National Agency for Food & Drug Administration & Control (NAFDAC)

Drug Registration & Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR REGISTRATION OF IMPORTED COSMETICS IN NIGERIA

1.0. General

1.1. These Guidelines are for the interest of the general public and in particular, importers of Cosmetics in Nigeria.

1.2. It is necessary to emphasize that, no Cosmetics products shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

1.3. NAFDAC will not entertain new application for the registration of imported regulated products on the Federal Government Import Prohibition List and NAFDAC Ceiling List.

2.0. Application

2.1. The Application for the registration of all Cosmetics products shall be submitted and processed on the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) portal - https://registration.nafdac.gov.ng. For more information see the NAPAMS User Manual

2.2 A separate application form shall be submitted for each product.

Step I

3.0. Documentations.

3.1. The following documents are uploaded on the NAPAMS portal. After successful submission, all original documents will be presented upon request.

3.2. The application letter addressed to the Director-General (NAFDAC), Attention: Director, Drug Registration & Regulatory Affairs Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State.

3.3. Evidence of Business Incorporation by the Corporate Affairs Commission.

3.4. Notarised Declaration (Appendix 1) to be completed (typed), signed by declarant and notarized by a Notary Public in Nigeria

3.5. Powder of Attorney. An applicant on behalf of a manufacturer outside Nigeria must file an evidence of Power of Attorney (POA) from the manufacturer which

authorizes the applicant to speak for his Principal; on all matters relating to the latter's specialties. The Power of Attorney shall (be):

3.5.1. Issued by the manufacturer of the product

3.5.2. Signed by the managing director, general manager, Chairman or President of the company, stating the names of the product to be registered. The Power of Attorney shall also indicate 'Authority to register the cosmetics product with NAFDAC'

3.5.3. State ownership of Brand Name(s)/Trademark.

3.5.4. Notarised by a Notary Public in the country of manufacture.

3.5.5. Valid for at least five years (5) years.

3.6. Contract Manufacturing Agreement: An applicant filing an application and being the owner of Brand name/Trademark, shall provide a Contract Manufacturing Agreement, which shall be signed by the applicant and the manufacturer. The Agreement shall be;

3.6.1. Notarized by a Notary Public in the country of manufacture.

3.6.2. Signed by both parties stating names and designation of the signatories with the names of all the products to be registered and other relevant clauses clearly explained in an unambiguous language.

3.7. Evidence of Registration of Brand Name with Trademark Registry in the Federal Ministry of Industry, Trade and Investment. This should be done in the name of the owner of the Trademark/Brand name.

3.8. Certificate of Manufacture and Free Sale. The manufacturer must show evidence that the company is licensed to manufacture cosmetics products and that the sale of the product does not constitute a contravention of the laws of that country, i.e. Free Sale Certificate/Certificate of Manufacture and Free Sale. The Free Sale Certificate should:

3.8.1. Be issued by a relevant Health/Regulatory body in the country of manufacture

3.8.2. Indicate the name and address of the manufacturer and product to be registered

3.8.3. Be authenticated by the Nigerian Embassy or High Commission in the country of Manufacture. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS Country can authenticate the document.

3.9. Product Labels/artwork.

3.10. Letter of Invitation for Good Manufacturing Practice (GMP): A letter of invitation to inspect the factory abroad shall be written by the manufacturer and state the following:

3.10.1. MANUFACTURER'S INFORMATION: Name of company, full location address of factory (not administrative office address), email, and current phone number. Details (name, phone number and email) of contact person abroad.

3.10.2. LOCAL AGENT INFORMATION: Name of company, full location address, functional phone number, email address. Details (Name, phone number and email address) of contact person in Nigeria.

3.10.3. NAME(S) OF PRODUCT(S): List of products submitted for registration should be included.

3.11. Comprehensive Certificate of Analysis. The certificate of analysis must be presented on a letter-headed paper of the Quality Control Laboratory where the sample was tested/evaluated and should contain all relevant technical parameters of interest in addition to the under-listed information:

3.11.1. The brand name of the product.

3.11.2. The batch number of the product

3.11.3. The manufacturing and expiry dates

3.11.4. The name, designation and signature of the analyst.

Step II

4.0. Import Permit

4.1. Upon successful screening of documentation and review of supporting documents, an electronic import permit shall be issued after which products are submitted for laboratory analysis.

Step III

5.0. Submission of products for laboratory analysis

5.1. After successful vetting of products, laboratory samples are submitted. The following documents are included;

5.2. Letter of submission of products for analysis

5.3. Receipt of payment

5.4. Certificate of analysis

Step IV

6.0. Product Approval Meeting

6.1. Upon satisfactory Documentation review, GMP inspection of the production facility and laboratory analysis of product (where applicable), products are presented for the Food and Drug Registration Committee (FDRC) Approval Meetings.

Step IV

7.0. Issuance of Certificate of Product Registration.

7.1. For Cosmetics products approved at the FDRC meeting, an electronic Certificate of Product Registration is issued to the Applicant.

8.0. Labelling Information

8.1. Labelling should be informative, accurate and in conformance with the Agency's Cosmetics Products Labelling Regulations https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Regulations/REGULATIONS_2021/COSMETIC-PRODUCTS-LABELLING-REGULATION.pdf and any other relevant Regulations.

9.0. Tariff

9.1. See NAFDAC Tariff section https://www.nafdac.gov.ng/resources/nafdac-tariff/.

10.0. Note

10.1. Failure to comply with these requirements may result in the rejection of the application or lead to considerable delay in the processing of registration.

10.2. A successful application will be issued a Certificate of Product Registration with a validity period of five (5) years.

10.3. Registration of a product does not automatically confer Advertising Permit. A separate application and subsequent approval by the Agency shall be required if the product is to be advertised. For further information on advert approvals, see Guidelines for Advertisement of NAFDAC Regulated Products in Nigeria https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/IIMPORTS/Guidelines-for-the-Advertisement-of-NAFDAC-Regulated-Products.pdf

10.4. NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period.

10.5. Filing and/or paying for an application form does not confer registration status.

10.6. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (within 90 working days) will automatically lead to the closure of the Application.

10.7. The time-line for product registration from acceptance of submissions to issuance of Registration number is one hundred and twenty (120) working days.

10.8. Please note that the clock stops once compliances are issued.

All correspondences should be addressed to:-

Director-General (NAFDAC),

Attn: The Director

Drug Registration and Regulatory Affairs Directorate,

National Agency for Food and Drug Administration and Control,

Ground Floor, NAFDAC Office Complex

Isolo Industrial Estate

Apapa-Oshodi Expressway, Isolo, Lagos

NAFDAC website: www.nafdac.gov.ng

E-mail: registration@nafdac.gov.ng

cosmeticsregistration@nafdac.gov.ng