

DIRECTORATE OF NARCOTICS AND CONTROLLED SUBSTANCES

NARCOTICS AND CONTROLLED SUBSTANCES DIVISION

GUIDELINES FOR PERMITS/AUTHORISATION TO IMPORT AND CLEAR CONTROLLED SUBSTANCES. NAFDAC/NCS/004/00

A GENERAL

1. These guidelines are for the interest of all stakeholders involved in Narcotics substances, Psychotropic substances, Precursor chemicals, controlled solvents and Drugs controlled under the Food and Drugs Act Cap F32 LFN and the Dangerous Drug Act Cap 91 LFN.
2. These guidelines are for obtaining
 - i. Permits to import/clear narcotics and psychotropic substances
 - ii. Permits to import/clear precursors and controlled chemicals
 - iii. Authorization /clearance letter for bulk narcotics
 - iv. Authorization to purchase finished narcotics from the Federal Medical Stores.
 - v. Authorization for purchase/sale of bulk Narcotic substances/precursors chemicals.
3. It is necessary to emphasize that no Narcotics/ Psychotropic substances and Controlled chemicals should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered and/or provided for in accordance with the provisions of Act Cap F33 LFN 2004 (formerly decree 19 of 1993)

B APPLICATIONS

1 APPLICATION FOR PERMIT/AUTHORIZATION TO IMPORT NARCOTICS AND PSYCHOTROPIC SUBSTANCE / BULK NARCOTICS

- (a) An application in duplicate on the company's letter head addressed to the Director Narcotics and Controlled Substances Directorate, NAFDAC, Oshodi and signed by the superintendent pharmacist should be submitted stating:
- i. Name of Product, Dosage form, Pack size (as applicable), quantity, strength per unit dose and total weight of controlled substance per consignment in kilograms
 - ii. Name and address of Manufacturer
 - iii. Name and address of Exporter.
 - iv. Name and Signature of Superintendent Pharmacist.

Please note that the address on the company's letterhead must be the same as the registered address on the certificate of Registration/Retention of Premises issued by Pharmacist Council of Nigeria.

- (b) Copies of documents to accompany application should be:
 - i. Current annual license to practice as a Pharmacist issued by Pharmacist Council of Nigeria to the Superintendent Pharmacist
 - ii. Current Certificate of Registration/Retention of Premises issued by Pharmacist Council of Nigeria.
 - iii. Proforma Invoice.
 - iv. Any supporting document to request large quantities of controlled substance e.g. Government Tender Award,
 - v. NAFDAC Product Registration Certificate (where applicable).
- (c) Original of documents (i - v) above must be sighted at the time of submission.
 - a. The Disposal Records of previous imports must be submitted before a fresh application for permit to import can be received (Repeat applications only)

2. APPLICATION FOR PERMIT TO CLEAR IMPORTED NARCOTICS / PSYCHOTROPIC SUBSTANCES

- (a) Upon importation of the Narcotic/Psychotropic substances, an application letter addressed to the Director, Narcotics and Controlled Substances Directorate, NAFDAC Oshodi and signed by the superintendent pharmacist should be submitted stating as follows:
Name (s) of Product, Dosage form, Pack size (as applicable), quantity, strength per unit dose and total weight of controlled substance per consignment in kilograms (kg).
- (b) Copies of documents to accompany application should be:
 - i. Single Goods Declaration Form
 - ii. Permit to import
 - iii. Bill of lading / Airway bill (where applicable)
 - iv. Commercial Invoice
 - v. Form M
 - vi. Packing List
 - viii. Certificate of Analysis/Quality Control Certification
 - ix. Risk Assessment Report
- (c) Original documents (i - ix) above must be sighted at the time of submission.

3. APPLICATION FOR PERMIT TO IMPORT PRECURSOR AND CONTROLLED CHEMICALS

- (a) An application on the company's letter head signed by the Technical Officer or the Managing Director should be addressed to the Director Narcotics and Controlled Substances Directorate, NAFDAC Oshodi stating the list of precursors/controlled chemicals required quantities and the uses for which they are intended.
- (b) Copies of documents to accompany application should be:

- i. Copy of certificate of Incorporation
 - ii. Copy of current tax clearance certificate
 - iii. One certified true copy of the memorandum and Articles of association
 - iv. One certified true copy of the Particulars of Directors form CO7/Business permit (where applicable).
 - v. Records of disposal of previous imported control chemicals (repeat applications only).
 - vi. Material Safety Data sheet (per Chemical)
 - vii. Particulars of the Technical Manager
- (c) Originals of documents (i - vii) above must be sighted at the time of submission.

4. **APPLICATION FOR PERMIT TO CLEAR PRECURSOR CHEMICALS/CONTROLLED SOLVENTS**

Upon importation of the precursor chemicals/controlled solvent, an application on company letterhead addressed to the Director (NCS) NAFDAC, Oshodi should be submitted stating name(s), quantities of products, port of entry and should be signed by the Technical Officer.

(a) Copies of documents to accompany application should be:-

- i. Permit to import
- ii. Commercial Invoice
- iii. Bill of entry.
- iv. Airway bill/ bill of Lading (As applicable)
- v. Risk Assessment Report
- vi. Form M
- vii. Packing List
- viii. Certificate of Analysis/Quality Control Certification

(d) Original documents (i - ix) above must be sighted at the time of submission.

5. **AUTHORIZATION TO PROCURE FINISHED NARCOTIC DRUGS FROM THE FEDERAL MEDICAL STORES:**

a. Application should be made in triplicate on the institution's letter head and addressed to the Director, Narcotics and Controlled Substances, NAFDAC, Oshodi, Lagos stating the following:

- i. Reference No. and date of application
- ii. Name and strength of drugs.
- iii. Quantity and pack size
- iv. Name and signature of the Pharmacist and/or Medical Director of Institution

- v. An endorsement by the State's Director of Pharmaceutical Services on the reverse side of the application. The endorsement is to have a reference number and date.
- b.** The application should be submitted personally with the following documents:
 - i. Dangerous Drugs Disposal Record Books consisting of Pharmacy, Ward Record and Ward Order Books must be checked each time application for a new stock is made.
 - ii. Where the signatory is not the collector of the dangerous drugs, there should be a letter of authority to collect (the representative), signed by the signatory to the application. This letter should be written on the letter head of the institution in duplicate and addressed to:
The Director, Federal Medical Stores, Oshodi, Lagos.
 - iii. The identity card of the representative along with copy of driver's license or International passport should be presented.
 - iv. First time applicants are to provide information on the number of beds, doctors, nurses and pharmacists in the institution.
 - v. Evidence of hospital's registration with the state private hospitals registration Board.(original for sighting)
 - vi. Evidence of the Medical Directors Registration with Nigerian Medical and Dental Council or evidence of Pharmacist's Annual License to Practice issued by Pharmacists Council of Nigeria. (original for sighting)
- c.** Note:
 - i. The documents in (b) should be submitted annually
 - ii. In the case of applications from State Governments, the number of hospitals being supplied the drugs should be stated.
 - iii. All satisfactory applications shall receive an authorization letter addressed to the Federal Medical Stores to supply the requested drugs.

6. APPLICATION FOR AUTHORIZATION TO PURCHASE/SELL BULK NARCOTIC DRUGS AND PRECURSOR CHEMICALS.

- a. Application should be made by companies that need to procure Narcotics/precursor chemicals from other companies within NIGERIA to service their need. Both seller and buyer must make applications as necessary to the Agency before the transaction can take place.
- b.** Application shall be company's letter head stating the name of products, quantity, Unit dose and dosage form (as applicable), companies involved, and signed by the Technical Officer/Superintendent Pharmacist
- c.** Authorization is then issued to the companies for the purchase/sell of the controlled products
- d.** Records of the transaction must be kept by all the parties involved.

c. TARRIF

All payments to the Agency should be in bank draft payable to National Agency for Food and Drug Administration & Control

- a. Permit for narcotics/ psychotropic substance ₦ 10,000.00 + 5% VAT
- b. Permit for precursors/controlled chemicals ~~₦~~ 10,000.00 + 5% VAT
- c. Authorization letter for bulk narcotics ₦ 10,000.00 + 5% VAT
- d. Authorization to purchase finished narcotics from Federal Medical Store.
NIL
- e. Authorization to purchase/sale bulk Narcotics/precursors. NIL
- f. Permit to clear narcotics/psychotropic substance ₦2500.00 + 5% VAT
- g. Permit to clear precursors/controlled chemicals ₦ 2500.00 + 5% VAT
- h. Clearance letter for bulk narcotics ₦-2500.00 + 5% VAT

D. PRODUCT

All controlled substances must be properly labeled in line with the Agency's labeling requirements.

E. INSPECTION

1 Personnel

A management representative [Superintendent Pharmacist /Technical officer (as applicable)] should be appointed with responsibility for ensuring that a quality system is implemented and maintained.

- a. For narcotics and psychotropic substances the qualified personnel must be a registered pharmacist with the Pharmacists Council of Nigeria
- b. For precursor chemicals, the representative should possess a minimum of Higher National Diploma [HND]/ B.SC in relevant science disciplines.
- c. Importers of finished food products containing caffeine [energy drinks] are exempted from requirements for Technical officer.

2. Premises and Storage

- a. The warehouse should be cited in location with low human traffic, away from dump sites.
- b. Access to the warehouse is to be restricted.
- c. The warehouse should be adequately ventilated and well lit.
- d. The materials are to be neatly stacked on pallets away from walls
- e. Controlled substances that require special storage conditions must be stored at the appropriate temperature.
- f. Materials should be stored according to their hazard level/types
- g. Materials should be labeled appropriately
- h. Temperature/humidity must be monitored
- i. Stock cards and disposal records should be available.

- j. Expired, obsolete or damaged chemicals are to be stored separately and labeled as such.
- k. Facilities for disposal of wastes should be put in place
- l. Fire extinguishers must be provided
- m. First aid box (well stocked with the necessary medicaments)
- n. Safety apparels such as coveralls, nose masks, hand gloves, boots, goggles, helmet are mandatory
- o. Water should be supplied to the premises.
- p. Routine medical check-up must be conducted for staff
- q. Hygiene of the environments

3. Permits to clear must be obtained before the clearance of imported goods

F. TIME LINE FOR PROCESSING

- 1. The process time for permit to clear is two work days from the day of complete documentation.
 - 2. The process time for permit/authorization to import is ten work days from the day complete documentation and satisfactory warehouse inspection.
- G. All correspondence in respect of these Guidelines should be addressed to Director Narcotics and Controlled Substances, NAFDAC, Oshodi Lagos

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