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

Drug Registration & Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR REGISTRATION OF IMPORTED DRUG PRODUCTS IN NIGERIA (HUMAN AND VETERINARY DRUGS)

1.0. General

1.1. These Guidelines are for the interest of the general public and in particular Importers of Pharmaceuticals for Human and Veterinary use in Nigeria.

1.2. It is necessary to emphasize that, no drug 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, NAFDAC Ceiling List and Banned formulations.

1.4 **NOTE: These Guidelines should be read in conjunction with all relevant ICH guidance documents including the following;**

a ICH Harmonised Tripartite Guideline Stability Testing of New Drug Substances and Products Q1A(R2)

https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf

b ICH Harmonised Tripartite Guideline Stability Testing for New Dosage Forms Annex to the ICH Harmonised Tripartite Guideline on Stability Testing for New Drugs and Products Q1C

https://database.ich.org/sites/default/files/Q1C%20Guideline.pdf

C ICH Harmonised Tripartite Guideline Pharmaceutical Development Q8(R2)

https://database.ich.org/sites/default/files/Q8_R2_Guideline.pdf

d ICH Harmonised Tripartite Guideline "Quality Risk Management Q9"

https://database.ich.org/sites/default/files/Q9_Guideline.pdf

e ICH Harmonised Guideline Technical and Regulatory considerations for Pharmaceutical Product Lifecycle Management Q12

https://database.ich.org/sites/default/files/Q12_Guideline_Step4_2019_1119.pdf

1.5 To initiate the registration process for a drug product, the Applicant is required to submit a Dossier of the drug product for screening. (See Dossier Submission Guide)

1.6 Dossier Screening clearance is a prerequisite for submission of applications for pharmaceuticals for human use.

2.0. Applications

2.1. The Application for the registration of all drug products should be 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

A separate application form shall be submitted for each product.

Step 1

3.0. Documentation

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

3.1.1 Dossier Screening Clearance

3.1.2 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.

3.1.3 Notarized Declaration (Appendix I). To be completed (typed), signed by Declarant and
notarized by a Notary Public in Nigeria.

3.1.4 Power of Attorney (where the Applicant does not own the Brand name) or Contract Manufacturing Agreement (where the Applicant owns the Brand name).

The Power of Attorney shall be:

3.1.4.1 Issued by the manufacturer of the product.

3.1.4.2 Signed by the Managing Director, General Manager, Chairman or President of the Company, stating the names of the products to be registered. The Power of Attorney shall also state 'Authority to register product with NAFDAC'.

3.1.4.3 State ownership of Brand name(s)/Trademark.

3.1.4.4 Notarized by a Notary Public in the Country of manufacture.

3.1.4.5 Valid for at least five (5) years.

Contract Manufacturer Agreement shall be:

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

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

3.1.5 Evidence of Business Incorporation of the Applicant with Corporate Affairs Commission in Nigeria.

3.1.6 Manufacturing License/Certificate of Free Sale

Evidence that they are licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate). The license shall be issued by a relevant Health/Regulatory body in the country of manufacture.

3.1.7 Certificate of Pharmaceutical Product (COPP-WHO Format)

There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country. The Certificate of Pharmaceutical Product (COPP) should;

3.1.7.1 Conform to WHO format.

3.1.7.2 Be issued by the Health/Regulatory body in the country of manufacture.

3.1.7.3 Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS country can authenticate the COPP.

3.1.8 Current Good Manufacturing Practice (cGMP) of the manufacturing facility. This is to be:

3.1.8.1 Valid at the time of submission.

3.1.8.2 Be issued by the Health/Regulatory body in the country of manufacture.

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

3.1.9 Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be registered in the name of the owner of the Trademark/Brand name as the case may be (Trademark Class 5 for Drugs).

3.1.10 Copy of valid Annual License to practice for the Superintendent Pharmacist for Human Drugs or Veterinary drugs, issued by the Pharmacists Council of Nigeria (PCN).

3.1.11 Evidence of valid Premises Retention License for the facility.

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

3.1.12.1 MANUFACTURER INFORMATION: Name of Company, full location address of factory (not administrative office address), e-mail, and current phone no. Details (name, phone number and email) of contact person overseas.

3.1.12.2 LOCAL AGENT INFORMATION: Name of company, full location address, functional phone no., e-mail address. Details (name, phone number and email) of contact person. Names(s) of product(s) for registration.

Step II

4.0. Import Permit and Label vetting

4.1. Upon satisfactory review of submitted documents and label, Permit to import registration sample shall be issued.

STEP III

5.0. Submission of laboratory samples

5.1. The following documents are required;

5.1.1. Letter for submission of laboratory samples.

5.1.2. Evidence of payment of processing fee.

5.1.3. 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 the under listed information:

5.1.3.1. The brand name of the product

5.1.3.2. The batch number of the product

5.1.3.3. The manufacturing and expiry dates

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

5.1.4. A copy of permit to import registration samples.

For more Information on the Inspection of manufacturing facility, Applicant should visit the Drug Evaluation and Research (DER) Directorate section of the Agency's website.

Step IV

6.0. Product Approval meeting

6.1. Upon satisfactory Dossier review, satisfactory GMP of the production facility and satisfactory laboratory analysis of product (where applicable), the Food and Drug Registration Committee (FDRC) Approval Meetings.

Step V

7.0. Issuance of Certificate of Product Registration

7.1. For products approved at the meeting, an electronic Certificate of Product Registration or Listing is issued to the applicant.

8.0. Labelling Guidelines for Imported Drugs

8.1. Labelling should be informative and accurate.

8.2. Minimum requirements on the package label in accordance with the Drug Labelling Regulations include:

8.2.1. Name of product (brand name) where applicable and generic name.

8.2.2. Name and full location address of the manufacturer.

8.2.3. Provision for NAFDAC Registration Number on product label

8.2.4. Batch No., Manufacturing date and Expiry date.

8.2.5. Dosage form & strength

8.2.6. Indications, frequency, route, conditions of administration (Over the counter; OTC drugs).

8.2.7. Dosage regimen on the package (Over-the-Counter; OTC drugs).

8.2.8. Patient Information Leaflet (PIL)

8.2.9. Prescribing information (for POM).

8.2.10. Net content of product

8.2.11. Quantitative listing of all the active ingredients per unit dose

8.2.12. Adequate warnings where necessary.

8.2.13. Storage conditions

8.2.14. Withdrawal Period for all Veterinary drugs.

8.2.15. Where a brand name is used, there MUST be the generic name which should be conspicuous in character, written directly under the brand name.

8.2.16. Any drug product whose name or package label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

8.2.17. Any drug product which is labelled in a foreign language shall NOT be considered for registration unless an English translation is included on the label and PIL (where applicable).

8.2.18. See the Agency's Drug Labelling Regulations and other relevant Regulations for specific details.

9.0. Tariff

9.1. Please refer to relevant section of the NAFDAC Tariff.

10.0. Note

10.1. For New Chemical Entities (NCE), there must be evidence that Clinical Trials have been undertaken in the relevant population. Such clinical trial reports must be submitted and reviewed. Please refer to the Drug Evaluation and Research (DER) Directorate.

10.2. For generic products, Bioequivalence study report/Biowaiver data shall be submitted on DMS using the CTD Dossier format. The Bioequivalence study report and/or Biowaiver application shall be assessed by the efficacy assessors.

10.3. No combination drug product shall be registered or considered for registration unless there is scientific documented evidence to prove that such a product has clinical advantage over the single drug available for the same indication(s).

10.4. Failure to comply with these requirements may result in the rejection of the application.

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

10.6. 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 NAFDAC Guidelines on Advertisement.

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

10.8. Filing an application form or paying an application fee does not confer registration status.

10.9. 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.

10.10. The timeline for product registration from acceptance of submissions to issuance of NAFDAC Registration number is two hundred and forty (240) working days.

10.11. 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

APPENDIX I

NOTARIZED DECLARATION

I **Applicant's Name** the Managing Director of **Applicant's Company Name** hereby declare on oath and state as follows:

1. That **Applicant's Company Name** of **Applicant's Company Address** forwarded an application to the National Agency for Food and Drug Administration and Control for the Registration of regulated products hereinafter listed:
   a. **List of Products (Product Names)**
   b. _____

   Pursuant to the provisions of Food and Drugs and Regulated Products (REG etc.) Act Cap F33 LFN 2004 and all relevant Regulations as representatives of **Manufacturer's Company Name.**

2. That the said application before the National Agency for Food and Drug Administration and Control for the registration of the above listed Products, the application No: **Applicant Form No** thereof and the attached documents viz:

   a. Power of attorney / Contract Manufacturing Agreement and notarization thereof
   b. Certificates of Pharmaceutical Product/ Certificate of Manufacture and/or Free Sale and the authentication thereof by the Nigerian Mission in the country of origin
   c. Manufacturing license / Certificate for companies from India and China and the authentication thereof by the Nigerian Mission in the country of origin
   d. Certificate of Good Manufacturing Practice (GMP) and the authentication thereof by the Nigerian Mission in the country of origin
   e. Certificate of Analysis of product
   f. Evidence of Registration of Trademark and the information contained in all the above referred documents is true and correct.

3. a. That the manufacturer **Manufacturer's Company Name** is or is not the owner of the trademark
   b. The product _____is generic

4. a. That **Applicant's Company Name** of **Applicant's Company Address** is or is not the owner of the Trademark.

b. The product _____is generic

5. That **Applicant's Company Name** and the declarant shall indemnify the National Agency for Food and Drug Administration and Control against any suit, claim, damages or liability arising from the use of all documents submitted and information declared by us in the processing, approval and grant of any certificate of registration in respect of **Product Name(s)**

6. We agree to be held criminally liable for any false declaration made herein and forged documents submitted to the National Agency for Food and Drug Administration and Control in respect of the application for the registration of Product **Name(s)**

Signature & Date

DECLARANT (Applicant)

BEFORE ME

NOTARY PUBLIC (NBA Seal)

NAME: _____

ADDRESS: _____

SIGNATURE: _____

DATE: _____