



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

Registration & Regulatory Affairs (R & R) Directorate

GUIDELINES FOR RENEWAL OF CERTIFICATE OF REGISTRATION FOR DRUGS MADE IN NIGERIA

1.0. General

- 1.1. The National Agency for Food and Drug Administration and Control has the responsibility of ensuring that drug made in Nigeria 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 drug made in Nigeria 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 licence for drug made in Nigeria.

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 applicant is required to submit an application letter stating their intention to renew the Certificate of Registration for the drugs made in Nigeria.
- 2.3. The application should be made on the company's letter head which should contain the current/valid email address and telephone number of the applicant.
- 2.4. The applicant should provide the details of the product(s) for renewal and clearly state the purpose in the body of the letter along with the contact details of the manufacturer of the product(s) (i.e. name, address email and telephone number of the contact person).
- 2.5. The letter should be dated and signed by Managing Director, Superintendent Pharmacist or a staff of the company so delegated to sign on behalf of the other two officers (evidence of delegation should be provided).
- 2.6. 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.
- 2.7. An online application form for Product Registration should be purchased at; <http://registration.nafdac.gov.ng> and completed.
- 2.8. 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 licence. Submission of application should follow the "NAFDAC Procedures for Submission of Applications".

3.1. Premises Registration

A copy of 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. Expired NAFDAC Licence

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

3.3. Certificate 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. Product Quality Review (PQR)

3.4.1. A Product Quality Review should be submitted with the objective of verifying the consistency of the quality of the FPP and its manufacturing process. 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. Batches manufactured at a scale lower than those stated above will be handled on a case by case basis and more extensive documentation may be required in such cases.

3.5. Contract Manufacturing Agreement (where applicable)

At the expiration of a product licence, the Contract Manufacturing Agreement may have lapsed except in cases when a specific expiration date was specified in the original contract manufacturing agreement or a statement that the agreement is for an indefinite period. Except 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:

3.5.1. The Issuer and the Receiver of the Contract Manufacturing Agreement, the parties involved with their specific roles and the terms of the contract agreement.

- 3.5.2. A list of the products covered by Contract Manufacturing 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 Contract).
- 3.5.3. State ownership of Brand name/s or Trademark.
- 3.5.4. The validity of the Contract Manufacturing Agreement should be stated and it should not be less than 5 years.
- 3.5.5. The document must be signed by the authorized person(s) and should be notarized by a notary public.

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

- 3.6.1. Indicate the type of variations and respective dates of approval

Step III

4.0. **Issuance of Notice of Renewal**

Upon successful submission of all required documents, the Notice of Renewal is issued to the applicant.

Step IV

5.0. **Product Sampling:**

- 5.1. Product sampling for Renewal of marketing authorization will be based on laboratory reports emanating from any of the following activities within the validity of current licence:
 - 5.1.1. Pharmacovigilance monitoring
 - 5.1.2. Ports Inspection and Distribution channels sampling
 - 5.1.3. Routine facility Inspections/Audits
- 5.2. In the event that there is a need to conduct laboratory analysis, there will be a request for samples of the product.

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, Notification of Renewal of Registration or Listing is issued to the applicant while compliance directive is issued to those not approved.

8.0. Labelling Guidelines for Imported Drugs

Labelling shall be in compliance with the Agency's Drug Labelling Regulations

9.0. Tariff

Please see Tariff section.

10. Note

- 10.1. 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.
- 10.2. A successful renewal application will be issued a Certificate of Registration with a validity period of five (5) years.
- 10.3. Renewal of Registration of a product does not automatically confer Advertising Permit (where applicable). 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.
- 10.4. NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period.
- 10.5. Filing a renewal application form or paying the renewal application fee does not confer registration status.
- 10.6. 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.
- 10.7. The time line for product registration from acceptance of submissions to issuance of Registration number is sixty (60) working days.
- 10.8. Please note that the clock stops once compliances are issued.

All correspondences should be addressed to:-

Director-General (NAFDAC),

Attn: The Director

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.