

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

Narcotics & Controlled Substances (NCS) Directorate

Guidelines for Obtaining Permit for Importation of Schedule 1 Narcotic 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 These Guidelines are for the interest of the public and in particular, importers of **Schedule 1** Narcotics (and Controlled Substances) 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 and Controlled should not be imported without obtaining Import Permit and Permit to Clear where applicable.
- 1.5 The Federal Ministry of Health (FMOH) is the sole Importer of Schedule 1 Narcotic Drugs. However, when the FMOH awards a contract to any organization/company to import on its behalf, the steps in this Guidelines should be followed

Step I

2. Documentation

- 2.1. Companies intending to import Schedule 1 Narcotic drugs should visit the Federal Government. of Nigeria Single Window for Trade Portal (www.trade.gov.ng) to fill the electronic application form for permit to import Schedule 1 Narcotic drugs.
- 2.2. The following documents are required to be attached for a successful Submission of the electronic form:
 - 2.2.1. An application from the Federal Ministry of Health stating that the company has been awarded contract to import narcotic drugs on her behalf.
 - 2.2.2. An application (on company's letter head paper) from the company requesting for Permit to Import Narcotic drugs as approved by Federal Ministry of Health; 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 following should be indicated:
 - 2.2.2.1. The name of substance(s) to be imported.
 - 2.2.2.2. The quantity(ies) of substance(s) to be imported (Kg)
 - 2.2.2.3. Country of origin

- 2.2.2.4. Name and address of the Manufacturer
- 2.2.2.5. Name and address of the (supplier) **exporter** (where applicable)
- 2.2.3. Valid Annual Licence to Practice of the Superintendent Pharmacist
- 2.2.4. Valid Certificate of registration/retention of Premises
- 2.2.5. Proforma Invoice

Step II

3. Processing of Permit

- 3.1. Permit to Import will be processed for satisfactory applications.
- 3.2. For unsatisfactory application/documentation, a Compliance Directive(s) will be issued to the company.

Step III

4. Collection of Permit

4.1. Collection of endorsed Permit to Import is at the office of the Director, NCS.

5. Tariff

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

6. Note:

- 6.1. That company shall import only quantities of Schedule 1 Narcotic drugs stated in the application.
- 6.2. That the medicines shall be warehoused at Federal Medical Stores, Oshodi, Lagos state at no cost to the company/organization for purposes of accountability and government control.
- 6.3. That company shall abide by Ministry's Standard Operating Procedures (SOPs) for pick-up of Schedule 1 Narcotic drugs.
- 6.4. That Federal Ministry of Health (FMOH) and NAFDAC staff shall jointly **confirm the inventory of Schedule 1 Narcotics supplied and warehoused at the Federal Central Medical Stores, Oshodi.**
- 6.5. That permit expires on the 31st of December of the year of issuance and shipment should be done before or on 31st December.
- 6.6. 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)