (5) The Agency shall, from time to time, publish the list of registered cosmetic products on the Agency's official website, notifying the registration of a cosmetic product.
- (6) The Agency may refuse or reject an application for registration if:
  - (a) it is found that the method, facilities or controls used in the manufacture, processing, and packaging of the cosmetic product are inadequate to ensure and preserve its identity, strength, quality, and purity consistently.
  - (b) laboratory report for the product is unsatisfactory
  - (c) good manufacturing practice inspection report is unsatisfactory
  - (d) product labeling contravenes the Cosmetic Products Labeling Regulations 2019

**4. Disclosure of information supplied by applicant**

- (1) A person shall not disclose any information supplied to the Agency in pursuance of Regulations 3 of these Regulations except-
  - (a) with the written consent of the person who supplied the information; or
  - (b) in accordance with the directive of the Agency; or
  - (c) for the purpose of a proceeding under these Regulations.

**5. Post-registration changes**

- (1) Except as prescribed in these regulations, no change shall be carried out to the terms and conditions under which a cosmetic product was registered without a prior approval of the Agency.
- (2) Every application for change to an approved product shall be submitted to the Agency describing in detail the changes to be carried out in accordance with the requirements as specified by the Agency.
- (3) Depending on the type of change, as may be determined by the Agency, the Certificate of Registration holder shall apply to the Agency for a post-registration change through:
  - (a) application along with the payment of the prescribed fee as may be determined by the Agency. The post approval change may include but not limited to;
    - (i) pack size extension, pack design change, label design change, change in formulation, promotional
    - (ii) Notification; which may include but not limited to change in location address of the manufacturer or packer.
- (4) Where a change is to be effected, the Certificate of Registration holder shall not distribute the cosmetic product unless:
  - (a) The effect of the change has been duly assessed and approved by the Agency

- (b) The product label has been revised to reflect the change, where applicable.

**(5) Changes requiring new application**

For the purpose of these Regulations, the following changes herein listed or as may be prescribed by the Agency shall require a new application:

- (a) Change in product formulation
- (b) Change in manufacturing site
- (c) Additional manufacturing site
- (d) Change in physical state
- (e) Any other changes as may be determined by the Agency.

**6. Suspension or cancellation of certificate of registration**

(1) The Agency may suspend or cancel the registration of a cosmetic product if:

- (a) the grounds on which the cosmetic product was registered were later found to be false or incomplete; or the circumstances under which the cosmetic product was registered no longer exist;
- (b) any of the conditions under which the cosmetic product was registered has been contravened;
- (c) the standard of quality, safety or efficacy as prescribed in the documentation for registration is not being complied with;
- (d) the product has proved to be ineffective for the approved use(s);
- (e) the premises in which the cosmetic product or part thereof is manufactured, assembled or stored on behalf of the holder of the Certificate of Registration are not in compliance with the requirements of current Good Manufacturing Practice (cGMP), or as may be determined by the Agency.
- (f) the Certificate of Registration holder has given a notice to the Agency in writing of any intentions to suspend product registration for a period not exceeding the validity of the certificate of registration.

(2) Where the registration of cosmetic product is suspended or cancelled, the Agency shall order the withdrawal from circulation of that cosmetic product and shall accordingly cause the suspension, cancellation or withdrawal to be published.

(3) Consequent upon the provisions in Regulations 6(1)(f), a Certificate of Registration holder may notify the Agency of his intention to resume marketing of a registered product and shall submit relevant documents and pay the prescribed renewal fee for product registration where the product registration certificate has expired.

**7. Global Listing of Supermarket Items**

(1) A person shall not, in the course of his business import or supply a cosmetic product or procure the importation or supply of a cosmetic product for the purpose under the Global Listing of Supermarket Items (GLSIs), unless he is a holder of a valid approval/certificate of Global Listing issued by the Agency for that purpose.

- (2) Application for importation of a cosmetic product under Global Listing Scheme for Supermarket Items shall be made to the Agency, in such a manner as may be prescribed by the Agency.
- (3) The use and sale of cosmetic products under the Global Listing Scheme for Supermarket Items shall be restricted to the receiving premises as indicated on the Global Listing Certificate.

#### 8. Co-Packaged Cosmetic Products

- (1) Each component of a co-packaged cosmetic product shall be registered in accordance with these Regulations and meet the requirements of the current Cosmetics Labeling Regulations.
- (2) The shelf life and expiration dating regarding co-packaged cosmetic products shall be determined by the shelf life of the components of the co-packaged products.

#### 9. Offences and Penalties.

- (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :
  - (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding 500,000 or to both such imprisonment and fine; and
  - (b) a body corporate, to a fine not exceeding N750, 000.
- (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-
  - (a) director, manager, secretary or other similar officer of the body corporate; or
  - (b) partner or officer of the firm or
  - (c) trustee of the body concerned ;or
  - (d) person concerned in the management of the affairs of the association; or
  - (e) person who purports to act in a capacity referred to in paragraphs (a) to (d) of this sub-regulation,is severally liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

#### 10. Forfeiture after conviction

- (1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-
  - (a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;
  - (b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.
- (2) In this regulation, "**proceeds**" means any property derived or obtained, directly or indirectly, through the commission of the offence.

#### 11. Interpretation

In these Regulations, unless the context otherwise requires -

**Agency** means the National Agency for Food and Drug Administration and Control (NAFDAC);

**Address** means the place where the business of manufacture or sale or distribution or storage or display of cosmetic product is carried out which includes the house number, plot number, street name, Town/City, State, Country;

**Cosmetic product** means any substance or mixture of substances intended to be rubbed, poured, sprinkled or sprayed, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the complexion, skin, hair or teeth and includes deodorants and detergent powder .

**Label** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a package (container) of a cosmetic product.

12. **Citation**

These Regulations may be cited as the Cosmetic Products Registration Regulations, 2019.

MADE at Abuja this .....day of .....2019

Draft

Inuwa / Abdulkarim Esq  
Chairman, Governing Council  
National Agency for Food and Drug Administration and Control (NAFDAC)