DIRECTORATE OF REGISTRATION AND REGULATORY AFFAIRS

GUIDELINES FOR REGISTRATION/ LISTING OF HERBAL MEDICINES AND RELATED PRODUCTS
NAFDAC/RR/006/00

A. GENERAL RULES

1. Herbal medicinal products to be considered for registration or listing may be categorized as

(a) Herbal medicinal products manufactured locally.
(b) Imported Herbal medicinal products.
(c) Homeopathic herbal medicinal products.

2 These guidelines do not apply to Extemporaneous preparations. This means preparations that are made by the practitioner and given to the patient on a one-to-one basis within the locality of its preparation.

3. The guidelines are for manufactured products that are intended for distribution outside the locality of production, i.e. to very wide areas through other outlets and for storage for a considerable long period of time. The preparation and shelf life of the products are therefore significant.

4. It is necessary to emphasize that no herbal medicinal products and related products shall be manufactured, imported, 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.

B APPLICATION

1 The applicant must submit to the Registration Division, NAFDAC, a written application for permit to import samples, stating the name of the manufacturer, name of the product, brand name (where applicable), and obtain the prescribed application form which must be properly filled, with all information required. This form shall be obtained on payment of the prescribed fee per product.

(b) A separate application form shall be submitted for each product

(c) In case of a manufacturer outside Nigeria, such should be represented in Nigeria by a duly registered company or individual with facilities to effect a recall of the product when necessary.

2 An applicant for a manufacturer 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 original Power of Attorney is to be notarized by a Notary Public in the country of origin, signed by the responsible officer and submitted to NAFDAC.

Or

Contract Manufacturing Agreement:

a. Notarized by a notary public in the country of manufacture.

b. Should be 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

NOTE:

The representative in Nigeria, whether a corporate body or an individual with the Power of Attorney, will be responsible for ensuring that the competent authority in the country is informed of any serious hazard newly associated with a product imported under the provisions of the Act or of any criminal abuse of the certificate in particular, to the importation of falsely labeled, spurious, corrosive, or sub-standard herbal products.

C DOCUMENTATION

1 The manufacturer, in the case of imported product, must show evidence that the company is licensed to manufacture and that the sale of the Product does not constitute a contravention of the Laws that country i.e **Free Sale Certificate** (Certificate of Manufacturer and Free Sale). Such evidence must be issued by the competent Authority in the country of manufacture, and should be authenticated by the Nigerian Mission in that Country. In countries where no Nigerian Embassy or High Commission exists, any other Embassy or High Commission of any Commonwealth or West African country can authenticate.

2 Comprehensive Certificate of analysis

3 Certificate of Business Incorporation with the corporate affairs commission in Nigeria

4 Certificate of Registration of Brand Name with trademark Registry (where necessary)

5 Applicants shall submit a letter of Invitation to inspect the factory abroad. They shall state the full location address of the manufacturer, Name of contact person, e-mail address, current phone no. & fax no., guide map illustrating the shortest land / air route to the factory overseas. (Two copies).

6 Applicants shall submit dossiers containing relevant information on the products format.

7 Evidence of satisfactory clinical trials conducted in the Country of origin and or any African Country.

8 Any other relevant information on the products.

9 A permit should be issued if documentation is satisfactory.

D LABELLING REQUIREMENTS

1 Labeling should be informative and accurate. In addition to the requirements of the drug labeling regulations, the following minimum requirements must appear on the label in English and may include other languages.

i Name of the product - Generic name, Brand name (where applicable).
ii Quantitative list of Ingredients by their Botanical or common names.
iii Dosage form and Net contents of product.
iv Directions for use
v Indications (shall be on the leaflet). No claim of cure is permitted until proven through clinical trial).
vi Batch number, manufacturing date, expiry date
vii Storage conditions.
viii Name and full location address of manufacturer.
ix Provision for NAFDAC registration / listing number
. x Specific symptoms of overdose and antidote on the leaflet
xi Contra-indications / drug interactions
xii Warnings, Precautions. (e.g. use in pregnant and lactating mothers not recommended).
xiii Disclaimer **"**these claims have not been evaluated by NAFDAC".

2 Any product whose name, package or label bears close resemblance and or is a sound-alike to an already registered/ listed product or is likely to be mistaken for such registered / listed product shall not be considered for registration

3 Brand names that a suggestive of therapeutic claims shall not be accepted.

E TARIFF

All payments to the Agency shall be in bank draft in favour of National Agency for Food and Drug Administration and Control (NAFDAC).

1	Application Forms	Five hundred naira only (₦500:00).
2	Per herbal product	₦375, 000:00 + 5% VAT
3	Per Nutraceuticals product	₦750, 000 + 5% VAT

F NOTE

1 The time line for registration from submission of sample to issuance of registration number shall be eighty (60) work days

2 Full registration status on herbal medicinal products shall depend on evidence of clinical trials to ascertain safety and efficacy.

3 Failure to comply with these requirements may result in the disqualification of the application or lead to considerable delays in the process of registration.

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

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

6 Filling and submission of duly completed application form or paying for an application form does not confer Registration status.

.7 Listing shall be for two (2) years period while registration shall be for (5) years.

All correspondences in respect of herbal medicines registration shall be addressed to

THE Director, Registration and Regulatory Affairs,
National Agency for Food and Drug Administration and Control
(NAFDAC)
CENTRAL LABORATORY COMPLEX,
OSHODI, LAGOS.
NAFDAC website: www.nafdac.gov.ng
E-mail address: registration@nafdac.gov.ng
Telephone numbers: 01-4772452, 01-4748627.