

**GUIDELINES FOR THE REGISTRATION OF FOOD,  
COSMETICS, MEDICAL DEVICES AND BOTTLED  
WATER IN NIGERIA**

ISSUED BY

NATIONAL AGENCY FOR FOOD AND DRUG  
ADMINISTRATION AND CONTROL  
(NAFDAC)

## A. GENERAL

1. THESE GUIDELINES ARE FOR THE INTEREST OF THE GENERAL PUBLIC AND IN PARTICULAR, FOOD, COSMETICS, MEDICAL DEVICES AND BOTTLED WATER MANUFACTURERS AND IMPORTERS IN NIGERIA.
2. IT IS NECESSARY TO EMPHASIZE THAT, NO FOOD, COSMETICS, MEDICAL DEVICES AND BOTTLED WATER (REGULATED PRODUCTS) SHALL BE MANUFACTURED, IMPORTED, EXPORTED, ADVERTIZED, SOLD OR DISTRIBUTED IN NIGERIA UNLESS IT HAS BEEN REGISTERED IN ACCORDANCE WITH THE PROVISIONS OF DECREE 19 OF 1993 AND THE ACCOMPANYING GUIDELINES.

## B. APPLICATION / MANUFACTURER

1. (a.) An application for registration of a regulated product shall be made by the manufacturer.  
(b) In case of a manufacturer outside Nigeria such shall be represented in Nigeria by a duly registered company or individual with facilities to effect a recall of the product when necessary.  
(c) An applicant for a manufacturer outside Nigeria, must file an 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 and submitted to NAFDAC.

NOTE: The representative 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 decree or of any criminal abuse of the certificate in particular to the importation of falsely labeled, spurious, counterfeited or sub-standard related products.

(d) The manufacturer, in the case of imported products, must show evidence that the company is licensed to manufacture the related product for sale in the country of origin (Manufacturer's Certificate). Such evidence must be by the competent Health Authority of the country of manufacture, and shall be authenticated by the Nigerian Mission in that Country.

2. a. The applicant must submit to the office of the Director (Registration and Regulatory Affairs) NAFDAC, a written application, stating name of manufacturer, name (brand name, where applicable) of the product 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 amount per product in Bank Draft (MICR) issued in favour of NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC).

b. A separate application form shall be submitted for each regulated product.

## C. PRODUCT

1. A food, cosmetic, medical device or bottled water product (Regulated Products) shall not be manufactured in Nigeria, unless the factory is inspected and Certification of Recognition is issued by NAFDAC.
2. In case of imported products:-
  - a. There must be evidence of registration of such product by the competent Health Authority of the country of manufacturer i.e., Product License / Certificate of Registration.
  - b. There must be evidence by the competent Health Authority, that the sale of the products does not constitute a contravention of the Food/Cosmetic/Medical Devices Laws of the country i.e. **Free Sale Certificate**.

3. In the case of an **imported new products** there must be evidence that such product is registered in the country of origin and that the ingredients are approved raw materials.
4. An applicant shall not be allowed to register a product in more than one brand name, except in cases where the manufacturers are different having different brand names for the same formulation.
5. Evidence of trade mark approval from Fed. Ministry of Commerce in Nigeria.
6. Notarized Declaration to be Notarized by a Notary Public.
7. Comprehensive Certificate of analysis of the batch of product to be registered.
8. Certification of Incorporation of the applicant.

## D. LABELING

1. Labeling shall be informative and accurate.
2. Minimum requirements on the package label:-
  - a. Name of product- brand name or common name (where applicable) must appear in bold letters.
  - b. Location address of the manufacturer.
  - c. Provision of NAFDAC Registration Number on product label.
  - d. Batch No., Date of Manufacture and Best Before Date.
  - e. Net contents of essential ingredients in metric weight units in case of solids, semi solids and aerosols and metric volume in case of liquids.
  - f. In case of food, the ingredients must be listed by their common names in order of their predominance by weight unless the food is standardized, in which case

the label must include only those ingredients which the standard makes optional.

- g. Food additives and colours must be declared on the label. Spices, flavour and colours may be listed as such, without naming the the specific materials, but any artificial colour or flavours must be identified as such.

**h. Labeling of Food for Special Dietary Uses:**

“Special Dietary Use” may be defined as a particular use for which a food purports or is represented to be used, including, but not limited to the following

- i. Supplying a special dietary need that exists by reason of a physical, physiological, pathologically other conditions, including the condition of disease, convalescence, pregnancy, lactation, infancy, allergic, hypersensitivity to food, under weigh for the need to control sodium intake.
- (ii) Supplying a vitamin, mineral or other ingredient for use by humans to supplement the diet by increasing total dietary intake.
- (iii) Supplying a special dietary need by reason of being a food for use as the sole item of the diet. Manufacturers and importers of food in this class (including infant formula) must consult the Registration Division of the Agency before importing or manufacturing food represented by labeling or otherwise as special dietary food.
- (i) When special dietary foods and cosmetics are labeled with claims of disease prevention, treatment, mitigation, cure or diagnosis they must comply with the guidelines for drugs and be registered as medicinal products.
- (j) The label must contain directions for safe use where appropriate or necessary (on the information panel (IP) or on the package insert (PI).

(k) Any regulated 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).

**NOTE:**

(i). Failure to comply with these requirements may result in the disqualification of the application or lead to considerable delays in processing and registration.

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

(iii) 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.

(iv) NAFDAC may withdraw the Certificate of Registration in the event that the product is advertised without the express approval from the Agency.

(v) NAFDAC reserves the right to revoke, suspend or vary the certificate during the validity period.

(vi) FILLING AN APPLICATION FORM OR PAYING FOR AN APPLICATION FORM DOES NOT CONFER REGISTRATION STATUS.

(vi) FAILURE TO RESPOND PROMPTLY TO QUERIES ON ENQUIRIES RAISED BY NAFDAC ON THE APPLICATION, WILL AUTOMATICALLY LEAD TO SUSPENSION OF FURTHER PROCESSING OF THE APPLICATION.

(vii) All correspondence in respect of Drug Registration should be addressed to:

The Director,  
Registration & Regulatory Affairs  
NAFDAC  
Federal Secretariat Phase II  
Ikoyi, Lagos.

ISSUED BY:  
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