Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, Muntinlupa City

QWP-007-050-01- ANNEX 01

CHECKLIST OF REQUIREMENTS FOR FOOD ESTABLISHMENT

I. GENERAL REQUIREMENTS

- ☐ **Accomplished Petition Form duly notarized with ID picture of Petitioner(erasures are not accepted)**
  Note: Petitioner should be one of the Incorporators. If the petitioner is not the owner/incorporator, copy of Secretary Certificate/ Board Resolution/ Authorization Letter /Special Power of Attorney must be submitted.
- ☐ **Proof of Registration** :
  - If Single Proprietorship, valid Certificate of Business Name Registration with the Department of Trade and Industry (DTI)
  - If Corporation or Partnership, valid Registration with Securities and Exchange Commission (SEC) and Articles of Incorporation or Partnership
  - If Cooperative, valid Certificate from Cooperative Development Authority and by laws

  Note: If the DTI or SEC has a different Business Address , copy of valid Mayor's Business Permit or Barangay Clearance must be submitted
  If the Corporate Name is different from the Business Name, copy of amendment of SEC Registration must be submitted .
  DTI Certificate or SEC Registration must indicate the actual activity/purposes
  In case of change of ownership copy of Deed of Sale must be submitted
  In case of merging /buy-out copy of Deed of Assignment must be submitted
- ☐ **Proof of Occupancy – Office**
  - Valid notarized Contract of Lease /Sub-Lease/ Certificate of Occupancy
  - Transfer Certificate of Title (TCT) if owned and notarized Certificate of Occupancy (if owned by one of the incorporators)
  - Clearance from the Condominium /Building Administration allowing the use of the unit for business purposes –as necessary
- ☐ **Proof of Occupancy –Warehouse/Stock room**
  - Valid notarized Contract of Lease/Sub-Lease/ Certificate of Occupancy
  - Transfer Certificate of Title (TCT) if owned and notarized Certificate of Occupancy (if owned by one of the incorporators)
  - Valid notarized Warehousing Agreement (Third Party Logistics)
- ☐ **Vicinity Map** (office and /or warehouse)
- ☐ **Floor Plan/Lay out with dimension** (office and /or warehouse)
- ☐ **List of Product/s /category/activity**

II.SPECIFIC REQUIREMENTS

A. For Importer

- ☐ Any one of the following from each supplier
  - Foreign Agency Agreement/Certificate of Distributorship/Appointment Letter
  - Proforma Invoice
- ☐ Any one of the following documents for the status of Manufacturer issued by the Regulatory/Health Authority from the country of origin:
  - Certificate of Registration of Manufacturer and its conformity with GMP from Regulatory/Health Authority or its equivalent
  - Phytosanitary Certificate
  - Certificate of Free Sale
  - HACCP Plan as applicable

Note: In the absence of a Regulatory/Health Authority in the country of origin, attestation by a recognized association which should be duly authenticated by the Philippine Consulate from the country of origin.

B. For Exporter

- ☐ Valid License to Operate (LTO) of Supplier/Manufacturer
- ☐ Valid notarized Distributorship Agreement or Letter of Appointment with FDA licensed Supplier/Manufacturer to distribute their products outside the Philippines
- ☐ List of food products with registration numbers and validities

C. For Wholesaler

a.) Locally procured raw materials in bulk and finished products in original container

- ☐ Valid License To Operate (LTO) of Supplier/Manufacturer
- ☐ Valid notarized Distributorship Agreement or Letter of Appointment with FDA licensed Supplier/Manufacturer
- ☐ List of food products with registration numbers and validities

b.) Subcontracts to a licensed Manufacturer/ Repacker

- ☐ Valid License To Operate (LTO) of Manufacturer and/or Repacker, (tolling /repacking activity and specific product should be indicated in the LTO)
- ☐ Valid notarized Toll Manufacturing and/or Repacking Agreement with FDA licensed Toll Manufacturer and/or Repacker

III.ADDITIONAL REQUIREMENTS – as applicable

A. For Salt Importer

- ☐ ***For Distribution*** (Iodized Salt) - Certificate of Analysis for the presence of iodine conducted by the Manufacturer/Supplier in conformance with RA 8172 (Asin Law)
- ☐ ***For Iodization*** - Valid License To Operate (LTO) of the Manufacturer and notarized Memorandum of Agreement (MOA) with FDA licensed Manufacturer
- ☐ ***For Industrial use***- Notarized Affidavit of Undertaking that the salt is for industrial use only and List of Customers indicating the name, address , contact numbers and the quantity allotted

B. For Staple Products (Wheat Flour, Cooking Oil and Rice premixes) Importer

- ☐ ***For Distribution*** - Certificate of Analysis for presence of fortificant (Vit.A and or Iron) , conducted by the Manufacturer/Supplier in conformance with RA 8976 (Phil. Food Fortification Act)
- ☐ ***For Fortification*** - Valid License To Operate (LTO) of the Manufacturer and notarized Memorandum of Agreement (MOA) with FDA licensed Manufacturer

C. For Other Products

- ☐ **For Raw Materials/Food Additives** –Certificate of Analysis/Material Safety Data Sheet
- ☐ **For Soy Sauce** - Certificate of Analysis for 3-MCPD and must be conformance with the allowable set limit
- ☐ **For Milk and milk products** – Certificate of Analysis that the product/s is free from the presence of melamine

IV. LICENSING FEE: Based on AO 50 s. 2001 & FDA Circular 2011-003 Collection of Legal Research Fee (LRF)
Opening fee - Php 4,000.00(x 1% legal research fee) (**1 year validity**) ,Salt Importer Opening fee - Php 1,000.00 (x 1% legal research fee) (**1 year validity**)

- **PLEASE BRING ORIGINAL COPIES FOR VERIFICATION.**
- **ALL DOCUMENTS SUBMITTED SHOULD BE PLACED IN A GREEN FILE FOLDER WITH DIVIDERS FOLLOWING THE ARRANGEMENT OF THE REQUIREMENTS AS INDICATED ABOVE.**
- **SUBMISSION OF APPLICATIONS IS EVERY MONDAY, FROM 7:00AM TO 3:00PM.**
- **IN CASE OF TURNED INITIAL APPLICATION /CHANGE OF OWNERSHIP /MERGING/BUY-OUT,SURRENDER ORIGINAL LTO**

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 (NCPAM)
- ☐ 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
- ☐ 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
- ☐ 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 (2) SETS of the application in the order written above with divider.
3) Acceptance of application : **Tuesdays and Wednesdays from 8:00 A.M. to 3:00 P.M** only

For Applicant:	**For FDA:**
Submitted by: _____ Date: _____	Received by: _____ Date: _____

CHECKLIST OF REQUIREMENTS FOR DRUG RETAILER (DRUGSTORE /*RONPD)

- ☐ *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 of the retailer
- ☐ *If Cooperative, registration with Cooperative Development Authority (CDA)
- ☐ *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 & address
- ☐ *If Franchisee, submit a copy of Franchise Agreement and proof of registration of franchisor
- ☐ *Pharmacist Clearance
- ☐ *Copies of Pharmacist Board Certificate, valid PRC-ID, current 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 (NCPAM)
- ☐ *Tentative list of products intended to be sold using generic names with brand names, if any
- ☐ *Notarized Contract of Lease for the space occupied 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 drugstore with signboard bearing exact registered business name
- ☐ Floor area not less than 15 square meters
- ☐ *Location Plan (sketch with landmark) and Floor Plan with dimension (square meters) of outlet (including compounding area and storage room / warehouse when applicable)
- ☐ *Rubber stamp of outlet bearing the exact registered business name and address
- ☐ Generic *White Label bearing the exact registered business name and address
- ☐ LICENSING FEE based on AO #50 s. 2001 Opening/Initial (1-year validity) :
  P 1,000.00 + 1% Legal Research Fee

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
- ✓ Remington: The Science and Practice of Pharmacy OR Goodman & Gilman's: The Pharmacological Basis of Therapeutics (latest edition)
- ☐ Record Books (Prescription Book, *Senior Citizen's, *Persons with Disability)
- ☐ Menu Cards (Generics, MDRP, GMAP)
- ☐ Dispensing Apparatus (spatula, tablet counter and graduated cylinder)
- ☐ Cold Storage for *vaccines and biological products*

NOTE:

1) Present original documents during inspection for verification.
2) Prepare TWO (2) SETS of the application in the order written above with dividers.
3) Acceptance of application: **Tuesdays and Wednesdays from 8:00 A.M. to 3:00 P.M** only.

For Applicant:	**For FDA:**
Submitted by: _____ Date: _____	Received by: _____ Date: _____

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

QWP-007-040-01-Annex 01

CHECKLIST OF REQUIREMENTS FOR COSMETIC DISTRIBUTOR

I. GENERAL REQUIREMENTS

- ☐ Accomplished Petition Form Duly Notarized with 2 x 2 ID picture of Owner/Incorporator/ Authorized Representative
  - o Secretary's Certificate/Special Power of Attorney for authorized representative
- ☐ Joint Affidavit of Undertaking Duly Notarized with 2 x 2 ID picture of Pharmacist
- ☐ For Registered Pharmacist
  - o Board Certificate
  - o Valid PRC ID
  - o Current PTR
  - o Signed Duties and Responsibilities
  - o Certificate of Attendance to a FDA sponsored seminar on licensing of establishments or promissory letter to attend
  - o Pharmacist's Clearance
- ☐ Proof of Business Registration
  - o If Single Proprietorship, Valid Certificate of Business Name Registration with the Department of Trade and Industry (DTI)
  - o If Corporation or Partnership, Valid Registration with SEC and Articles of Incorporation and other pertinent documents
  - o If the Business Name is different from the Corporate Name, SEC Certificate must reflect " Doing Business under the name and style of ..(Name of Establishment)"
  - o If Cooperative, Certificate of Cooperative Development Authority (CDA)
  - o Valid Mayor's Business Permit OR Barangay Business Permit, if the business name and address is different from the registered name and address in the DTI or SEC
  - o For Change of Ownership: Deed of Sale
  - o For Merging/ Buy-out : Deed of Assignment
- ☐ Proof of Occupancy – Office
  - o Valid Contract of Lease/Sublease
  - o Transfer Certificate of Title (if owned)
  - o Notarized Certificate of Occupancy (if owned by one of the incorporators)
  - o Valid Homeowner's Association (HOA) Clearance if the establishment is located inside a subdivision or residential condominium
  - o Floor plan, vicinity map and picture with signage
- ☐ Proof of Occupancy – Warehouse
  - o Valid Contract of Lease/Sublease
  - o Transfer Certificate of Title (if owned)
  - o Notarized Certificate of Occupancy (if owned by one of the incorporators)
  - o Valid Homeowner's Association (HOA) Clearance if the establishment is located inside a subdivision or residential condominium
  - o Valid and duly notarized Warehousing Agreement (Third Party Logistics)
  - o Floor plan, vicinity map and picture with signage

II. SPECIFIC REQUIREMENTS

A. FOR IMPORTER

- ☐ Valid Foreign Agency Agreement from each supplier duly authenticated by the Territorial Philippine Consulate
  - Additional Requirement, if the supplier is not the manufacturer:
    - o Valid Supply Agreement between the foreign source & manufacturer
    - o Valid Tripartite Agreement duly Authenticated by the Territorial Philippine Consulate
- ☐ Valid GMP Certificate of manufacturer issued by the government agency or accredited business association in the country of origin or self-declaration of compliance to GMP (ASEAN, WHO, ECC/EU, COLIPA)
  - o For raw materials, an ISO/Business License/Manufacturer's License may be submitted in lieu of GMP Certificate

B. FOR EXPORTER

- ☐ Duly notarized and valid distribution agreement with FDA-licensed Supplier (Manufacturer/Distributor/Trader) indicating the countries where the products are to be exported
- ☐ Valid License To Operate (LTO) of the Manufacturer/Distributor/Trader
- ☐ List of products with notification numbers and validities

C. FOR WHOLESALER

- ☐ Duly notarized and valid distribution agreement with FDA-licensed Supplier (Manufacturer/Distributor/Trader)
- ☐ Valid License To Operate (LTO) of the Manufacturer/Distributor/Trader
- ☐ List of products with notification numbers and validities

III. LICENSING FEE based on AO #50 s. 2001 Opening/Initial (1-year validity) : P 3,000.00 + 1% Legal Research Fee- P3,030.00

REMINDER: THE FOLLOWING MUST BE PRESENTED DURING INSPECTION:

- ☐ RA 9711, RA 3720, RA 5921, RA 7394
- ☐ ASEAN Cosmetic Directive (ACD) with ACD Ingredient Listing
- ☐ Batch Distribution Record Book
- ☐ Standard Operating Procedures: **1)** Handling Product Complaints **2)** Handling Product Recall **3)**Handling Rejects and Returns **4)** Good Distribution Practice **5)** Good Storage Practice **6)** Good Housekeeping/Pest Control Program **7)** Proper Disposal of Expired, Damaged and Deteriorated Products

NOTE:

1. PLEASE BRING ORIGINAL DOCUMENTS FOR VERIFICATION UPON SUBMISSION OF APPLICATION
2. SUBMIT THE APPLICATION IN ORANGE FOLDER WITH SEPARATORS ARRANGED ACCORDING TO THE ABOVE LIST OF REQUIREMENTS
3. SUBMISSION OF APPLICATION IS EVERY THURSDAY FROM 7:00AM TO 3:00 PM
4. INCOMPLETE DOCUMENTS WILL NOT BE ACCEPTED
5. IN CASE OF TURNED INITIAL APPLICATION/ CHANGE OF OWNERSHIP/ MERGING OR BUY-OUT, SURRENDER PREVIOUSLY ISSUED LTO (ORIGINAL)
6. PETITION FORM & JOINT AFFIDAVIT WITH ERASURES WILL NOT BE ACCEPTED

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

QWP-007-040-01-ANNEX-01-1

REGULATION DIVISION I – COSMETIC/HHS SECTION

IN THE MATTER OF PETITION OF:

_____
(Name of Owner/Incorporator/Authorized Representative)

2x2
Picture
(Owner)

TO OPEN A **COSMETIC ESTABLISHMENT** PARTICULARLY AS:
( ) Importer
( ) Exporter
( ) Wholesaler

PETITION

COMES now the undersigned petitioner unto the Food and Drug Administration, Department of Health, Manila respectfully alleges;

FIRST – That the petitioner is of legal age, married/single, Filipino citizen and residing at _____;
(Complete Address)

SECOND – That the petitioner desires to open a cosmetic establishment particularly as _____ to be located at _____
(Flr.) (Bldg.) (No.) (Street) (Subdivision) (Brgy.) (City) (Province)
and shall be known as _____;
(Exact Business Name)

THIRD – That the petitioner has the authority to file this application as the:
( ) Sole Proprietor/Owner ( ) Incorporator ( ) Authorized Representative;

FOURTH - That said establishment shall be open for business from _____ A.M. to _____P.M. and shall be under the personal and immediate supervision of _____, a duly registered pharmacist with Certificate of Registration No. _____ issued on _____;

FIFTH – That the petitioner hereby agrees to change the business name of the establishment in the event that there is a similar or same name registered with the Food and Drug Administration if it rules later that it is misleading;

SIXTH – That the petitioner will be held liable for not informing FDA of any changes in the status of business such as ownership, transfer of office/warehouse address, activities and suppliers/sources;

SEVENTH – That the amount of Capital invested for said establishment is Php _____; and

EIGHTH – That the petitioner and the establishment's registered pharmacist shall sign a joint affidavit of undertaking.

WHEREFORE, the petitioner respectfully prays that he/she be granted a license to operate a cosmetic establishment after inspection thereof and after compliance with the requirements, rules and regulations of the Food and Drug Administration.

Metro Manila, Philippines _____, 20 _____

Respectfully submitted by:

_____
SIGNATURE OVER PRINTED NAME OF PETITIONER
Contact No.:_____

SUBSCRIBED AND SWORN to before me this _____ day of _____ 20 ___. Affiant exhibited to me his/her Residence Certificate No. _____ issued at _____ on _____ day of _____ 20 ____.

NOTARY PUBLIC

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

QWP-007-040-01-Annex-01-2

JOINT AFFIDAVIT OF UNDERTAKING

2x2
Picture
(Pharmacist)

_____
(PRC Registered Name of Pharmacist-in-Charge)

_____ _____
(Maiden or Married Name, if different from above)

PRC Registration No.: _____
Issued on _____
PTR NO.: _____

of legal age, single/married, and a resident of _____ and
(Complete Address)
_____ of _____ located at
(owner incorporator//authorized representative) *(Exact Business Name)*
_____ of legal age and a resident
(Complete Address of Establishment)
of _____ after having been sworn in
(Complete Address of owner/incorporator/authorized representative)
accordance with law hereby declare:

That we are fully aware of the provisions of the Pharmacy Law, the Food, Drugs and Devices, and Cosmetics Act, The Food and Drug Administration Act of 2009, ASEAN Cosmetic Directive and other pertinent laws, rules and regulations;

That we are aware of the specific requirements that the operation of a cosmetic establishment shall be under the PERSONAL SUPERVISION of the Pharmacist- In-Charge, the business hours being from _____A.M. to _____P.M.;

That we agree to change the business name if there is already a validly registered name similar to our business name;

That we shall display our approved License to Operate and pharmacist's board certificate in a conspicuous place in our establishment;

That we shall notify FDA in case of any change(s) in the circumstances of our application for a License to Operate, including but not limited to change of location, change of pharmacist-in-charge, and change in drug products;

That the pharmacist-in-charge is not and will not in any way be connected with any cosmetic or similar establishment/outlet;

That the owner/authorized representative and the pharmacist undertake to be jointly liable for any violation committed relating to the operation of a cosmetic establishment.

WITNESS WHEREOF, we hereunto affix our signature this _____ day of _____ 20___.

_____
OWNER
Res. Cert. No.:_____
Issued on _____
at _____

_____
PHARMACIST
Res. Cert. No.: _____
Issued on _____
at _____

SUBSCRIBED AND SWORN to before me this _____ day of _____ 20 ___. Affiants exhibited to me their Residence Certificates

NOTARY PUBLIC

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

QWP-007-040-01-Annex 01

CHECKLIST OF REQUIREMENTS FOR HOUSEHOLD HAZARDOUS SUBSTANCES DISTRIBUTOR

I. GENERAL REQUIREMENTS

- ☐ Accomplished Petition Form Duly Notarized with 2 x 2 ID picture of Owner/Incorporator/ Authorized Representative
- ☐ For Authorized Representative
  - o Secretary's Certificate
  - o Signed Duties and Responsibilities
  - o Certificate of Attendance to a FDA sponsored seminar on licensing of establishments or promissory letter to attend
- ☐ Proof of Business Registration
  - o If Single Proprietorship, Valid Certificate of Business Name Registration with the Department of Trade and Industry (DTI)
  - o If Corporation or Partnership, Valid Registration with SEC and Articles of Incorporation and other pertinent documents
  - o If the Business Name is different from the Corporate Name, SEC Certificate must reflect " Doing Business under the name and style of ..(Name of Establishment)"
  - o If Cooperative, Certificate of Cooperative Development Authority (CDA)
  - o Valid Mayor's Business Permit OR Barangay Business Permit, if the business name and address is different from the registered name and address in the DTI or SEC
- ☐ Proof of Occupancy – Office (with vicinity map and floor plan)
  - o Valid Contract of Lease/Sublease
  - o Transfer Certificate of Title (if owned)
  - o Notarized Certificate of Occupancy (if owned by one of the incorporators)
  - o Valid Homeowner's Association (HOA) Clearance if the establishment is located inside a subdivision or residential condominium
- ☐ Proof of Occupancy – Warehouse (with vicinity map and floor plan)
  - o Valid Contract of Lease/Sublease
  - o Transfer Certificate of Title (if owned)
  - o Notarized Certificate of Occupancy (if owned by one of the incorporators)
  - o Valid Homeowner's Association (HOA) Clearance if the establishment is located inside a subdivision or residential condominium
  - o Valid and duly notarized Warehousing Agreement (Third Party Logistics)
- ☐ Picture of office and warehouse with signage

II. SPECIFIC REQUIREMENTS

A. FOR IMPORTER

- ☐ Valid Foreign Agency Agreement from each supplier duly authenticated by the Territorial Philippine Consulate
  - o Additional Requirement, if the supplier is not the manufacturer
    - Valid Supply Agreement between the foreign source & manufacturer
    - Valid Tripartite Agreement duly Authenticated by the Territorial Philippine Consulate
- ☐ Valid GMP Certificate of manufacturer issued by the government agency or accredited business association in the country of origin or ISO/Business License/Manufacturer's License in lieu of GMP.
  - o For raw materials, an ISO/Business License/Manufacturer's License may be submitted in lieu of GMP Certificate
- ☐ List of Product to be imported or distributed

B. FOR EXPORTER

- ☐ Duly notarized and valid distribution agreement with FDA-licensed Supplier (Manufacturer/Distributor/Trader) indicating the countries where the products are to be exported
- ☐ Valid License To Operate (LTO) of the Manufacturer/Distributor/Trader
- ☐ List of HHS products with registration numbers and validities

C. FOR WHOLESALER

- ☐ Duly notarized and valid distribution agreement with FDA-licensed Supplier (Manufacturer/Distributor/Trader)
- ☐ Valid License To Operate (LTO) of the Manufacturer/Distributor/Trader
- ☐ List of HHS products with registration numbers and validities

III. LICENSING FEE based on AO #50 s. 2001 Opening/Initial (1-year validity): P 3,000.00 + 1% Legal Research Fee- P3, 030.00

REMINDER: THE FOLLOWING MUST BE PRESENTED DURING INSPECTION

- ☐ Republic Act 9711 Republic Act 3720 Republic Act 7394 Presidential Decree 881
- ☐ Batch Distribution Record Book
- ☐ Standard Operating Procedures: 1) Handling of Product Complaints 2) Handling of Product Recall 3) Handling of Rejects and Returns 4) Proper Disposal of Expired, Damaged and Deteriorated Products 5) Good Storage Practice 6) Good Distribution Practice 7) Good Housekeeping/ Pest Control Program

NOTE:

1. **PLEASE BRING ORIGINAL DOCUMENTS FOR VERIFICATION UPON SUBMISSION OF APPLICATION**
2. **SUBMIT THE APPLICATION IN RED FOLDER WITH SEPARATORS ARRANGED ACCORDING TO THE ABOVE LIST OF REQUIREMENTS**
3. **SUBMISSION OF APPLICATION IS EVERY THURSDAY FROM 7:00AM TO 3:00 PM**
4. **INCOMPLETE DOCUMENTS WILL NOT BE ACCEPTED**

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

QWP-007-040-01-ANNEX-01-1

REGULATION DIVISION I – COSMETIC/HHS SECTION

IN THE MATTER OF PETITION OF:

_____
(Name of Owner/Incorporator/Authorized Representative)

TO OPEN A **HOUSEHOLD HAZARDOUS SUBSTANCES** ESTABLISHMENT PARTICULARLY AS:
( ) Importer
( ) Exporter
( ) Wholesaler

2x2
Picture
(Owner)

PETITION

COMES now the undersigned petitioner unto the Food and Drug Administration, Department of Health, Manila respectfully alleges;

FIRST – That the petitioner is of legal age, married/single, Filipino citizen and residing at _____;
(Complete Address)

SECOND – That the petitioner desires to open a HHS establishment particularly as _____ to be located at _____
(Flr.) (Bldg.) (No.) (Street) (Subdivision) (Brgy.) (City) (Province)
and shall be known as _____;
(Exact Business Name)

THIRD – That the petitioner has the authority to file this application as the:
( ) Sole Proprietor/Owner ( ) Incorporator ( ) Authorized Representative;

FOURTH – That the petitioner hereby agrees to change the business name of the establishment in the event that there is a similar or same name registered with the Food and Drug Administration if it rules later that it is misleading;

FIFTH – That the petitioner will be held liable for not informing FDA of any changes in the status of business such as ownership, transfer of office/warehouse address, activities and suppliers/sources;

SIXTH – That the amount of Capital invested for said establishment is Php _____; and

WHEREFORE, the petitioner respectfully prays that he/she be granted a License To Operate a HHS establishment after inspection thereof and after compliance with the requirements, rules and regulations of the Food and Drug Administration.

Metro Manila, Philippines _____, 20 ____

Respectfully submitted by:

_____
SIGNATURE OVER PRINTED NAME OF PETITIONER
Contact No.: _____

SUBSCRIBED AND SWORN to before me this ____ day of _____ 20 ___. Affiant exhibited to me his/her Residence Certificate No. _____ issued at _____ on _____ day of _____ 20 ____.

NOTARY PUBLIC

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

QWP-007-040-01-Annex-01-2

JOINT AFFIDAVIT OF UNDERTAKING

2x2
Picture
(Pharmacist)

_____
(PRC Registered Name of Pharmacist-in-Charge)

_____
(Maiden or Married Name, if different from above)

PRC Registration No.: _____
Issued on _____
PTR NO.: _____

of legal age, single/married, and a resident of _____ and
(Complete Address)
_____ of _____ located at
(owner incorporator//authorized representative) *(Exact Business Name)*
_____ of legal age and a resident
(Complete Address of Establishment)
of _____ after having been sworn in
(Complete Address of owner/incorporator/authorized representative)
accordance with law hereby declare:

That we are fully aware of the provisions of the Pharmacy Law, the Food, Drugs and Devices, and Cosmetics Act, The Food and Drug Administration Act of 2009, ASEAN Cosmetic Directive and other pertinent laws, rules and regulations;

That we are aware of the specific requirements that the operation of a cosmetic establishment shall be under the PERSONAL SUPERVISION of the Pharmacist- In-Charge, the business hours being from _____A.M. to _____P.M.;

That we agree to change the business name if there is already a validly registered name similar to our business name;

That we shall display our approved License to Operate and pharmacist's board certificate in a conspicuous place in our establishment;

That we shall notify FDA in case of any change(s) in the circumstances of our application for a License to Operate, including but not limited to change of location, change of pharmacist-in-charge, and change in drug products;

That the pharmacist-in-charge is not and will not in any way be connected with any cosmetic or similar establishment/outlet;

That the owner/authorized representative and the pharmacist undertake to be jointly liable for any violation committed relating to the operation of a cosmetic establishment.

WITNESS WHEREOF, we hereunto affix our signature this _____ day of _____20___.

_____
OWNER
Res. Cert. No.:_____
Issued on _____
at _____

_____
PHARMACIST
Res. Cert. No.: _____
Issued on _____
at _____

SUBSCRIBED AND SWORN to before me this _____ day of _____ 20 ___. Affiants exhibited to me their Residence Certificates

NOTARY PUBLIC

CHECKLIST OF REQUIREMENTS FOR OPENING OF FOOD ESTABLISHMENT

For Pre-Application as Manufacturer of Bottled Water

_____1. Submit letter of Intent for pre-site inspection (Fee: P500.00)

GENERAL REQUIREMENTS:

_____1. Information as to activity(ies) of establishment
_____2. Notarized Accomplished Petition Form
(If the petitioner is not the owner/one of the incorporators as registered with DTI/SEC, submit a notarized certificate authorizing the person who signed in behalf of the establishment/company)
_____3. ID picture of Owner/Authorized Representative (size: 5cm x. 5cm)
_____4. Photocopy of Business Name Registration
a. For **single proprietorship,** registration from the Department of Trade & Industry (DTI)
b. For **corporation/partnership,** registration from the Securities & Exchange Commission (SEC) and Articles of Incorporation
c. For **cooperative**, registration from the Cooperative Development Authority (CDA)

Note: a. If the registered address with DTI/SEC is different from the address of the establishment to be licensed, submit a photocopy of the Business/Mayor's Permit.
b. If the establishment adopts another business name/ style different from the corporation name, the business/trade name shall be indicated in the SEC registration certificate.

_____5. Photocopy of Notarized valid Contract of Lease of the space/building occupied if the space/bldg. is not owned; If not, copy of Transfer Certificate Title (TCT)
_____6. Photocopy of financial statement duly notarized or received by Bureau of Internal Revenue (BIR), if not available, submit notarized certification of initial capital invested
_____7. Location Plan/Site (Indicate size, location, immediate environment, type of building)
_____8. List of products to be processed/repacked/imported
_____9. Photocopy of the notarized valid Franchise Agreement (For Franchisee Only)

ADDITIONAL REQUIREMENTS:

A. For Repacker
_____1. Photocopy of notarized valid contract/agreement with the manufacturer with stipulation that both are jointly responsible for the quality of the product.
_____2. Photocopy of the License to Operate (LTO) of the Manufacturer

B. For Importer of Raw Materials/Finished Products in Bulk:
_____1. Photocopy of Foreign Agency Agreement duly authenticated by the Territorial Philippine Consulate
_____2.Photocopy of Certificate of Status of Manufacturer (CGMP Certificate) issued by a Government Health Agency Duly authenticated by the Territorial Philippine Consulate.
_____3. Certificate of analysis (raw materials/ finished products)
_____4. Material Safety Data Sheet (MSDS)
_____5. Proforma Invoice

Note:
- Inspection shall be scheduled only after compliance with all documentary and technical requirements.
- Bring Original copy of Photocopied Documents submitted for verification.
- Only owner and/or authorized technical staff will be entertained.
- Arrange according to checklist and submit in **BLUE FOLDER**

Interviewed By:

_____
Date: _____

Received By:

_____
Date: _____

SCHEDULE OF FEES (Imposed by R.A. No. 3870, as amended by PD 200 and further amended by PD 1856)

A. Food Manufacturer / Repacker of Food Products

CAPITAL INVESTED	Opening (1 yr. validity)	LRF	Total	Renewal (2 yrs. Validity)	LRF	Total
Not more than 250,000	500.00	10.00	510.00	1,000.00	20.00	1,020.00
Over 250,000 but not more than 500,000	750.00	10.00	760.00	1,500.00	20.00	1,520.00
Over 500,000 but not more than 1 million	1,000.00	10.00	1,010.00	2,000.00	20.00	2,020.00
Over 1 Million but below 5 Million	2,000.00	20.00	2,020.00	4,000.00	40.00	4,040.00
5 Million but below 10 Million	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
10 Million but below 20 Million	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
20 Million but below 50 Million	10,000.00	100.00	10,100.00	20,000.00	200.00	20,200.00
50 Million and above	15,000.00	150.00	15,150.00	30,000.00	300.00	30,300.00

B. Bottled Water — Opening Fee : ₱ 3,030.00

C. Iodized Salt — Filing Fee : ₱ 50.00

Opening Fee:

- Large & Medium Manufacturer : ₱ 1,060.00
- Small Manufacturer : ₱ 560.00
- Subsistence Manufacturer : ₱ 260.00

OTHERS:

- Amendment of LTO or LTO Re-Issuance : ₱ 510.00
- Addition /Deletion of Sources : ₱ 60.00
- Certification/Clearance for BOC purpose and Donation : ₱ 310.00
- Change of Business Name/Address of Supplier : ₱ 310.00

SCHEDULE FOR SUBMISSION OF APPLICATION:
MONDAY - FOOD
Tuesday& Wednesday -DRUGS
Thursday – COSMETICS / HHS

CHECKLIST FOR INCLUSION/DELETION OF TOLL MANUFACTURER/REPACKER/TRADER/SOURCE/PRODUCT/ACTIVITY (FOOD/ DRUGS/COSMETICS /HHS ESTABLISHMENTS)

ADDITIONAL TOLL MANUFACTURER/REPACKER/TRADER

____1 Official letter request
____2. Photocopy of notarized Contract/Agreement indicating products to be manufactured
____3. Photocopy of the License to Operate (LTO) of the Manufacturer/Repacker/Trader

ADDITIONAL SOURCE AND/OR CHANGE OF NAME OF SOURCE
(for importer of finished bulk products locally repacked and/or raw materials for their own use)

____1. Official letter request
____2. Photocopy of the Foreign Agency Agreement duly authenticated by the Territorial Philippine Consulate
____3. Photocopy of the GMP Certificate of manufacturer duly authenticated by the Territorial Philippine Consulate
____4. List of products/raw materials
____5. Photocopy of the License to Operate (LTO) & Attachment of the Manufacturer/Repacker/Trader

ADDITIONAL PRODUCT(S)

____1. Official letter request
____2. Photocopy of the Addendum to Contract/Agreement re-additional product(s) to be manufactured
____3. Photocopy of the License to Operate (LTO) & Attachment of the Manufacturer/Repacker/Trader

ADDITIONAL ACTIVITY

____1. Official letter request
____2. For Importer of finished bulk products and/or raw materials see Nos.2-4 requirements for Additional Source
____3. For Exporter of own products submit list of products with CPR No. and validity
____4. Photocopy of the License to Operate (LTO) & Attachment of the Manufacturer/Repacker/Trader

DELETION OF TOLL MANUFACTURER/REPACKER/TRADER/SOURCE/PRODUCT

____1. Official letter request
____2. Certification or acknowledgement letter re-termination of Contract/Agreement/Foreign Agency Agreement
____3. Photocopy of the License to Operate (LTO) & Attachment of the Manufacturer/Repacker/Trader

FEE: P50.00 per addition/deletion of toll manufacturer/source
P300.00 - for change of name of source

SCHEDULE FOR SUBMISSION OF APPLICATION

MONDAY – FOOD

TUESDAY – WEDNESAY – } **DRUGS**

THURSDAY – COSMETICS / HHS

CHECKLIST OF REQUIREMENTS FOR CHANGES IN CIRCUMSTANCES (FOOD /DRUGS/ COSMETICS/ HHS ESTABLISHMENTS)

CHANGE OF BUSINESS NAME

____1. Official letter regarding the change of business name
____2 Notarized Accomplished Petition Form
Note: Notarized Certificate authorizing the person who signed in behalf of the establishment/company, if he/she is not the owner or one of the incorporators as registered with DTI/SEC
____3. Joint Affidavit of Undertaking/Information Sheet *(for drugs &cosmetics only)*
____4. Photocopy of Business Name Registration
a. For **single proprietorship**, registration from the Department of Trade & Industry (DTI)
b. For **corporation/partnership**, registration from the Securities & Exchange Commission (SEC) and Articles of Inc.
Note: a. If the registered address with DTI/SEC is different from the address of the establishment to be licensed, submit a photocopy of the Business/Mayor's Permit
b. If the establishment adopts another business name style different from the corporation name, the business/trade name shall be indicated in the SEC registration certificate.
____5. ID pictures (5cm x 5xm) of the Owner /Authorized Representative and Pharmacist *(for drugs & cosmetics only)*
____6. Photocopy of Contract/Agreement with Manufacturer reflecting new business name (for Trader/Repacker only)
____7. Photocopy of Contract of Lease (if a lease) reflecting the new business name
____8. Surrender original License to Operate (LTO)

CHANGE OF BUSINESS ADDRESS

A. For Manufacturer /Repacker - All the general and additional requirements for opening

B. For Trader (Drug & Cosmetic establishments only)
____1. Official letter regarding the change of business address
____2. Photocopy of Business Name Registration
a. For **single proprietorship**, registration from the Department of Trade & Industry (DTI)
b For **corporation/partnership**, registration from the Securities & Exchange Commission (SEC) and Articles of Incorporation
Note: If the registered address with DTI/SEC is different from the address of the establishment to be licensed, submit a photocopy of the Business/Mayor's Permit
____3. Notarized valid Contract of Lease of the space/building occupied (if the space/building is not owned) if owned, photocopy of Transfer Certificate Title (TCT)
____4. Floor plan and location plan of the office/storage areas
____5. Photocopy of Contract/Agreement with Manufacturer reflecting the new address
____6. Surrender original License to Operate (LTO)

CHANGE OF OWNERSHIP

____1. Official letter regarding the change of ownership
____2 Notarized Accomplished Petition Form
Note: Notarized Certificate authorizing the person who signed in behalf of the establishment/company, if he/she is not the owner or one of the incorporators as registered with DTI/SEC
____3. Joint Affidavit of Undertaking/Information Sheet (for drugs &cosmetics only)
____4. Photocopy of Business Name Registration
a. For **single proprietorship**, registration from the Department of Trade & Industry (DTI)
b. For **corporation/partnership**, registration from the Securities & Exchange Commission (SEC) and Articles of Incorporation
Note: a. If the registered address with DTI/SEC is different from the address of the establishment to be licensed, submit a photocopy of the Business/Mayor's Permit
b. If the establishment adopts another business name style different from the corporation name, the business/trade name shall be indicated in the SEC registration certificate.
____5. ID pictures (5cm x 5xm) of the Owner /Authorized Representative and Pharmacist (for drugs &cosmetics only)
____6. Photocopy of Contract/Agreement with Manufacturer reflecting new owner (for Trader/Repacker only)
____7. Photocopy of Deed of Sale/Transfer of Rights
____8. . Photocopy of Contract of Lease (if a lease) reflecting the new business name
____9. Photocopy of Dissolution Papers from SEC (for corporation/partnership)
____10. Photocopy of Financial Statement duly notarized or received by Bureau of Internal Revenue (BIR)
____11. Surrender original License to Operate (LTO)

CHANGE OF PHARMACIST (for Drugs &Cosmetics Establishments only)

____1. Accomplished Notice/Affidavit for Change of Pharmacist duly notarized
____2. ID pictures of the Owner /Authorized Representative and Pharmacist (size: 5cm x 5xm)
____3. Photocopy of Pharmacist's Registration Board **Certificate**, PRC ID and PTR
____4. Photocopy of Certificate of FDA Seminar on Licensing of Establishment by the pharmacist
____5. Duties & Responsibilities of the pharmacist
____6. Photocopy of the resignation letter from the previous company
____7. Pharmacist Clearance

FEE: P500.00 (Except for change of pharmacist)

SCHEDULE FOR SUBMISSION OF APPLICATION:
MONDAY – FOOD
TUESDAY } DRUGS
WEDNESDAY }
THURSDAY – COSMETICS / HHS

SCHEDULE OF FEES
DRUGS/COSMETICS MANUFACTURER/TRADER
PER A.O. 50 s. 2001

CAPITAL INVESTMENT (Based on Financial Statement)	COMPANY CLASSIFICATION	CORRESPONDING FEE
20 Million and below	Drug Manufacturer	P 10,000.00
	Cosmetic Laboratory	P 5,000.00
	Medical Device Manufacturer	P 5,000.00
	Drug/Cosmetic/Medical Device Trader	P 3,000.00
Over 20 Million but below 50 Million	Drug Manufacturer	P 15,000.00
	Cosmetic Laboratory	P 10,000.00
	Medical Device Manufacturer	P 7,000.00
	Drug/Cosmetic/Medical Device Trader	P 5,000.00
50 Million and above	Drug Manufacturer	P 20,000.00
	Cosmetic Laboratory	P 15,000.00
	Medical Device Manufacturer	P 10,000.00
	Drug/Cosmetic/Medical Device Trader	P 7,000.00

SCHEDULE FOR SUBMISSION OF APPLICATION

MONDAY – FOOD

TUESDAY – } DRUGS
WEDNESAY – }

THURSDAY – COSMETICS / HHS

CHECKLIST OF REQUIREMENTS FOR OPENING OF DRUGS / COSMETICS ESTABLISHMENTS

For Pre-application as Manufacturer/Repacker:

____1. Submit Letter of Intent for pre-site inspection (Fee: P500)

GENERAL REQUIREMENTS:

____1. Information as to activity(ies) of establishment
____2. Notarized Accomplished Petition Form/Joint Affidavit of Undertaking
____3. Photocopy of Business Name Registration
   a. For **single proprietorship**, registration from the Department of Trade & Industry (DTI)
   b. For **corporation/partnership**, registration from the Securities & Exchange Commission (SEC) and Articles of Incorporation
   c. For Cooperative, registration from the Cooperative Development Authority

Note: a. If the registered address with DTI/SEC is different from the address of the establishment to be licensed, submit a photocopy of the Business/Mayor's Permit
b. If the establishment adopts another business name style different from the corporation name, the business/trade name shall be indicated in the SEC registration certificate.

____4. ID pictures of the Owner /Authorized Representative and Pharmacist (size: 5cm x 5xm)
____5. Photocopy of Pharmacist's Registration Board Certificate, PRC ID and PTR
____6. Photocopy of Certificate of FDA Seminar on Licensing of Establishment by the pharmacist
____7. Photocopy of notarized valid Contract of Lease of the space/building occupied (if the space/bldg. is not owned) If owned, copy of TCT (Transfer Certificate Title)
____8. Photocopy of Financial Statement duly notarized or received by Bureau of Internal Revenue (BIR), if not available, submit notarized certification of initial capital invested
____9. Location Plan/Site (indicate size, location, immediate environment, type of building)
____10. List of products to be manufactured/distributed in generic and brand names (indicate dosage form and strength)
____11. Duties and responsibilities of the pharmacist
____12. Pharmacist Clearance
____13. Reference Books:
   a. USP/NF (latest edition)
   b. R.A. 9711, R.A. 3720, R.A. 6675, R.A. 5921
   c. Remington's Pharmaceutical Sciences (latest edition)
   d. Goodman & Gilman Pharmaceutical Basis of Therapeutics
   e. British Pharmacopoeia (BP)
   f. Philippine National Drug Formulary
   g. Philippine Pharmacopoeia

*For Drugs - a & b (mandatory) and any reference from c - g
*For Cosmetics – b, other official monographs, if applicable (e.g. USP, BP) and other FDA regulation

ADDITIONAL REQUIREMENTS:

I. A For Manufacturer:
____1. Site Master File (SMF)

B. For Repacker:
____1. Site Master File (SMF)
____2. Notarized valid Contract/Agreement with the Manufacturer with stipulation that both the Manufacturer and Repacker are jointly responsible for the quality of the products

C. For Trader:
____1. Notarized valid Contract/Agreement with the manufacturer with stipulation that both the Manufacturer and Trader are jointly responsible for the quality of the products and statement of ownership of formulation
____2. Floor plan of office and storage area

D. For Importer of Raw Materials/Finished Products in Bulk:
____1. Foreign Agency Agreement duly authenticated by the Territorial Philippine Consulate
____2. Certificate of Status of Manufacturer (CGMP Certificate) issued by a Government Health Agency duly authenticated by the Territorial Philippine Consulate (for API, finished cosmetics product/s)
____3. Certificate of Analysis (Raw Materials, Finished Products)
____4. Material Safety Data Sheet (MSDS)

Note: Notarized certificate authorizing the person who signed in behalf of the establishment/company if he/she is not owner or one of the incorporators as registered with DTI/SEC

FEES: See Schedule of Fees of LTO at the back page

CHECKLIST OF REQUIREMENTS FOR OPENING OF HOUSEHOLD HAZARDOUS SUBSTANCE ESTABLISHMENT

For Pre-application as Manufacturer/Repacker

____1. Submit Letter of Intent for pre-site inspection (Fee: P500)

GENERAL REQUIREMENTS:

____1. Information as to activity(ies) of establishment
____2. Notarized Accomplished Petition Form

Note: Notarized Certificate authorizing the person who signed in behalf of the establishment/company, if he/she is the owner or one of the incorporators as registered with DTI/SEC

____3. ID picture of Owner/Authorized Representative (size: 5cm x 5cm)
____4. Photocopy of Business Name Registration
   a. For **single proprietorship**, registration from the Department of Trade & Industry (DTI)
   b. For **corporation/partnership**, registration from the Securities & Exchange Commission (SEC) and Articles of Incorporation

Note: a. If the registered address with DTI/SEC is different from the address of the establishment to be licensed, submit a photocopy of the Business/Mayor's Permit
b. If the establishment adopts another business name style different from the corporation name, the business/trade name shall be indicated in the SEC registration certificate.

____5. Photocopy of notarized valid Contract of Lease of the space/building occupied (if the space/bldg. is not owned) If owned, copy of TCT (Transfer Certificate Title)
____6. Photocopy of Notarized Fixed Asset & Operating Capital or Financial Statement, if available
____7. Location Plan/Site (indicate size, location, immediate environment, type of building)
____8. List of products to be processed/repacked/imported
____9. List of personnel - technical & non-technical (indicate academic qualifications & relevant experiences)
___10. Clearance from Department of Environment & Natural Resources (DENR)
___11. Clearance from Barangay and Homeowner's Association
___12. References: RA 9711, RA 3720, PD 881 s. 1976 and other related FDA regulations pertaining to HHS

ADDITIONAL REQUIREMENTS

I. A. For Manufacturer

____1. Floor plan with complete dimensions in meters & proper identification of areas with description
____2. Organizational Structure
____3. List of manufacturing & quality control equipment & facilities

B. For Repacker

____1. Floor plan with complete dimensions in meters & proper identification of areas with description
____2. Organizational Structure
____3. List of repacking & quality control equipment & facilities
____4. Photocopy of notarized valid contract/agreement with the manufacturer with stipulation that both the Manufacturer and Repacker are jointly responsible for the quality of the products
____5. Photocopy of the License to Operate (LTO) of the Manufacturer

SCHEDULE OF FEES (based on total Itemized Fixed Assets & Operating Capital/ Financial Statement)

CAPITAL	CORRESPONDING FEE
1 Million and below	P1,000.00
Over 1 Million but below 5 Million	P2,000.00
5 Million but below 10 Million	P3,000.00
10 Million but below 20 Million	P5,000.00
20 Million but below 50 Million	P10,000.00
50 Million and above	P15,000.00

- Submission of application and other document every **THURSDAY ONLY**