QWP-007-030-01-Annex 02

CHECKLIST OF REQUIREMENTS FOR DRUG DISTRIBUTOR

- ☐ Notarized Duly Accomplished Petition Form and Joint Affidavit of Undertaking (no erasures)
- ☐ Proof of Registration: If Single Proprietorship, Certificate of Business Name Registration with the Department of Trade and Industry (DTI)
  - ✓ Valid Mayor's Business Permit or Barangay Business Permit bearing the exact registered business name and address
- ☐ If Corporation or Partnership, Registration with Securities and Exchange Commission (SEC) and Articles of Incorporation; Secretary's Certificate when applicable
  - ✓ If the Corporate Name is different from the Business Name, to reflect Business Name to be used in SEC Registration
  - ✓ If the Corporate Address is different from the Business Address, secure either Mayor's Business Permit or Barangay Business Permit reflecting the exact registered business name and address
- ☐ If Franchisee, submit a copy of Franchise Agreement and proof of registration of franchisor
- ☐ Pharmacist Clearance
- ☐ Copies of Pharmacist Board Certificate, PRC-ID, valid PTR, Duties and Responsibilities of the pharmacist and Certificate of Attendance of Owner/Pharmacist to an FDA sponsored/accredited Seminar on Licensing of Drug Establishments and Outlets (AO 56 s. 1989) and Seminar on EDPMS, Resignation Letter from the previous employer and Contract of Employment.
- ☐ List of Products to be distributed identified by their generic names and brand names, if any
- ☐ Notarized Contract of Lease of the space to be occupied (office and storage room/warehouse) if not owned or any proof of ownership if owned (e.g. Tax Declaration) or notarized Certificate of Occupancy
- ☐ Valid Homeowner's Association (HOA) Clearance when applicable
- ☐ Picture of establishment (façade) bearing the exact registered business name
- ☐ Location Plan (sketch with landmark) and Floor Plan with dimension (square meters) of the space to be occupied (office and storage room/warehouse)
- ☐ LICENSING FEE based on AO #50 s. 2001 Opening/Initial (1-year validity) : P 5,000.00 + 1% Legal Research Fee

FOR IMPORTER

- ☐ Foreign Agency Agreement from each supplier duly authenticated by the Territorial Philippine Consulate
- ☐ Certificate of Registration of Manufacturer and its conformity with GMP from Health Authority (GMP Certificate)

FOR EXPORTER

- ☐ Valid contract with FDA-licensed Supplier/Manufacturer (notarized)
- ☐ Valid License To Operate (LTO) of Supplier/Manufacturer
- ☐ Certificate of Product Registration (CPR) issued by FDA or Certificate that the products it sells are registered with FDA

FOR WHOLESALER

- ☐ Valid contract with FDA-licensed Supplier/Manufacturer (notarized)
- ☐ Valid License To Operate (LTO) of Supplier/Manufacturer
- ☐ Certificate of Product Registration (CPR) issued by FDA or Certification that the product it sells are registered with FDA

SUBMIT PICTURES FOR VERIFICATION DURING INSPECTION:

- ☐ *Reference Materials/Textbook:
  - ✓Philippine National Drug Formulary (latest edition)
  - ✓R.A. 3720 Foods, Drugs and Devices, and Cosmetics Act
  - ✓R.A. 6675 Generics Act of 1988 and Relevant Implementing Rules & Regulations
  - ✓R.A. 5921 Pharmacy Law as amended and Relevant Implementing Rules & Regulations
  - ✓R.A. 8203 Special Law on Counterfeit Drugs
  - ✓R.A. 9502 The Universally Accessible Cheaper and Quality Medicines Act of 2008, E.O.#821 Prescribing the Maximum Drug Retail Prices for Selected Drugs and Medicines that Address Diseases that Account for the Leading Causes of Morbidity and Mortality (MDRP) , Advisory Council for Price Regulation#2009-001 Government-Mediated Access Price (GMAP)
  - ✓R.A. 9711 The Food and Drug Administration Act of 2009
  - ✓A.O.# 56 s.1989 Licensing of Drug Establishments and Outlets
  - ✓United States Pharmacopoeia/National Formulary (USP/NF) or Remington: The Science and Practice of Pharmacy OR Goodman & Gilman's: The Pharmacological Basis of Therapeutics (latest edition)
- ☐ Batch Distribution Record Book
- ☐ Cold Storage for *vaccines and biological products*

NOTE: 1) Present original documents during inspection for verification. 2) Prepare TWO (3) SETS of the application in the order written above with eartags. 3) Acceptance of application : **Monday to Friday, from 8:00 A.M. to 5:00 P.M** only	
For Applicant:	**For FDA:**
Submitted by: _____ Date: _____	Received by: _____ Date: _____