

DIRECTORATE OF REGISTRATION AND REGULATORY AFFAIRS

**GUIDELINES FOR RENEWAL OF IMPORTED REGISTERED REGULATED
PRODUCTS
NAFDAC/RR/010/00**

A. GENERAL:

1. These guidelines are for the industries who have registered their products with NAFDAC and to renew the expired product registration certificates.
2. It is necessary to emphasize that no regulated products shall 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. No importation shall be made by the applicant of regulated products with expired licence until it is renewed.
4. Initiating a renewal process on expiration of a product license should attract a fee of ₦50,000 per product

B. APPLICATION:

1. An application for renewal of product registration certificate shall be made on company's letterhead addressed to Director, Registration and Regulatory Affairs Directorate, NAFDAC.
2. Applicant shall purchase and duly fill out the prescribed Form.
3. If the status of the product is the same as when it was registered, the applicant shall submit only current renewable documents as follows:
 - i. Current Certificate of Pharmaceutical Product (drugs products only).
 - ii. Authenticated Good Manufacturing Practice Certificate (GMP).
 - iii. Annual licence to practice of the Superintendent

Pharmacist (for drug product only) issued by Pharmacists Council of Nigeria.

iv. Current Certificate of Registration Retention of Premises issued by the Pharmacists Council of Nigeria (for drug products).

v. Combined Certificate of Manufacture and Free Sales.

vi. Certificate of Analysis.

vii. The applicant shall submit evidence of registration of the brand name (where applicable)

viii. copy of the registration certificate of the product.

4. If change occurred in the status of the product at renewal e.g. in manufacturing source, application should be processed as new. (Please refer to Guidelines for product registration as appropriate).

5. The applicant shall submit three (3) vetting samples per product as it was registered by NAFDAC.

C. PRODUCT LABEL:

1. The product sample submitted for registration renewal shall conform to NAFDAC's labeling requirements (as applicable).

2. The labeling shall be informative, clear and accurate.

3. The labeling should be in English.

4. The product samples shall bear the registration number assigned to it when first registered on the labels.

D. TARIFF:

The applicant shall pay the prescribed fees in the bank draft in favour of National Agency for Food and Drug Administration and Control as follows:

- | | | | |
|----------------------------|---|------------------------|-------|
| (1) a. Drug Products: | - | =N=600,000.00 + 5% VAT | (OTC) |
| | - | =N=250,000.00 + 5% VAT | (POM) |
| b. Drug Products | | | |
| from ECOWAS:- | - | =N=125,000.00 + 5% VAT | (POM) |
| | - | =N=250,000.00 + 5% VAT | (OTC) |
| (2) Cosmetics: | | =N=450,000.00 + 5% VAT | |
| (3) Veterinary Drugs: | | =N=250,000.00 + 5% VAT | |
| (4) Pesticides: | | =N=200,000.00 + 5% VAT | |
| (5) Medical Devices | | =N=250,000.00 + 5% VAT | |
| (6) Vaccines/Biologicals : | | =N=150,000.00 + 5% VAT | |
| (7) Herbal Medicines: | | =N=225,000.00 + 5% VAT | |
| Herbal medicines from | | | |
| ECOWAS | | =N=150,000.00 + 5% VAT | |
| (8) Nutraceuticals | | =N=450,000.00 + 5% VAT | |
| (9) Imported Foods: | | =N=450,000.00 + 5% VAT | |
| Foods from ECOWAS | | =N=112,000.00 + 5% VAT | |
| (10) Drug Form | | =N=500 | |
| (11) Herbal drug form | | =N=500 | |
| (11) Food Form | | | |
| and other related | | | |
| products forms | | =N=250 | |
| Late renewal | | =N=50,000.00 + 5% VAT | |

E. TIME LINE

Time line for renewal of regulated products should be as follows:

- | | | | |
|----|-----------------------------------|---|--------------|
| 1. | Drug | - | 35 work days |
| 2. | Food and other regulated products | - | 30 work days |

All correspondences and applicant should be:

The Director
 Registration and Regulatory Affairs Directorate
 NAFDAC
 Central Laboratory Complex
 Oshodi
 NAFDAC website: www.nafdac.gov.ng.
 e-mail address: registration@nafdac.gov.ng.
 tel number: +234-1-4772452