Effective Date: 01/06/2018



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

Ports Inspection Directorate (PID)

GUIDELINES FOR ISSUANCE OF EXPORT CERTIFICATE FOR NAFDAC REGULATED PRODUCTS

Effective Date: 01/06/2018

1. **General**

1.1. These Guidelines are for the interest of the general public and in particular exporters of Drugs, Food, Cosmetics, Medical Devices and other regulated products intended for commercial purpose.

- 1.2. It is necessary to emphasize that, no regulated product 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.
- 1.3. NAFDAC will not issue any Export Approval for products that have already left the shores of the country.

Step I

2. Application

- 2.1. Applicants intending to export Drugs, Food, Cosmetics, Medical Devices and other regulated products should submit an application letter addressed to the Director-General, National Agency for Food and Drug Administration and Control (NAFDAC); ATTENTION: The Director, Ports Inspection Directorate (PID), NAFDAC, Yaba, Lagos State.
- 2.2. The following information should be indicated in the application letter;
 - 2.2.1. Full Name and address of manufacturer's warehouse
 - 2.2.2. List of product(s) intended for Export
 - 2.2.3. Quantity of each product
 - 2.2.4. Pack size of each product
 - 2.2.5. Batch Number of each product
 - 2.2.6. Manufacturing date and Best Before/ Expiry Date (as applicable)
 - 2.2.7. Country of Destination
 - 2.2.8. Consignee's name and address
- 2.3. The following documents should be attached to the application letter;
 - 2.3.1. Evidence of Product Registration issued by NAFDAC (where applicable)
 - 2.3.2. Evidence Valid GMP certificate
 - 2.3.3. Evidence of Registration with Nigeria Export Promotion Council (NEPC)
 - 2.3.4. NXP Forms for commercial export
 - 2.3.5. Proforma Invoice
 - 2.3.6. Packing List
 - 2.3.7. One sample of each product
 - 2.3.8. Original copy of Certificate of analysis

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2.3.9. Letter of No Objection (for 2nd party exporters)

Step II

3. Submission of application

3.1. The application letter, accompanying documents and samples should be submitted via email (ports@nafdac.gov.ng) at the Ports Inspection Directorate, NAFDAC Office, Yaba, Lagos state or the nearest NAFDAC Office (outside Lagos) does this statement apply?

Step III

4. Review of application

4.1. The application and accompanying documents are subsequently reviewed.

Step IV

5. Request for inspection and sampling

- 5.1. A request is sent to the relevant Directorate for the Inspection of the Warehouse. Upon satisfactory inspection of the Warehouse, samples are collected for laboratory analysis.
- 5.2. In case of unsatisfactory Warehouse Inspection and/or laboratory report, a Compliance Directive is issued to the applicant.

6. **Issuance of Export Approval**

- 6.1. Upon satisfactory review of the documents, warehouse inspection and laboratory analysis, the relevant export document is issued:
 - 6.1.1. Drugs Certificate of Pharmaceutical Products (COPP)
 - 6.1.2. Other regulated products Combined Certificate of Manufacture and Free Sale (CCMFS),
 - 6.1.3. Products not manufactured in Nigeria Certificate of Free Sale (CFS)

7. Tariff

7.1. NAFDAC Export Processing is **FREE!**

8. **Note**

- 8.1. NAFDAC does not take responsibility for any risk associated with the mode of transportation of the products being exported.
- 8.2. A period (Timeline) of twenty-one (21) working days from time of submission should be allowed for issuance of approval subject to satisfactory review of documents, warehouse

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inspection and laboratory analysis.

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

- 8.4. Applicants are to ensure that products intended for export are in good condition at the time of departure.
- 8.5. Issuance of Export Approval does not guarantee admittance of the product into the country of destination. All products must comply with the requirements of the country of destination.
- 8.6. The batch (es) of product(s) to be exported must be same as that collected for laboratory analysis by the Agency for the purpose of export.

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).