

**DIRECTORATE OF REGULATORY AND REGISTRATION AFFAIRS**  
**GUIDELINES FOR PACKAGING BULK SEMI – FINISHED DRUG PRODUCTS**  
**IN NIGERIA**  
**NAFDAC/RR/009/00**

**A. GENERAL**

1. These guidelines are for the interest of the general public and in particular pharmaceutical industries in Nigeria.
2. These guidelines are for industries that may wish to import bulk semi – finished drug products and other regulated products i.e. nutraceuticals, food supplements in drums or sacks for the purpose of packaging them in Nigeria.
3. It is necessary to emphasis that, no drug 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 (as amended)) and the accompanying guidelines.
4. The guidelines also apply to manufacturer of an already registered imported drug product who may choose to import the semi – finished bulk product to package in Nigeria.

**B. APPLICATIONS**

1.
  - (a) An application for registration of a drug / related product should be made by the manufacturer or importer on the company's letter head paper.
  - (b) In case of a drug manufacturer outside Nigeria, such should be represented in Nigeria by a duly registered pharmaceutical company. Therefore, the application should be accompanied with
    - i. Current Certificate of Registration/ Retention of Premises issued by the Pharmacists Council of Nigeria.
    - ii. Current Annual Licence to Practise as a Pharmacist issued by the Pharmacists Council of Nigeria to the Superintendent Pharmacist
  - (c) In the case of other regulated products, companies duly registered in Nigeria could represent.
2.
  - (a) The applicant must also submit duly filled prescribed application form.
  - (b) A separate application form should be submitted for each product. In this context, a product means a separate formulation. However the application

for registration of one dosage form with different strengths should be made on a separate application form

## **C DOCUMENTATION**

- 1 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 should be signed stating name and designation of the officer and should be notarized by a notary Public in the country of origin. This shall be submitted to NAFDAC.

Or

Where the applicant in Nigeria owns the trademark of the drug manufactured outside Nigeria under contract arrangement, such applicant should submit a Contract Manufacturing Agreement which:

- (i) Should be notarized by a notary public in the country of manufacture.
- (ii) Should be signed by both parties stating names and designations of the signatories with the names of all the products to be registered.

### **NOTE:**

The representative or applicant in Nigeria, whether a corporate body or an individual with the power of attorney, will be held 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, counterfeited or sub-standard medicinal products.

2. (a) The manufacturer, in the case of imported drug / related products (from Asia), must show evidence that he or she is licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate).
- (b) There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country. i.e. Certificate of Pharmaceutical Product (COPP) that conforms to WHO format. (Drugs only)
- (c) Certificate of Free Sale (For herbal, nutraceuticals and food supplements products only).
- (d) Current Good Manufacturing Practice (GMP) Certificate of the manufacturing facility shall be submitted (for manufacturers from Asian countries).

The documents in respect of (a) to (d) above should be issued by the relevant health/regulatory body in the country of manufacture and authenticated by the

Nigerian Mission in the country of manufacture. In countries where no Nigerian Embassy or High Commission exists, authentication by the British Embassy or High Commission of any Commonwealth or West African country shall be acceptable.

3. Applicant should submit Certificate of Registration of Brand Name with the trademark Registry in Nigeria.(where applicable). The trademark registration should be done in the name of the trademark owner as the case may be.
4. A letter of Invitation to inspect the factory abroad. This should be written by the applicant in Nigeria and should 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.
5. Certificate of Incorporation of the importing company issued by the Corporate Affairs commission in Nigeria. (Except for drugs).
6. Upon satisfactory assessment of all the above documents, permit to import the bulk semi-finished product should be issued to the applicant after the payment of necessary fees
7. If a product is already registered with subsisting product license, a permit to import bulk semi finished product should be issued without need to re-submit documents listed in B1 – B5 above. (The manufacturer’s information should remain the same as registered otherwise treat as Change of source)

#### **D INSPECTION**

Upon satisfactory evaluation of documents, Establishment Inspection Directorate should assess the GMP of the plant intended for packaging.

#### **E. PRODUCTS**

Upon satisfactory inspection of the packaging line, three (3) samples of the product intended for registration should be submitted with the following documents:

- i. A letter on the company’s letter head stating the company’s intention i.e. ‘Submission of product samples for registration’.
- ii. Copy of permit to import bulk semi – finished product.
- iii. Copy of receipt of payment for inspection.
- iv. Copy of product dossier with the product’s Certificate of Analysis for the batch submitted. (For drugs only).
- v. Certificate of analysis (For other regulated products)

## **F. LABELLING**

1. Product label should be clear, informative and accurate.
2. The minimum requirements on the package label are as follows:-
  - (a) Name of medicine (brand name) where applicable and generic name.
  - (b)
    - i. Name and full plant address of the manufacturer, vendor, packer or distributor etc.
    - ii. Name and address of manufacturer shall read manufactured by .....; Packaged by ..... (for drugs only).
  - (c) Provision for NAFDAC Registration / Listing Number on product label.
  - (d) Batch Number, Manufacturing date and Expiry date.
  - (e) Dosage form & strength. (as appropriate).
  - (f) Indications, frequency, route, conditions of administration (may be on the primary and secondary package label of OTC drugs but not on POM drugs).
  - (g) Dosage regimen on the package (OTC labels only).
  - (h) Package leaflet insert (as appropriate).
  - (i) Quantitative listing of all the active ingredients per unit dose.
  - (j) Adequate warnings (where necessary).
  - (k) Net content.
  - (l) A disclaimer stating “These claims have not been evaluated by NAFDAC” should be prominently written on the labels and literature insert of the product. (For herbal products only).
3. Where a brand name is used, the generic name should be conspicuous in character, VENTOLIN “SALBUTAMOL”
4. Any drug / related product whose name, package or 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 / related 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
6. Information on indication carried on package labels and package insert of imported drug products shall not differ from that in other countries, and in particular the country of origin of the product.

## **G TARIFF**

All payments to the Agency should be in bank draft in favour of the National Agency for Food and Drug Administration and Control.

1	Application Form =N=500:00.	
2	Prescription-only drug product	=N=175, 000:00 + 5% VAT
3	Over-the-Counter drug product	=N=700, 000:00 + 5% VAT
4	Nutraceuticals / food supplement product	=N=525, 000:00 + 5% VAT
5	Herbal drug product	=N=262, 500:00 + 5% VAT
6	Herbal drug product from ECOWAS.	=N=105, 000:00 + 5% VAT
7	Product line as GMP inspection fee	=N=10, 000: 00 + 5% VAT

#### NOTE

- (i) Registration of a product does not automatically confer Advertising permit. A separate approval by the Agency should be required for product advertisement.
- (ii) NAFDAC may withdraw the certificate of Registration in the event that the product is advertised without express approval from Agency.
- (iii) NAFDAC reserves the right to revoke, suspend or vary the certificate during its validity period.
- (iv) Filling an application form or paying for registration processing does not confer registration status.
- (v) Failure to respond promptly in writing to queries raised by NAFDAC on the application will automatically lead to suspension of further processing of the application.
- (vi) A successful application attracts a Certificate of Registration with a validity period of five (5) years or listing for two (2) years.

All correspondence in respect of registration should be addressed to:

THE DIRECTOR (R&R)  
NATIONAL AGENCY FOR FOOD & DRUG  
ADMINISTRATION AND CONTROL, CENTRAL LABORATORY  
COMPLEX, OSHODI, LAGOS  
NAFDAC website: [www.nafdac.gov.ng](http://www.nafdac.gov.ng)  
E-mail address: [registration@nafdac.gov.ng](mailto:registration@nafdac.gov.ng)  
telephone numbers: 234-1-4772452 - 3, 4772456, 4772458, 4703688, 4748627