



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

Registration & Regulatory Affairs (R & R) Directorate

Guidelines for Renewal of Certificate of Product Registration for (Imported and Locally Manufactured) Medical Devices in Nigeria

1.0. **General**

- 1.1. The National Agency for Food and Drug Administration and Control has the responsibility of ensuring that imported Medical Devices placed on the Nigerian market for use meet the requirements for Quality, Safety and Efficacy throughout the life cycle of the product.
- 1.2. The procedure for registration of imported Medical Devices 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 imported Medical Devices.
- 1.5. **NOTE: These Guidelines should be read in conjunction with all relevant IMDRF guidance documents including the following;**
 - a. GHTF/SG1/N71:2012 "Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'" [GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical Device's \(imdrf.org\)](#)
 - b. In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC), IMDRF/RPS WG/N13(Edition 2) FINAL:2019
<https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-ivd-mdma-toc-n13.docx>
 - c. GHTF/SG1/N70:2011 "Label and Instructions for Use for Medical Devices" [GHTF SG1 - Label and Instructions for Use for Medical Devices - September 2011 \(imdrf.org\)](#)
 - d. Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVDMAToC), IMDRF/RPS WG/N9(Edition 3) FINAL:2019
[Non-In Vitro Diagnostic Device Market Authorization Table of Contents \(nIVD MA ToC\) \(imdrf.org\)](#)

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 medical devices 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 or Chief Executive Officer

- or a staff of the company so delegated to sign (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; <https://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. **Certificate of Manufacture and Free Sale** (for imported Medical Devices only)
 - 3.1.1. To be issued by a relevant Health/Regulatory body in the country of Manufacture.
 - 3.1.2. Indicate the name of manufacturer and products registered.
 - 3.1.3. 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 this document.
- 3.2. **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.
- 3.3. **Expired NAFDAC Licence**

A copy of the Certificate of Registration for the product(s).
- 3.4. **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 1 in this guideline. This document must be notarized by a notary public.
- 3.5. **Power of Attorney** (for imported Medical Devices only)/**Contract Manufacturing Agreement** (where applicable)

At the expiration of a product licence, 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:

 - 3.5.1. 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.
 - 3.5.2. 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).

- 3.5.3. State ownership of Brand name/s or Trademark.
- 3.5.4. The validity of the power of attorney 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 in the country of manufacture.

Step III

4.0 Issuance of Notice of Renewal

Upon successful submission of all required documents and completion of GMP processing on the NAPAMS e-reg portal, a Notice of Renewal is issued to the applicant via the portal

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 New Certificate

For products approved at the meeting, a new Certificate of Registration or Listing is issued to the applicant while compliance directive is issued to those not approved.

8.0 Labelling Guidelines for Imported Medical Devices

Labelling shall be in compliance with the Agency's Medical Devices and related products 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. 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 an application form or paying an application fee does not confer registration status.
- 10.6. Failure to respond promptly to queries or enquiries raised by NAFDAC on the renewal application (within 45 working days) will automatically lead to the closure of the Application.
- 10.7. The time line for the renewal of 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
Notarised 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. 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 licence/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:.....