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

Ports Inspection Directorate (PID)

GUIDELINES FOR CLEARING IMPORTED FINISHED PHARMACEUTICAL, NUTRACEUTICALS AND HERBAL PRODUCTS (HUMAN AND VETERINARY) AT PORTS OF ENTRY IN NIGERIA

1. **General**

1.1. These Guidelines are for the interest of the general public and in particular importers of Finished Pharmaceutical, Nutraceutical and Herbal products (Human and Veterinary) into Nigeria.

1.2. It is necessary to emphasize that, no Finished Pharmaceutical, Nutraceutical and Herbal products (Human and Veterinary) shall be manufactured, imported, advertised, offered for sale, 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.

Step I

2. **Payment**

2.1. The applicant is required to visit:

2.1.1. E-clearance office at Ports Inspection Directorate, Yaba, Lagos State to obtain Payment Advice for the clearance of the products (applicable for applicants not online).

2.1.2. www.remita.net to generate Remita invoice and print out a copy of the invoice.

2.1.3. Any nearest commercial bank for payment.

2.1.4. NAFDAC Accounts Office to collect receipt of payment.

Step II

3. **Submission of Documents for First Endorsement**

3.1. The applicant is to write an Indemnity Letter addressed to the Director-General, National Agency for Food and Drug Administration and Control (NAFDAC); ATTENTION: The Director, Ports Inspection Directorate, NAFDAC, Yaba, Lagos State. The letter should state that:

3.1.1. The Agency will be informed 48hrs before the arrival of the product.

3.1.2. The Agency will be duly invited for examination of the consignment.

3.1.3. Product will not be sold or distributed without the satisfactory pronouncement by the Agency.

3.2. The letter should be submitted via email (ports@nafdac.gov.ng) or at the Ports Inspection Directorate, Yaba, Lagos State [or any NAFDAC Office (outside Lagos)] and should be accompanied with the following documents;

3.2.1. Single Goods Declaration (SGD) Form

3.2.2. Commercial invoice
3.2.3. Pre-Arrival Assessment Report (PAAR)
3.2.4. Form M
3.2.5. Bill of Lading/Airway Bill
3.2.6. Packing List
3.2.7. Form C-30
3.2.8. Evidence of payment advice issued
3.2.9. Valid Import Permit (for products containing Narcotic and Controlled Substances)
3.2.10. Valid Permit to Clear (for products containing Narcotic and Controlled Substances)
3.2.11. Evidence of valid product registration with NAFDAC
3.2.12. Original copy of Certificate of analysis from manufacturer
3.2.13. Original copy of Clean Report of Inspection and Analysis (CRIA) for products coming from China, Egypt and India.
3.2.14. Evidence of payment to the Agency
3.2.15. Pre-shipment notice
3.2.16. Valid Certificate of registration of premise by Pharmacists Council of Nigeria
3.2.17. Valid Pharmacist's Annual License to Practice
3.2.18. Approval for Letter of no objection (where applicable?)

Step III

4. **First Endorsement**

4.1. Upon satisfactory vetting of the application and accompanying documents, the Single Declaration Goods Form (SGD) is given the First Endorsement.

Step IV

5. **Joint Inspection of Consignment**

5.1. Joint Inspection of the consignment is carried out by NAFDAC and other relevant Government organizations.

Step V

6. **Second Endorsement**

6.1. The company representative is required to re-present all documents presented for First Endorsement. This should be accompanied with the report of the Joint Inspection and sample of product (s) in line with the Agency's applicable sampling Guideline for verification.

Step VI

7. **Release of consignment**

7.1. Upon satisfactory verification of the documents and product sample for the purpose of Second Endorsement, the Single Goods Declaration Form is given Second Endorsement which is the release of the consignment to the importer.

8. **Note**

8.1. Finished Pharmaceutical, Nutraceutical and Herbal products can only be marketed and used after a satisfactory Laboratory evaluation. In case of unsatisfactory laboratory analysis report, the consignment is placed on Hold. This may be for destruction or for further investigation which may include retest by the Agency and/or independent laboratory.

8.2. The timelines for the various processes include;

8.2.1. Cost assessment and issuance of Payment Advice is Ten (10) minutes

8.2.2. Issuance of first endorsement is Thirty (30) minutes

8.2.3. Physical inspection as determined by the Joint Task Force is Two (2) hours

8.2.4. Issuance of second endorsement is Fifteen (15) minutes

8.3. Note that the timeline for processing is suspended when there is a compliance directive and resumes when applicant complies and communicates compliance to the Agency.

All correspondence should be addressed to:-

The Director-General (NAFDAC)
Attn: The Director,
Ports Inspection Directorate,
NAFDAC Laboratory Complex,
Edmund Crescent, Medical Compound,
Yaba, Lagos state.
Website: www.nafdac.gov.ng
E-mail address: ports@nafdac.gov.ng

All submissions should be made at the Office of the Director, Ports Inspection Directorate, NAFDAC Laboratory Complex, Edmund Crescent, Medical Compound, Yaba, Lagos state or

the nearest NAFDAC Office (outside Lagos).