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

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

GUIDELINES FOR RENEWAL OF CERTIFICATE OF REGISTRATION FOR LOCALLY MANUFACTURED 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 a locally manufactured 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 applying for renewal of product license for a locally manufactured drug product.

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, Drug Registration & Regulatory Affairs (DR&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. **Annual License/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. **Evidence of expired NAFDAC license**

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

3.3. **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.

3.4. **Contract Manufacturing Agreement** (where applicable) At the expiration of a product license, Contract Manufacturing Agreement may have lapsed except in cases when a specific expiration date was specified in the original contract manufacturing agreement. in the cases stated above, an applicant will be required to submit a new contract manufacturing agreement at renewal.

The document shall give details of:

3.4.1. In the Contract Manufacturing Agreement, the parties involved with their specific roles and the terms of the contract agreement should be stated.

3.4.2. A list of the products covered by the agreement (this can come as an annexure for large number of products but must form part of the Contract Manufacturing Agreement with a specific reference to the annexure stated on the agreement).

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

3.5. **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**

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

Step IV

5.0. **Product Approval meeting**

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

Step V

6.0. **Issuance of Notification**

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

7.0. **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.

8.0. **Tariff**

Please see relevant section of the NAFDAC Tariff.

9.0**. Note**

9.1. 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.

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

9.3. 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.

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

9.5. Filing an application form or paying an application fee does not confer registration status.

9.6. 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.

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

9.8. 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.