DIRECTORATE OF REGISTRATION AND REGULATORY AFFAIRS

GUIDELINES FOR REGISTRATION OF DRUGS AND RELATED PRODUCTS MANUFACTURED IN NIGERIA
NAFDAC/RR/003/00

A. GENERAL

1. These guidelines are for the interest of the general public and in particular pharmaceutical, herbal and cosmetics industries in Nigeria.

2. It is necessary to emphasize that, no drug and related products should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of ACT CAP F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

3. A manufacturer who intends to register a drug or related product in Nigeria should first have the factory inspected by the Establishment Inspection Directorate of NAFDAC and be assigned a Certificate of Recognition as a manufacturer before an application to register the product can be made.

B. APPLICATIONS/MANUFACTURER

(a) The applicant should purchase and fill the prescribed application form. A separate application form shall be submitted for each drug product. In this context, a drug product means a separate drug formulation. However the application for registration of one dosage form with different strengths shall be made on separate application forms.

(b) A written application for product registration shall be made to the Director (Registration and Regulatory Affairs), stating the name of the manufacturer, the generic name of product, brand name (where applicable), product strength, and indications.

4. Product found to be of doubtful, little or no therapeutic value shall not be considered for registration.

5. An applicant shall not be allowed to register a formulation in more than one brand name even where different dosages of the active ingredient(s) are used.

6. All dosage forms of a particular brand name must contain the same active ingredient(s) or at least the major active ingredient(s) e.g.

A cream	-	Betamethasone 10mg
A soap	-	Betamethasone 20mg

C DOCUMENTATION

Documents required for submission for product registration as applicable shall be:

1) Evidence of pre-production inspection/ Certificate of Recognition issued by NAFDAC.
2) Current Certificate of Registration/ Retention Premises, issued by the Pharmacists' Council of Nigeria (Drugs only)
3) Current annual License to Practice as a Pharmacist issued by the Pharmacists' Council of Nigeria to the superintendent Pharmacist. (Drugs only)
4) Evidence of PMG-MAN membership (Drugs only)
5) Two copies of Product Dossiers made out in accordance with the Agency's format (Drugs only)
6) Evidence of Approval for brand name from Federal Ministry of Commerce
7) Certificate of Incorporation of the company issued by the Corporate Affairs Commission (except for drugs).
8) Comprehensive Certificate of analysis of the batch of the product for registration from the manufacturer stating name and signature of the analyst.
9) Evidence of Membership of the State's Traditional Medicines Board (Herbal Medicines)
10) Technical Document (Herbal Medicines).

C. PRODUCT

1. Three vetting samples shall be submitted upon satisfactory Pre- Registration inspection.

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

D. LABELLING

1. Labeling shall be informative, clear and accurate.

2 Minimum requirements on the package label in accordance with the drug labeling regulations shall be:
(a) Name of medicine (brand name) where applicable and generic name.
(b) Name and full location address of the manufacturer.

(c) Provision for NAFDAC Registration Number on product label.
(d) Batch No., Manufacturing date and Expiry date.
(e) Dosage form & strength
(f) Indications, frequency, route, conditions of administration.
(g) Dosage regimen on the package (OTC drugs only if there is no accompanying leaflet insert.
(h) Leaflet insert, if prescription product and hospital packs with Pharmacokinetic and Pharmacodynamics information.
(i) Net content of product.
(j) Quantitative listing of all the active ingredients per unit dose.
(k) Adequate warnings where necessary.

3 Minimum labeling requirements for herbal, nutraceuticals and cosmetics

(a) Name of medicine-brand name (where applicable) and generic/botanical name.
(b) Name and full location address of the manufacturer or distributor or vendor, etc
(c) Provision for NAFDAC Registration Number/listing on product label.
(d) Batch No., Manufacturing date and Expiry date.
(e) Dosage form & strength.
(f) Indications, frequency, route, conditions of administration. (where applicable)
(g) Dosage regimen on the package (where applicable)
(h) Leaflet insert (where applicable)
(i) Net content of product.
(j) Quantitative listing of all the active ingredients per unit dose.
(k) Adequate warnings (where necessary).

4 Where a brand name is used, there MUST be the generic name which should be conspicuous in character, written directly under the brand name e.g.:-
VENTOLIN TABLETS
"SALBUTAMOL"

4. 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.

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

6. The time line for product registration from submission of samples up to issuance of registration number is hundred (100) work days. However, this depends on satisfactory compliance by the applicant.

7. A successful application attracts a Certificate of Registration with a validity period of five (5) years.

E TARRIFF

All payments to the Agency should be in Bank Draft payable to National Agency for Food and Drug Administration and Control (NAFDAC)

(i) Drug: - The sum of seventy thousand naira (₦70, 000.00) only plus 5% VAT per product, covering processing, analysis and license

(ii) Traditional Medicines - Categorized as follows:
   (a) Small Scale Industry:-Ten thousand naira (₦10, 000.00) only plus 5% VAT.
   (b) Medium Scale Industry: - Twenty thousand naira (₦20,000:00) only plus 5% VAT
   (c) Large Scale Industry: - Forty thousand naira (₦40,000:00) only plus 5% VAT

(iii) Phytomedicines: - Seventy thousand naira (₦70,000:00) only plus 5% VAT

(iv) Nutraceuticals: - Seventy thousand naira (₦70,000:00) only plus 5% VAT

(v) Cosmetics: - Fifty thousand naira (₦50,000:00) only plus 5% VAT

F NOTE

1 Registration of a product does not automatically confer Advertising permit. A separate approval by the Agency shall be required if the product is to be advertised.

2 NAFDAC may withdraw the certificate of Registration in the event that the product is advertised without express approval from the Agency.

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

4 Filling an application form or paying for an application form does not confer registration status.

5 Failure to respond promptly within 30 work days to queries or enquiries raised by NAFDAC on the application, will automatically lead to suspension of further processing of the application.

6 Registration time line after submission of vetting samples is hundred (100) work days.

All correspondence in respect of Drug registration should be addressed to:

The Director,
Registration & Regulatory Affairs
NAFDAC
Central Laboratory Complex
Oshodi, Lagos.
NAFDAC website: www.nafdac.gov.ng
e-mail address: registration@nafdac.gov.ng
Telephone number: +234-1-4772452, 01-4748627