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

Ports Inspection Directorate (PID)

GUIDELINES FOR ISSUANCE OF LICENSE FOR NON-OBJECTION TO UTILIZE NAFDAC REGISTRATION CERTIFICATE

1 General

1.1 This Guideline is for the interest of the general public and in particular, holders of NAFDAC Certificate of Registration for regulated products, who may wish to grant License for Non-Objection to utilize NAFDAC Registration Certificate for the importation of their registered products by another company.

1.2 It is necessary to emphasize that, no Food, Drug, Cosmetics, Packaged water, Detergent, 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.

1.3 For Pharmaceutical product(s), License for Non-Objection to utilize NAFDAC Registration Certificate can only be granted for applications made in favor of a duly registered Pharmaceutical company with Pharmacy Council of Nigeria (PCN).

1.4 This license does not apply to NAFDAC Regulated products containing restricted, controlled and psychotropic substances requiring permits to import and permits to clear.

2 Application

2.1 The intending 3rd party importer of NAFDAC Registered product(s) shall log on to the National Single Window (NSW) portal with the URL, https://nsw.gov.ng/ using company's TIN and Password.

2.2 After logging into the portal, the applicant should click on **Application Submission > submit Master Document.**

2.3 Under the **Header**, the following are the field and button description of the Master Document submission page;

FIELD/BUTTON DESCRIPTION	ACTION/INPUT REQUIRED
Document category	Preselected by system as Master Document
MDA code	NAFDAC
MDA office	NAFDAC ABUJA HQ
Document	8403L
Document type	Preselected by system
Regime	Preselected by system
Applicant type	Manufacturer/ Marketer/ Market Authorization Holder
Facility code	As previously registered on the NSW portal
Provisional Ref. No	System generated
Facility Link	As previously registered on the NSW portal

2.4 Under the **Item** icon, click on the add button (+): Each product(s) should be filled in turns as follows:

i. Product registration number (of the finished product)
ii. Fill the HS Code
iii. Description (auto-filled)
iv. Country of Origin
v. Quantity
vi. Quantity unit of measurement UOM
vii. Package Type
viii. Product brand Name

The above process is repeated for each product to be imported on the same application.

2.5 Under **Document** icon: attach the following in PDF/JPEG format but **not Microsoft Word document**

2.5.1 A duly signed application letter on the certificate of registration holder's letterhead and titled **License for Non-Objection to utilize NAFDAC Registration Certificate** addressed to the Director, Ports Inspection. The letter must be signed by the MD/CEO or one of the directors listed on the certificate of registration holder's CAC Form CO7 or the Regulatory Officer/Superintendent Pharmacist.

2.5.2 An affidavit deposed to by the signatory to the application in 2.5.1 above at Federal/State High Court.

2.5.3 Evidence of current product(s) registration with NAFDAC and approval for pack size extension (where applicable).

2.5.4 Valid Beneficiary's Pharmacist' Annual License to Practice for the Superintendent Pharmacist issued by the Pharmacy Council of Nigeria **(for pharmaceutical products) or Annual practicing license for the Veterinary Doctor issued by Veterinary**

Council of Nigeria (for Veterinary products).

2.5.5 Valid Beneficiary's Certificate of Registration/Retention of Premises issued by the Pharmacy Council of Nigeria **(for pharmaceutical products) or Veterinary Council of Nigeria (for Veterinary products)**

2.5.6 Certificate of registration holder's CAC Form CO7 or valid Official Identity card for the regulatory officer or Superintendent Pharmacist.

2.6 Under the **Summary** icon, agree with the **terms and conditions** then **Submit.**

3 Review of application

3.1 The application and accompanying documents are reviewed.

The Agency receives submitted application automatically.

3.2 The Agency officers review submitted documents and may;

3.2.1 Approve the application.
3.2.2 Reject the application for amendment.
3.2.3 Reject the application entirely with reasons.

4 Responding to queries

4.1 Clients receive notifications for queries or requests for additional information.
4.2 Client logs in to the NSW portal.
4.3 Client uploads required documents or clarification.
4.4 Client resubmits the application.

5 Approval, Payment and LPCO Issuance

5.1 The Agency approves application.
5.2 Client receives email notification to make payment.
5.3 Client logs into account module and checks pending payment for invoice to make payment.
5.4 Client makes payment online or through the bank.
5.5 The LPCO is generated automatically.
5.6 Client can download the approved document from NSW.
5.7 The approval is automatically shared with other relevant Agencies such as the Central Bank of Nigeria (CBN) and the Nigeria Customs Service (NCS).

6 The risk profile of the company is verified after documentation review. The application will only be processed further on positive profile verification.

7 Tariff

7.1 Please see the tariff section of the NAFDAC website on https://nafdac.gov.ng/regulatory-resources/nafdac-tariff/.

8 Note

8.1 NAFDAC does not take responsibility for any risk associated with the mode of transportation of the products being imported.

8.2 The timeline for the Issuance of **License for Non-Objection to utilize NAFDAC Registration Certificate** is Forty- Eight (48) working hours for an application with a single item (one product) from time of submission. The timeline is suspended when there is a compliance directive and resumes when the applicant complies and communicates compliance to the Agency.

8.3 This **License** expires 31st of December every year.

8.4 Regulated products containing restricted, controlled and psychotropic substances requiring permits to import and permits to clear cannot be processed via this document.

All correspondence should be addressed to:

The Director-General (NAFDAC),

Attn: The Director,
Ports Inspection Directorate,
Medical Compound,
8/10, Merret Road, Off Herbert Macaulay Way,
Yaba,
Lagos State.

Website: www.nafdac.gov.ng
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