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

Registration & Regulatory Affairs (R & R) Directorate

GUIDELINES FOR REGISTRATION OF DRUG PRODUCTS MADE IN NIGERIA

1. **General**

1.1. These Guidelines are for the interest of the general public and in particular, manufacturers of pharmaceuticals made 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.

2. **Applications**

2.1. A written application for Registration of Drugs made in Nigeria shall be made on the company's letter head paper to the Director-General (NAFDAC), ATTENTION: The Director, Registration and Regulatory Affairs (R & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, and Lagos State.

2.2. An online application form for Product Registration should be purchased at; http://registration.nafdac.gov.ng and completed.

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

Step 1

3. **Documentation**

3.1. The application letter and print-out of the registration form are to be accompanied with two (2) sets of the following documents are to be submitted at the Liaison Office of the Director (LOD), R & R Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State or any NAFDAC Office (outside Lagos):

3.1.1. Evidence of Business Incorporation. In-case of Micro, Small and Medium Enterprises (MSMEs); evidence of Business name.

3.1.2. Evidence of payment to the Agency.

3.1.3. Contract Manufacturing Agreement (where applicable).

3.1.4. 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 (Trademark Class 5 for Drugs).

3.1.5. Copy of valid Annual License to practice for the Superintendent Pharmacist issued by Pharmacists Council of Nigeria.

3.1.6. Copy of valid Premises Retention License for the facility.

3.1.7. Evidence of PMG-MAN membership.

3.1.8. Evidence of satisfactory Inspection issued by the relevant Directorate or Good

Manufacturing Practice (GMP) certificate for product line (companies with registered products).

3.1.9. Product Labels/artwork.

3.1.10. Comprehensive Certificate of Analysis. The certificate of analysis must be presented on a letter-headed paper of the Quality Control Laboratory where the product was tested/evaluated and should contain the under listed information:

3.1.10.1. The brand name of the product

3.1.10.2. The batch number of the product

3.1.10.3. The manufacturing and expiry dates

3.1.10.4. The name, designation and signature of the analyst

3.1.10.5. Product Dossiers which should be;

3.1.10.5.1. In a Compact Disc (CD).

3.1.10.5.2. Searchable Portable Document Format (pdf).

3.1.10.5.3. Common Technical Document (CTD) format

Step 2

4. **Product Approval meeting**

4.1. Upon satisfactory Documentation review, GMP inspection of the production facility and laboratory analysis of product, products are presented for Approval Meetings.

4.2. For products labels with compliance issues, compliant artworks may be submitted with a commitment letter from manufacturer (stating that the commercial products will be in compliance).

Step 3

5. **Issuance of Notification**

5.1. For products approved at the meeting, Notification of Registration is issued to the applicant while Compliance Directive is issued to those not approved.

6. **Labelling Guidelines for Drugs made in Nigeria**

6.1. Labelling should be informative and accurate.

6.2. Minimum requirements on the product label in accordance with the Drug Labelling Regulations include:

6.2.1. Generic name and product brand name (where applicable).

6.2.2. Name and full location address of the manufacturer.

6.2.3. Provision for NAFDAC Registration Number on product label

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

6.2.5. Dosage form & strength

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

6.2.7. Dosage regimen on the package (Over the counter; OTC drugs).

6.2.8. Patient Information Leaflet (PIL)

6.2.9. Net content of product

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

6.2.11. Adequate warnings where necessary.

6.2.12. Storage conditions

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

6.2.14. 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.

6.2.15. 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).

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

7. **Tariff**

7.1. Please refer to Tariffs section.

8. **Note:**

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

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

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

8.4. 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. Simultaneous submission of registration and advertisement applications are allowed.

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

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

8.7. 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.

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

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

All correspondences should be addressed to:-

Director-General (NAFDAC),
Attn: The Director
Registration and Regulatory Affairs Directorate,
National Agency for Food and Drug Administration and Control (NAFDAC),
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
Telephone no.: +234-1-4772452

All submissions should be made at the Office of the Director, R & R, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (outside Lagos).