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

Registration and Regulatory Affairs (R & R) Directorate

GUIDELINES FOR REGISTRATION OF IMPORTED MEDICAL DEVICES IN NIGERIA

1. **General**

1.1. These Guidelines are for the interest of the general public and in particular Importers of Medical Devices in Nigeria.

1.2. It is necessary to emphasize that, no Medical Device shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

2. **Applications**

2.1. A written application for registration of imported medical devices should be made on the company's letter head paper to the Director-General (NAFDAC), ATTENTION: The Director, Registration and Regulatory Affairs (R & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, and Lagos State.

2.2. The application letter should include the common name of product and brand name (where applicable).

2.3. An online application form for Product Registration should be purchased at; http://registration.nafdac.gov.ng and completed.

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

Step 1

3. **Documentation**

3.1. The following documents (all originals) and two (2) sets of photocopies (including print-out of the completed online Registration form) are to be submitted at the Liaison Office of the Director (LOD), R & R Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State or any NAFDAC Office (outside Lagos):

3.1.1. Notarised Declaration (Appendix 1). To be completed (typed), signed by Declarant and notarized by a Notary Public in Nigeria.

3.1.2. Power of Attorney or Contract Manufacturing Agreement. An applicant on behalf of a manufacturer outside Nigeria must file an evidence of Power of Attorney from the manufacturer which authorizes him to speak for his Principal, on all matters relating to the latter's specialties. The Power of Attorney shall (be):

3.1.2.1. Issued by the manufacturer of the product.

3.1.2.2. Signed by the Managing Director, General Manager, Chairman or President of the company, stating the names of the products to be

registered. The power of attorney shall also indicate 'Authority to register product with NAFDAC'.

3.1.2.3. State ownership of Brand name(s)/Trademark.

3.1.2.4. Notarized by a Notary Public in the country of manufacture.

3.1.2.5. Valid for at least five (5) years.

3.1.3. Contract Manufacturing Agreement: An applicant filing an application on behalf of his company, and being the owner of the product, shall provide a Contract Manufacturing Agreement, which shall be signed by himself (or his competent representative) and the manufacturer. The Agreement shall be

3.1.3.1. Notarized by a Notary Public in the country of manufacture.

3.1.3.2. Signed by both parties stating names and designations of the signatories with the names of all the products to be registered and other relevant clauses clearly explained in an unambiguous language.

3.1.4. Certificate of Manufacture and Free Sale. The manufacturer must show evidence that the company is licensed to manufacture medical devices and that the sale of the product does not constitute a contravention of the laws of that country, i.e. Free Sale Certificate (Certificate of Manufacture and Free Sale). The Free Sale Certificate should:

3.1.4.1. Be issued by a relevant Health/Regulatory body in the country of manufacture.

3.1.4.2. Indicate the name of manufacturer and products to be registered.

3.1.4.3. 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 the document.

3.1.5. Comprehensive Certificate of Analysis. The certificate of analysis must be presented on a letter-headed paper of the Quality Control Laboratory where the sample was tested/evaluated and should contain the under listed information:

3.1.5.1. The brand name of the product

3.1.5.2. The batch number of the product

3.1.5.3. The manufacturing and expiry dates

3.1.5.4. The name, designation and signature of the analyst.

3.1.6. Evidence of Business Incorporation of the importing company with the Corporate Affairs Commission in Nigeria.

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

of the Trademark/Brand name as the case may be.

3.1.8. Label or artwork of the product

3.1.9. Letter of Invitation for Good Manufacturing Practice (GMP) Inspection: A letter of invitation to inspect the factory abroad shall be written by the manufacturer and shall state the following:

3.1.9.1. MANUFACTURER INFORMATION: Name of Company, full location address of factory (not administrative office address), e-mail, and current phone no. Details (name, phone number and email) of contact person overseas.

3.1.9.2. LOCAL AGENT INFORMATION: Name of company, full location address, functional phone number. and e-mail address. Details (name, phone number and email) of contact person. Names(s) of product(s) for registration.

Step II

4. **Import Permit**

4.1. Upon successful screening of documentation and review of supporting documents, an Import Permit shall be issued after which the product will be submitted for vetting.

Step III

5. **Submission of products for laboratory analysis**

5.1. After successful vetting of product labels, laboratory samples are submitted. The following documents are included;

5.1.1. Evidence of payment to the Agency

5.1.2. Certificate of analysis

5.1.3. Evidence of submission for vetting

Step IV

6. **Product Approval meeting**

6.1. Upon satisfactory documentation review, satisfactory GMP of the production facility and satisfactory laboratory analysis of product, products are presented for Approval Meetings.

6.2. For products labels with compliance issues, compliant artworks may be submitted with a commitment letter from the manufacturer (stating that the commercial products will be in compliance).

STEP 5

7. **Issuance of Notification**

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

8. **Labelling Guidelines for Imported Medical Devices**

8.1. Labelling should be informative, accurate and in conformance with the Agency's Medical Devices Labelling Regulations and any other relevant Regulations.

9. **Tariff**

9.1. Please refer to Tariff section.

10. **Note**

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

10.2. A successful application will be issued a Certificate of Registration with a validity period of five (5) years or two (2) years as applicable.

10.3. 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 application (within 90 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 one hundred and twenty (120) working days.

10.8. Please note that the clock stops once compliance directives 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

All submissions should be made at the Office of the Director, R & R, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (for those outside Lagos).

APPENDIX I

NOTARIZED DECLARATION

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

   c. The product _____ 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: _____