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

Drug Registration & Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR RENEWAL OF IMPORTED HERBAL REMEDIES/DIETARY SUPPLEMENTS IN NIGERIA

1.0. General

1.1. These Guidelines are for the interest of the General Public and in particular, importers of Herbal Medicines and dietary Supplements.

1.2. It is necessary to emphasize that, no Herbal Medicines and Dietary supplements 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/renewal of imported regulated products on the Federal Government Import Prohibition List and NAFDAC Ceiling List.

2.0. Application

2.1. The Application for the renewal of all Herbal Medicines and Dietary Supplements should 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 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 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.

3.2 Evidence of Business Incorporation by the Corporate Affairs Commission.

3.3 Notarised Declaration (Appendix 1).To be completed (typed), signed by Declarant and notarized by a Notary Public in Nigeria.

3.4 Power of Attorney (where the Manufacturer owns the Brand name) OR Contract Manufacturing Agreement (where the Applicant owns the Brand name).

3.4.1 An applicant on behalf of a manufacturer/Owner outside Nigeria must file evidence of Power of Attorney from the manufacturer which authorizes him to speak for his Principal, on all matters relating to the latter's specialties. The Power of Attorney shall (be):

3.4.1.1 Issued by the manufacturer/Owner of the product.

3.4.1.2 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 indicate 'Authority to register product with NAFDAC'.

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

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

3.4.1.5 Valid for at least five (5) years.

3.4.2 Contract Manufacturing Agreement: An applicant filing an application on behalf of his company, and being the owner of the product, shall provide a Contract Manufacturing Agreement, which shall be signed by himself (or his competent representative) and the manufacturer. The Agreement shall be:

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

3.4.2.2 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.

3.5 Certificate of Manufacture and Free Sale. The manufacturer must show evidence that the company is licensed to manufacture Herbal Remedies/Dietary Supplement 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:

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

3.5.2 Indicate the name of manufacturer and products to be registered.

3.5.3 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.

3.6 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 the under listed information:

3.6.1 The brand name of the product

3.6.2 The batch number of the product

3.6.3 The manufacturing and expiry dates

3.6.4 The pack size of the product

3.6.5 The name, designation and signature of the analyst

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

3.8 Coloured artwork/label and leaflet insert of the product.

3.9 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:

3.9.1 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.

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

4.0 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 2

4.0 Submission of retention samples

5.1 After successful vetting of product labels, retention samples are submitted. The following documents are included;

5.1.1 Evidence of payment to the Agency.

5.1.2 Certificate of analysis.

5.1.3 Evidence of submission for retention sample.

Step 3

6.0 Product Approval Meeting

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

Step 4

7.0 Issuance of Certificate of Product Registration.

7.1 For products approved at the 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 Medical Devices Labelling Regulations and any other relevant Regulations.

9.0 Tariff

9.1 See NAFDAC Tariff section.

10.0 Note

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

10.2 A successful application will be issued a Certificate of Registration with a validity period of five (5) years OR two (2) years.

10.3 Registratiion/Renewal 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 Advert

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

10.5 Filing an application and/or paying an application fee 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

drugherbalregistration@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: _____