Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

06 March 2013

FDA CIRCULAR
No. 2013-009

Subject: **REVISED GUIDELINES IN LICENSING HOUSEHOLD HAZARDOUS SUSBTANCES (HHS) ESTABLISHMENTS**

Pursuant with the provisions of R.A. 9711 and its implementing rules and regulations, Presidential Decree 881 and Administrative Order 303. 1976, the FDA hereby set revised rules and regulations in licensing of HHS establishments that would engage their business here in the Philippines:

(1) All that will engage in manufacturing, trading, and distribution of Household Hazardous Substance (HHS) products shall secure appropriate licenses in accordance to the existing rules and regulations set by the FDA.

(2) All establishments shall institute their own regulatory mechanism, in ensuring the quality, efficacy and safety of all HHS products in the market.

(3) For renewal and amendments of the license, all HHS establishments shall surrender their license to operate to reflect changes in the format, text and signatory in the revised LTO. A fee of PhP 500.00 + 1% LRF will be charged.

(4) HHS Distributors who owns the HHS product formulation and falls under the activity of trader as prescribed in the RA 9711, which is, "any establishment who is a registered owner of the health product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer". In addition, a trader may also engage in the distribution and/ or marketing of its products shall be re-classified as HOUSEHOLD HAZARDOUS SUBSTANCE TRADER.

(5) All HHS establishments are required to renew at least there (3) months before expiration of the LTO. Strictly adhere to the schedule of submission business transaction of LTO and CPR.

(6) The FDA and the establishments shall use the revised checklist of requirements and licensing forms for Household Hazardous Substance. (See Annex- I Checklist of Requirements for Household Hazardous Substances Establishments; Annex II- Petition Form and Annex- III Requirements for Changes in Circumstances).

(7) All amendments shall be coursed in the new FDA Circular.

This guideline shall take effect on 15 March 2013.

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Food and Drug Administration

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

CENTER FOR COSMETICS REGULATION AND RESEARCH

CHECKLIST OF REQUIREMENTS FOR HOUSEHOLD HAZARDOUS SUBSTANCES ESTABLISHMENTS

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
  - o Signed Duties and Responsibilities
  - o Certificate of Attendance to FDA sponsored seminar on licensing of establishment or promissory note to attend
- ☐ Notarized Accomplished Petition Form
- ☐ 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 / 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
  - o Notarized valid Contract of Lease/Sublease (if the space/ building being occupied is not owned)
  - o Transfer Certificate of Title (if owned)
  - o Notarized Certificate of Occupancy (if owned by one of the incorporators)
  - o Valid and duly notarized Warehousing Agreement (Third Party Logistics)
  - o Valid Homeowner's Association (HOA) and Clearance if the establishment is located inside a subdivision or residential condominium
  - o Floor plan, vicinity map and picture with signage

II. SPECIFIC REQUIREMENTS

A. FOR MANUFACTURER

- ☐ Pre-Site Inspection
  - o Letter of Intent indicating the intended products to be manufactured and location of the site with contact details
  - o Proof of payment (P510.00)

- ☐ After Pre-site Inspection:
  - ☐ Copy of Pre-Site Inspection Report
  - ☐ Photocopy of the Financial Statement duly notarized/ received by the Bureau of Internal Revenue (BIR); if not available submit notarized certification of initial capital invested.
  - ☐ Accomplished Site Master File
  - ☐ Clearance from Department of Environment & Natural Resources (DENR)
  - ☐ List of personnel, technical and non-technical (indicate academic qualifications and relevant experience)
  - ☐ List of products to be manufactured in actual product dosage form (e.g. liquid/ solution, gel, lotion, aerosol spray)
  - ☐ List of manufacturing and quality control facilities and equipment

- ☐ **FOR REPACKER**
  - o Floor plan with complete dimensions in meters and proper identification of areas with description
  - o Organizational Structure
  - o List of repacking and quality control facilities and equipment
  - o Photocopy of valid contract/ agreement with the manufacturer stipulating that both the manufacturer and repacker are jointly responsible for the quality of the products
  - o Photocopy of License to Operate (LTO) of the Manufacturer

- ☐ **FOR IMPORTER OF RAW MATERIALS (RM)/ FINISHED PRODUCTS (FP) IN BULK:**
  - o Foreign Agency Agreement duly authenticated by the Territorial Philippine Consulate
  - o List of source(s) and RM/ FP in bulk being imported
  - o Submit any of the following:
    - ISO Certificate based on current ISO standards
    - Certificate of Analysis (Raw Materials and/ or Finished Products in Bulk)
    - Safety Data Sheets (SDS)

B. FOR DISTRIBUTOR:

- ☐ List of Products distributed in matrix format indicating the name of raw material and/ or product, manufacturer, supplier/ trader, country of origin
- ☐ Proof of Occupancy – Warehouse
  - o Notarized valid Contract of Lease/Sublease (if warehouse being occupied is not owned)
  - 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

(1) 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
  - o For raw materials, an ISO/Business License/Manufacturer's License may be submitted in lieu of GMP Certificate

(2) 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 of the Manufacturer/ Distributor/ Trader
- ☐ List of HHS products with registration numbers and validity

(3) 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 validity

III. SCHEDULE OF FEES:

Licensing fees are based on A.O. 50 s. 2001

A. DISTRIBUTOR

1. **INITIAL/ OPENING** (1 year LTO validity)
   P 3,000.00 + 1% Legal Research Fee = Php 3,030.00

2. **RENEWAL** (2 years LTO validity)
   P 6,000.00 + 1% Legal Research Fee = Php 3,060.00

B. MANUFACTURER

1. **INITIAL/ OPENING** (1 year LTO validity);

CAPITAL INVESTMENT (based on financial statement)	COMPANY CLASSIFICATION	CORRESPONDING FEE (+ 1% Legal Research Fee)
1 Million and below	HHS Manufacturer/ Repacker	Php 1,000.00 + Php 10.00 = **Php 1,010.00**
Over 1 Million But Below 5 Million	HHS Manufacturer/ Repacker	Php 2, 000.00 + Php 20.00 = **Php 2,020.00**
5 Million but below 10 Million	HHS Manufacturer/ Repacker	Php 3, 000.00 + Php 30.00 = **Php 3,030.00**
10 Million but below 20 Million	HHS Manufacturer/ Repacker	Php 5, 000.00 + Php 50.00 = **Php 5,050.00**
20 Million but below %0 Million	HHS Manufacturer/ Repacker	Php 10,000.00 + Php 100.00 = **Php 10,100.00**
50 Million and Above	HHS Manufacturer/ Repacker	Php 15,000.00 + Php 150.00 = Php 15,150.00

2. **RENEWAL** (2 years LTO validity) =- Initial Fee x 2

C. **CHANGES IN CIRCUMSTANCES** – refers to changes in business name, business address, ownership and authorized person (Pharmacist/Allied Health Science Profession) and also refers to any changes if activities as to the inclusion and or deletion of toll manufacturer(s), trader(s), source and/ or name of source, products or activity
* Php 500.00 + 1% Legal Research Fee = **Php 510.00**

D. **AMENDMENTS** – refers to the inclusion and/ or deletion of activity, product, source or client; it also encompasses corrections done on LTO, GMP Certificate, CPR or notification
*Php 500.00 + 1% Legal Research Fee = **Php 510.00**

Legend: * - minimum of P10.00 LRF if amount to be payed is below P1,000.00

NOTE:

1. **STRICTLY FOLLOW PROCEDURES IN ACCORDANCE TO FDA MEMORANDUM CIRCULAR 2013-001 "Guidelines on the Submission of Company Applications and Product Dossiers in Electronic Copy".**
2. **IN CASES OF APPLICATIONS TURNED INITIAL, CHANGE OF OWNERSHIP, MERGING OR BUY-OUT, SURRENDER PREVIOUSLY ISSUED LTO (ORIGINAL).**
3. **SUBMISSION OF APPLICATION IS EVERY THURSDAYS FROM 7:00AM TO 3:00 PM**

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CENTER FOR COSMETICS REGULATION AND RESEARCH

IN THE MATTER OF PETITION OF:

_____
(Name of Owner/Incorporator/Authorized Representative)

TO OPEN A **HOUSEHOLD HAZARDOUS SUBSTANCES** ESTABLISHMENT PARTICULARLY AS:
( ) MANUFACTURER ( ) TRADER ( ) DISTRIBUTOR

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 an 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 aforesaid establishment desires to engage in the sale, distribution or manufacture of household hazardous substances;

FOURTH - That the petitioner has the authority to file this application as the:
( ) Sole Proprietor/Owner ( ) Incorporator ( ) Authorized Representative of the Establishment;

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

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

_____, Philippines _____, 20 _____.
(City,Province) *(DD/MM)*

Respectfully submitted by:

_____
SIGNATURE OVER PRINTED NAME OF PETITIONER
Contact Number/s:_____
Email Address:_____

VERIFICATION

Petitioner after having sworn in accordance wit law, hereby states that:

(1) He / She is the petitioner in the above entitled petition;
(2) The Petitioner has caused the preparation of the said petition and has read and understood the contents thereof; and
(3) The allegations are true and correct to his/her knowledge.