

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

Ports Inspection Directorate (PID)

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

1. General

- 1.1 These guidelines are intended for the benefit of the general public, especially importers of Finished Pharmaceutical (Human and Veterinary), Nutraceutical, and Herbal products into Nigeria.
- 1.2 It is crucial to emphasize that no Finished Pharmaceutical (Human and Veterinary), Nutraceutical, or Herbal products shall be manufactured, imported, advertised, offered for sale, distributed, or used in Nigeria unless they have been registered in accordance with the provisions of the NAFDAC Act CAP N1 (LFN) 2004, other related legislation, and the accompanying guidelines.

Step I

2. Application.

- 2.1 An Applicant intending to clear Finished Pharmaceutical (Human and Veterinary), Nutraceutical, and Herbal products at the port of entry in Nigeria should submit their request through the Ports Inspection Data Capture and Risk Management System (PIDCARMS) portal on URL: https://ports.nafdac.gov.ng.
- 2.2 Applicant should follow the link "Submit New SGD Clearance Request/Check Request Status" on the PIDCARMS Home Page and follow the prompt on the portal to submit the request. For clarity, the Applicant should follow the instructions on the "User Manual" available for download on the site.
- 2.3 The following documents are required to be uploaded in PDF file;
 - 2.3.1 The applicant must write an Indemnity Letter addressed to the Director-General of the National Agency for Food and Drug Administration and Control (NAFDAC), attention: The Director, Ports Inspection Directorate, NAFDAC, Yaba, Lagos State. The letter should state:
 - 2.3.1.1 The Agency will be informed 48hrs before the arrival of the product.
 - 2.3.1.2 The Agency will be duly invited for examination of the consignment.
 - 2.3.1.3 Product will not be sold or distributed without the satisfactory pronouncement by NAFDAC.
 - 2.3.1.4 That the product(s) will be forfeited for destruction if found unsatisfactory.
 - 2.3.1.5 The location address of the company's warehouse.
 - 2.3.1.6 The letter should be signed by the Importer/ Superintendent Pharmacist/CEO.
- 2.4 Current NAFDAC import permit.
- 2.5 Original copy of Certificate of Analysis from manufacturer.
- 2.6 Letter of authority introducing the declarant with means of identification.

- 2.7 The letter should be submitted along with the following documents:
- 2.8 Single Goods Declaration (SGD) Form
- 2.9 Commercial invoice
- 2.10 Pre-Arrival Assessment Report (PAAR)
- 2.11 Bill of Lading/Airway Bill
- 2.12 Packing List
- 2.13 Form M
- 2.14 Form C30
- 2.15 Clean Report of Inspection and Analysis- (where applicable)
- 2.16 Evidence of Product registration with NAFDAC (Where applicable)
- 2.17 Certificate of analysis from the manufacturer
- 2.18 Valid Certificate of registration of premises by the Pharmacists Council of Nigeria/Veterinary Council of Nigeria (for Pharmaceuticals)
- 2.19 Valid Pharmacist's Annual License to Practice/Veterinary License (For Pharmaceuticals)
- 2.20 Approval of Letter of Non-Objection (Where applicable).

Step II:

3. Cost Assessment/ Payment:

- 3.1. Upon satisfactory verification of the application and accompanying documents (referred to as an entry), and cost assessment is carried out on the entry, an electronic invoice (e-invoice) is issued and sent to the applicant via the e- mail address provided on Ports Inspection Data Capture and Risk Management Systems (PIDCARMS).
- 3.2. Upon receipt of e- invoice, Applicant should make payment using the Remita Retrieval Reference (RRR) number on the e- invoice by either visiting any nearest bank or via on-line platform (s).
- 3.3. Payment is auto detected and NAFDAC receipt of payment is sent to applicant's registered email.

Step III.

4. Tariff

4.1 Please refer to tariff section.

Step IV

5. Endorsement

5.1 Upon satisfactory vetting of the application and accompanying documents, the client receives a notification to proceed for physical inspection at the port of entry. However, a compliance directive is issued for any deficiencies in documentation or observed violations.

Step V 6. Physical examination

- **6.1** Physical examination of the consignment should be conducted by NAFDAC with other relevant Government Agencies at the port of entry or Importer's warehouse where applicable.
- 6.2 Samples of the imported product(s) should be drawn during physical examination by NAFDAC Inspectors and forwarded to the relevant NAFDAC laboratory for analysis.
- 6.3 The client also receives a sample receipt form indicating the products sampled in accordance with the approved sampling guideline.

Step VI:

7. Release of Consignment

- 7.1 The company's representative proceeds to NAFDAC office at the port of entry with the physical inspection form, product samples, and original documents and their copies for submission.
- 7.2 Upon satisfactory verification of the documents, physical inspection form, and product(s) sampled in line with the Agency's approved sampling Guideline, the client receives a notification of release in their email address. However, a compliance directive is issued for any deficiencies in documentation or observed violations.

8. Note

- 8.1 Finished Pharmaceutical, Nutraceutical, and Herbal products can only be marketed and used after satisfactory Laboratory evaluation. In case of an unsatisfactory laboratory analysis report, the consignment is placed on Hold. This may be for destruction or for further investigation which may include a retest by the Agency and/or independent laboratory.
- 8.2 The timelines for the various processes are as follows:
 - 8.2.1. Cost assessment and issuance of Payment Advice: Thirty (30) minutes.
 - 8.2.2. Endorsement: Thirty (30) minutes.
 - 8.2.3. Physical inspection as determined by the Joint Task Force: Two (2) hours.
 - 8.2.4. Release: Thirty (30) minutes.

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

All correspondence should be addressed to:

The Director-General (NAFDAC) Attention: The Director, Ports Inspection Directorate, Medical Compound, 8/10, Merret Road, Off Herbert Macaulay Way, Yaba, Lagos State. Website: www.nafdac.gov.ng Email address: ports@nafdac.gov.ng

All submissions (where applicable) should be made at the Office of the Director, Ports Inspection Directorate, Medical Compound, 8/10, Merret Road, Off Herbert Macaulay Way, Yaba, Lagos state, or the nearest NAFDAC Office (outside Lagos).