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

Narcotics & Controlled Substances (NCS)Directorate

Guidelines for Obtaining Permit to Clear Narcotic Drugs, Psychotropic Substances and Drug Precursors

Guidelines for Obtaining Permit to Clear Narcotic Drugs, Psychotropic Substances, Drug Precursors and Nationally Controlled Drugs

1. General

1.1. This Guideline was developed following the Pharmaceutical Quality System ICH Q(10) requirement which applies to the systems supporting the development and manufacture of pharmaceutical drug substances (i.e API), drug products, including biotechnology and biological products, throughout the product lifecycle.

1.2. The Guidelines are for the interest of the general public and in particular, importers of Narcotic Drugs, Controlled/Psychotropic Substances, Drug Precursors and nationally controlled drugs into Nigeria.

1.3. It is necessary to emphasize that, no product containing Narcotic and Controlled Substances 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

1.4. It is also necessary to emphasize that Narcotics, Controlled/Psychotropic substances, Drug precursors and nationally controlled drugs should not be imported without obtaining Import Permit and Permit to Clear where applicable.

Step 1

2. Documentation

2.1. Companies intending to clear imported Narcotic Drugs, Controlled/ Psychotropic substances, Drug Precursors and nationally controlled drugs from the Ports are required to submit the following documents:

2.1.1. An application on the company's letter head addressed to:

The Director-General,
National Agency for Food and Drug Administration (NAFDAC),
Attention: Director, Narcotics and Controlled Substances (NCS) Directorate,
NAFDAC Office Complex,
Isolo Industrial Estate,
Apapa-Oshodi Expressway,
Isolo, Lagos State.
The letter should be duly signed by the Superintendent Pharmacist.
The name of the substance(s) to be imported; brand name(s) of registered controlled drug product where applicable; physical quantity of each item for finished products; quantity of controlled substance imported in kg and the port of entry should be indicated.

2.1.2. Single Goods Declaration (SGD) Form

2.1.3. Commercial Invoice
2.1.4. Pre-arrival Assessment Report (PAAR)
2.1.5. Certificate of analysis from manufacturer
2.1.6. Clean Report of Inspection and Analysis (CRIA) for shipments of finished products from China, India and Egypt
2.1.7. Packing list
2.1.8. Form M
2.1.9. Bill of lading/ Airway bill
2.1.10. Photocopy of Permit to import
2.1.11. Evidence of product registration
2.1.12. Letter of recommendation from R & R (new applicants only)
2.1.13. Evidence of payment of stipulated fee

Step II

3. Processing of Permit

3.1. Upon satisfactory documentation, the application will be processed further and permit to clear will be issued.
3.2. For unsatisfactory application, a Compliance Directive(s) will be issued to the company.

Step III

4. Collection of Permit

4.1. Collection of endorsed permit to clear is at the office of the Director. Endorsed permit to clear is forwarded to company's email address duly provided to the Agency

5. Tariffs

5.1. Please refer to Tariff section: https://nafdac.gov.ng/regulatory-resources/nafdac-tariff/

6. Note:

6.1. Failure to submit adequate documents may lead to considerable delay in processing the application.
6.2. Failure to respond promptly to Compliance Directives will lead to suspension of further processing of the application.
6.3. Allocation of controlled substances is based on availability**.**
6.4. Submission of fake documents will be considered as a violation and may result in regulatory action and/or prosecution.
6.5. The Pharmacist's Annual License to Practice does not confer authorization to import and clear Narcotic drugs, Controlled/Psychotropic substances, Drug Precursors or other nationally controlled drugs.
6.6. The consignment must not be shipped without obtaining a Permit to import from the Agency. Any applicant/importer that ships (precursor chemicals) narcotic drugs, psychotropic substances, drug precursors and other nationally controlled drugs before Permit to import is issued will be sanctioned appropriately.
6.7. The consignment will only be cleared from the Ports upon obtaining a Permit to Import and Permit to Clear. Failure to present these documents will be considered an offence.
6.8. The permit expires on the 31st of December of the year of issuance and shipment should be

done before or on 31st December, and clearing of all shipments should be done before or on 31st December).

6.9. The timeline for this process is 5 working days from the submission of a satisfactory application.

All correspondence should be addressed to:

Director-General (NAFDAC)
Attention: The Director,
Narcotics and Controlled Substances Directorate
3rd Floor, NAFDAC Office Complex,
Apapa-Oshodi Expressway, Lagos state.

Website: www.nafdac.gov.ng.
E-mail address: ncs@nafdac.gov.ng

All submissions should be made at the Office of the Director, NCS, 3rd. Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (outside Lagos).

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