# National Agency for Food & Drug Administration & Control (NAFDAC)

## Drug Registration & Regulatory Affairs (Drug R&R) Directorate

# GUIDELINES FOR RENEWAL OF CERTIFICATE OF REGISTRATION FOR IMPORTED DRUG PRODUCTS IN NIGERIA (HUMAN AND VETERINARY DRUGS)

## 1.0. General

1.1. The National Agency for Food and Drug Administration and Control has the responsibility of ensuring that imported drugs placed on the Nigerian market for use meet the requirements for Quality, Safety and Efficacy throughout the lifecycle of the product.

1.2. The procedure for registration of imported drugs outlines the process to be followed and the technical requirements to be met before a product can be placed on the Nigerian market.

1.3. A product authorized for marketing in Nigeria will be issued a Certificate of Registration valid for 5 years (or less in some cases) and should be renewed upon expiration.

1.4. These guidelines are intended to provide guidance on the technical and other general data requirements when submitting an application for renewal of product license for an imported drug.

1.5 To initiate the renewal process for a drug product, the Applicant is required to submit a Product Quality Review (PQR)/ Dossier of the drug product. (See Guidance Document for Submission of Dossier)

**Step I**

## 2.0. Application Letter for Renewal of Product Licence

2.1. An application for renewal should be initiated not later than 30 calendar days to the date of expiration of the current/valid Licence.

2.2. An application for the renewal of drug products should be submitted and processed on the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) portal - https://registration.nafdac.gov.ng. For more information see the NAPAMS User Manual

2.3. The renewal application should be addressed to the Director-General (NAFDAC), ATTENTION: The Director, Registration & Regulatory Affairs (R & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, and Lagos State.

2.4. A separate application form should be submitted for each product

**Step II**

3.0. **Documentation**

The following documents are the requirements for submission of an application for renewal of product license. Submission of application should follow the "NAFDAC Procedures for Submission of Applications"

3.1. **Premises Registration**

The current Annual Licence to practice and the Certificate of Retention of Premises for the

Superintendent Pharmacist issued by the Pharmacy Council of Nigeria should be submitted.

3.2. **Manufacturing Licence**

3.2.1. Issued by a relevant health/regulatory body in the country of manufacture

3.2.2. Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian embassy exists, any Commonwealth or ECOWAS country can authenticate.

3.2.3. Indicate Name and address of manufacturer and the products to be registered.

3.3. **Certificate of Pharmaceutical Product (COPP-WHO Format)**

3.3.1. Issued by a relevant health/regulatory body in the country of manufacturer

3.3.2. Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian embassy exists, any Commonwealth or ECOWAS country can authenticate. Indicate Name and address of manufacturer and the products to be registered.

3.4. **Evidence of expired NAFDAC licence**

A copy of the expired Certificate of Registration for the product(s).

3.6. **Evidence of Registration of Brand Name/Trademark**

Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be done in the name of the owner of the Trademark/Brand name.

3.7. **Notarized Declaration**

A declaration by the applicant regarding the correctness, completeness and accuracy of all documents submitted should be provided. The format should be in line with the template attached as Annex 2 in this guideline. This document must be notarized by a notary public.

3.8. **Power of Attorney/Contract Manufacturing Agreement** (where applicable) At the expiration of a product license, the Power of Attorney or Contract Manufacturing Agreement may have lapsed except in cases when a specific expiration date was specified in the original power of attorney or contract manufacturing agreement or a statement that the power of attorney is for an indefinite period. Except in the cases stated above, an applicant will be required to submit a new power of attorney or contract manufacturing agreement at renewal.

The document shall give details of:

3.8.1. The Issuer and the Receiver of the Power of Attorney and in the case of a Contract Manufacturing Agreement, the parties involved with their specific roles and the terms of the contract agreement.

3.8.2. A list of the products covered by the power of attorney (this can come as an annexure for large number of products but must form part of the power of attorney with a specific reference to the annexure stated on the power of attorney).

3.8.3. State ownership of Brand name/s or Trademark.

3.8.4. The validity of the power of attorney should be stated and it should not be less than 5 years.

3.8.5. The document must be signed by the authorized person(s) and should be notarized by a notary public in the country of manufacture.

3.9. **List of Approved Variations** (where applicable)

Indicate the type of variations and respective dates of approval

For Information on the Inspection of manufacturing facility, applicant should visit the Drug Evaluation and Research (DER) Directorate section of the Agency's website.

**Step III**

4.0. **Issuance of Notice of Renewal**

3.1 Upon satisfactory review of submitted documents and satisfactory GMP notice of renewal shall be issued.

**Step IV**

5.0. **Submission of laboratory samples**

The following documents are required;

5.0.1 Letter for submission of laboratory samples.

5.0.2 Evidence of payment of processing fee.

5.0.3 Certificate of analysis.

The Certificate of Analysis must be presented on a letter-head of the quality control laboratory where the sample was tested/evaluated and should contain the under listed information:

5.0.3.1 The brand name of the product

5.0.3.2 The batch number of the product

5.0.3.3 The manufacturing and expiry dates

5.0.3.4 The name, designation and signature of the analyst

5.0.4 A copy of Notice of Renewal

**Step V**

6.0. **Product Approval meeting**

Upon meeting all regulatory requirements, product is presented for Approval Meeting.

**Step VI**

7.0. **Issuance of Notification**

For products approved at the meeting, an electronic certificate of Renewal of Product Registration is issued to the applicant.

8.0. **Labelling Guidelines for Imported Drugs**

The product label at renewal should be the same as first approval, unless an approval for a change in Labelling was gotten.

9.0. **Tariff**

Please see relevant section of the NAFDAC Tariff.

10.0**. Note**

10.0. Failure to comply with these requirements may result in the disqualification of the renewal application or lead to considerable delay in the processing of registration.

10.1. A successful renewal application will be issued a Certificate of Registration with a validity period of five (5) years.

10.2. Renewal of Registration of a product does not automatically confer Advertising Permit. A separate application and subsequent approval by the Agency shall be required if the product is to be advertised. Simultaneous submission of registration and advertisement applications are allowed.

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

10.4. Filing an application form or paying an application fee does not confer

registration status.

10.5. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (within 45 working days) will automatically lead to the closure of the Application.

10.6. The timeline for product registration from acceptance of submissions to issuance of Registration number is sixty (60) working days.

10.7. Please note that the clock stops once compliances are issued.

All correspondences should be addressed to:-

Director-General (NAFDAC),
**Attn:** The Director,
Drug Registration and Regulatory Affairs Directorate,
National Agency for Food and Drug Administration and Control,
Ground Floor, NAFDAC Office Complex
Isolo Industrial Estate
Apapa-Oshodi Expressway, Isolo, Lagos

NAFDAC website: www.nafdac.gov.ng
E-mail: registration@nafdac.gov.ng
Telephone no.: +234-1-4772452

## Annex 1

## Product Quality Review (PQR)

A product quality review should be submitted with the objective of verifying the consistency of the quality of the FPP and its manufacturing process.

Rejected batches should not be included in the analysis but must be reported separately together with the reports of failure investigations, as indicated below.

Reviews should be conducted with no fewer than 10 consecutive batches manufactured over the period of the past 12 months or, where 10 batches were not manufactured in the past 12 months, no fewer than 25 consecutive batches manufactured over the period of the past 36 months and should include at least:

1. a review of starting and primary packaging materials used in the FPP, especially those from new sources;
2. a tabulated review and statistical analysis of quality control and in-process control results;
3. a review of all batches that failed to meet established specification(s);
4. a review of all critical deviations or non-conformances and related investigations;
5. a review of all changes carried out to the processes or analytical methods;
6. a review of the results of the stability-monitoring programme;
7. a review of all quality-related returns, complaints and recalls, including export-only medicinal products;
8. a review of the adequacy of previous corrective actions;
9. a list of validated analytical and manufacturing procedures and their revalidation dates.
10. a review of all adverse drug reactions observed and action taken.
11. Review of Periodic Risk-Benefit Evaluation (PBRER) Reports.
12. Review of Post Marketing Surveillance activities.

Further Notes

1. Reviews must include data from all batches manufactured during the review period.
2. Data should be presented in tabular or graphical form, when applicable.
3. The above listing of requirements is specific to the dossier assessment process requirements and does not relieve the applicant of related GMP requirements.

## Annex 2

## Notarized Declaration Template

I Applicant's Name the Managing Director of Applicant's Company Name hereby declare on oath and state as follows:

1. That Applicant's Company Name of Applicant's Company Address forwarded an application to the National Agency for Food and Drug Administration and Control for the Registration of regulated products hereinafter listed:
   a. List of Products (Product Names)
   b. _____

Pursuant to the provisions of Food and Drugs and Regulated Products (REG etc.) Act Cap F33 LFN 2004 and all relevant Regulations as representatives of Manufacturer's Company Name

2. That the said application before the National Agency for Food and Drug Administration and Control for the registration of the above listed Products, the application No: Applicant Form No thereof and the attached documents viz:
   a. Power of attorney / Contract Manufacturing Agreement and notarization thereof
   b. Certificates of Pharmaceutical Product/ Certificate of Manufacture and/or Free Sale and the authentication thereof by the Nigerian Mission in the country of origin
   c. Manufacturing license / Certificate for companies from India and China and the authentication thereof by the Nigerian Mission in the country of origin
   d. Certificate of Good Manufacturing Practice (GMP) and the authentication thereof by the Nigerian
      Mission in the country of origin
   e. Certificate of Analysis of product
   f. Evidence of Registration of Trademark and the information contained in all the above referred documents is true and correct.
3. a. That the manufacturer Manufacturer's Company Name is or is not the owner of the trademark b. The product name(s) is generic

4. a. That Applicant's Company Name of Applicant's Company Address is or is not the owner of the trademark.

   b. The product _____ is generic
5. That Applicant's Company Name and the declarant shall indemnify the National Agency for Food and Drug Administration and Control against any suit, claim, damages or liability arising from the use of all documents submitted and information declared by us in the processing, approval and grant of any certificate of registration in respect of Product Name(s)
6. We agree to be held criminally liable for any false declaration made herein and forged documents submitted to the National Agency for Food and Drug Administration and Control in respect of the application for the registration of Product Name(s)

Signature & Date
DECLARANT (Applicant)

BEFORE ME

NOTARY PUBLIC (NBA Seal)

NAME: ……
ADDRESS: ……
SIGNATURE: ……
DATE: ……