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

Drug Registration & Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR REGISTRATION OF HERBAL MEDICINES AND DIETARY SUPPLEMENTS MADE IN NIGERIA

1.0. General

1.1. These Guidelines are for the interest of the general public and in particular, manufacturers of Herbal Medicine and dietary Supplements made in Nigeria.

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 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 Herbal medicines and dietary Supplements 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

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. Contract Manufacturing Agreement (where the Applicant owns the Brand name).

3.5. 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.

3.6. Fill the Herbal Medicine Technical Information Submission Template using the link (HMTIST)

3.7. Product Labels/artwork (should be in line with the Label Guidance)

3.8. 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:

3.8.1. The brand name of the product.

3.8.2. The batch number of the product

3.8.3. The manufacturing and expiry dates

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

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 III

5.0. Product Approval Meeting

5.1. 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

6.0. Issuance of Certificate of Product Registration.

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

7.0. Labelling Information

7.1. Labelling should be informative, accurate and in conformance with the Agency's Medical Devices Labelling Regulations and any other relevant Regulations.

8.0. Tariff

8.1. See NAFDAC Tariff section.

9.0. Note

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

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

9.3. 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 NAFDAC Guidelines on Advert

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

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

9.6. 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.

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

9.8. 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