Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

4 February 2013

FDA CIRCULAR
No. 2013-002

SUBJECT: REVISED GUIDELINES IN LICENSING COSMETIC ESTABLISHMENTS

Consistent and consonance with the provisions of RA 9711 and its implementing rules and regulations, the FDA hereby set the revised rules and regulations in licensing cosmetic establishments that would engage their business here in the Philippines:

(1) All establishments that will engage in cosmetics manufacture, trader, importer, distributor shall secure appropriate licenses in accordance to the existing rules and regulations set by FDA;

(2) Institute their own regulatory mechanism, aligned with ASEAN Cosmetic Directive (ACD), in ensuring the quality, efficacy and safety of all cosmetic products in the market.

(3) For renewal and amendments of the license, all cosmetic 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) Cosmetic traders who does not own the cosmetic product formulation but owns the cosmetic brand shall be re-classified as COSMETIC DISTRIBUTOR.

(5) The person (natural or juridical) placing the product in the Philippine market shall be regarded as the product owner, whether manufacturer, trader or distributor/importer. Thus, the ownership of the formulation of a cosmetic product must be determined and explicitly stated in the manufacturing or distributorship agreement.

(6) In that, the Product Information File (PIF) must be updated and accessible during inspection.

(7) All cosmetic establishments are required to renew at least three months before expiration of the LTO. Strictly adhere to the schedule of submission business transaction of LTO and CPR.

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(8) The FDA and the company shall use the revised checklist of requirements and licensing forms for Cosmetics. (see Annex)

This guideline shall take effect immediately after posting in the FDA website.

KENNETH Y. HARTIGAN-GO, MD
Acting, Director IV
Food and Drug Administration

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Alabang, City of Muntinlupa

CENTER FOR COSMETICS REGULATION AND RESEARCH

IN THE MATTER OF PETITION OF:

_____
(Name of Owner/Incorporator/Authorized Representative of Establishment)

TO OPEN A **COSMETIC 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 Home 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 of Establishment;

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 _____, an authorized person with
(Name of Authorized Person [Pharmacist or any Allied Health Science Profession])
PRC Certificate of Registration No.: _____ issued on _____valid until _____;
(DD/MM/YY) (DD/MM/YY)

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 circumstances or amendments;

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

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

WHEREFORE, the petitioner respectfully prays that he/she be granted a License to Operate as a cosmetic 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.:_____
E-mail 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.

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JOINT AFFIDAVIT OF UNDERTAKING

2x2
Picture
(Pharmacist)

_____
(PRC Registered Name of Authorized Person)

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

Profession : _____ *(Pharmacist/Allied Health Science Profession)*
PRC Registration No.: _____ Issued on _____ Validity: _____
PTR NO.: _____ Issued on: _____
of legal age, single/married, and a resident of _____ and
(Complete Address)
_____ of _____ located at
(Name of Owner/Incorporator/Authorized representative of Establishment) *(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 or other Allied Health Science regulations, Food and Drug Administration Act of 2009, ASEAN Cosmetic Directive and other pertinent FDA 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 Authorized Person, 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 Authorized Person'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 (s) of location, change of business name, change of ownership, change of Authorized Person and change in cosmetic products;

That, the Authorized person is responsible for any adverse events, complaints, product returns and recalls if any and subsequently notifies the Food and Drug Administration;

That the Authorized Person is not and will not in any way be connected with any health product regulated or similar establishment/outlet;

That the owner and authorized person 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 _____

_____
AUTHORIZED PERSON
Res. Cert. No.: _____
Issued on _____at _____

VERIFICATION

The Owner and Authorized Person after having sworn in accordance with the law, hereby states that:
(1) He / She is the owner and authorized person in the above entitled joint affidavit of undertaking;
(2) Both the undersigned has caused the preparation of the said joint affidavit of undertaking and has read and understood the contents thereof; and
(3) The allegations are true and correct to their knowledge.

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CENTER FOR COSMETICS REGULATION AND RESEARCH

CHECKLIST OF REQUIREMENTS FOR COSMETIC ESTABLISHMENTS

I. GENERAL REQUIREMENTS

- ☐ Notarized Accomplished Petition Form 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 with 2 x 2 ID picture of Authorized Person
- ☐ For Authorized Person (Pharmacist/Allied Health Science Profession), copy of the following:
  - 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
- ☐ 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 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 DISTRIBUTOR:

- ☐ List of Products distributed in matrix format indicating the name of raw material and/ or product, manufacturer, supplier/ trader, country of origin
- ☐ For Raw Material Distributor, submit Safety Date Sheet (SDS) with complete data
- ☐ 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 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
- ☐ 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) or Certificate of Free Sale (CFS).
- ☐ For raw materials, an ISO/Business License/Manufacturer's License may be submitted in lieu of GMP Certificate

(2) FOR EXPORTER

- ☐ Valid Distribution Agreement with the FDA-licensed Supplier (Manufacturer/Distributor/Trader)
- ☐ Valid Distribution agreement with the country where the products are to be exported
- ☐ Valid License to Operate of the Manufacturer/ Distributor/ Trader
- ☐ List of Products with notification numbers and validity

(3) FOR WHOLESALER

- ☐ 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 valid notification numbers

B. FOR TRADER:

- ☐ List of products manufactured by toll manufacturer
- ☐ Copy of Notarized Manufacturing Agreement stipulating the ownership of formulation and the joint responsibility of the manufacturer and trader in placing the product in the market.
- ☐ Copy of notarized agreement with the third-party warehousing services, if any
- ☐ 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 notarized Warehousing Agreement (Third Party Logistics)
  - o Floor plan, vicinity map and picture with signage

C. FOR MANUFACTURER

- ☐ **Pre-approval:** Letter of Intent for Pre-Site Inspection with location/vicinity map (Fee: 510.00)
- ☐ **After approval of pre-site inspection:**
  - o Pre-Site Inspection Report
  - o Photocopy of the Financial Statement notarized/ received by the Bureau of Internal Revenue (BIR); if not available submit notarized certification of initial capital invested.
  - o Location plan/ Site (indicate size, location, immediate environment and type of building)
  - o Site Master File (See attached form)
  - o List of products to be manufactured in actual product dosage form (e.g. liquid/ solution, gel, lotion, cream)
- ☐ **For Importer of Raw Materials/ Finished Products in Bulk:**
  - o Foreign Agency Agreement duly authenticated by the Territorial Philippine Consulate
  - o Certificate of Status of Manufacturer (CGMP Certificate) issued by the Government Health Agency duly authenticated by the Territorial Philippine Consulate (for API, finished cosmetic product/s)
  - o Certificate of Analysis (Raw Materials and/ or Finished Products in Bulk)
  - o Safety Data Sheet (SDS)
- ☐ **For Exporter of Finished bulk/Finished product:**
  - o Distribution Agreement with the country where the product will be exported
  - o List of Products/Finished bulk in matrix to be exported reflecting CPR number and validity and the country to be exported

III. SCHEDULE OF FEES:

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

A. DISTRIBUTOR - Initial / Opening (LTO valid for 1 year)
P 3,000.00 + 1% Legal Research Fee (LRF) =
Php 3,030.00

B. MANUFACTURER/ TRADER

1. INITIAL/ OPENING (LTO valid for 1 year)

CAPITAL INVESTMENT (based on financial statement)	COMPANY CLASSIFICATION	CORRESPONDING FEE/ YEAR (+ 1% Legal Research Fee)
20 Million and below	Cosmetic Manufacturer	Php 5,000.00 + Php 50.00 = **Php 5,050.00**
	Cosmetic Trader	Php 3,000.00 + Php 30.00 = **Php 3,030.00**
Over 20 Million But Below 50 Million	Cosmetic Manufacturer	Php 10,000.00 + Php 100.00 = **Php 10,100.00**
	Cosmetic Trader	Php 5,000.00 + Php 50.00 = **Php 5,050.00**
50 Million and Above	Cosmetic Manufacturer	Php 15,0000.00 + Php 150.00 = **Php 15,150.00**
	Cosmetic Trader	Php 7,000.00 + Php 70.00 = **Php 7,070.00**

2. RENEWAL (LTO valid for 2 years)– corresponding fee/ year (+1% LRF) x 2 years

3. AMENDMENTS / CHANGES IN CIRCUMSTANCES – refers to changes in business name, business address, ownership and authorized person (Pharmacist/Allied Health Science Profession)
Php 500.00 + 1% Legal Research Fee = **Php 510.00**

NOTE:

1. PLEASE BRING ORIGINAL DOCUMENTS FOR VERIFICATION UPON SUBMISSION OF APPLICATION
2. SUBMIT APPLICATION THROUGH ELECTRONIC COPY IN CD FORMAT AND HARD COPY
3. SUBMISSION OF APPLICATION IS EVERY FRIDAY 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

SPECIFIC REQUIREMENTS FOR CHANGE OF CIRCUMSTANCES/AMENDMENTS FOR COSMETICS/HHS

ADDITIONAL ACTIVITY (IMPORTER, EXPORTER, TOLL MANUFACTURER, PACKER, REPACKER • Letter of Request • Original LTO • Re-issuance fee of Php 500.00 (based on A.O. 50 series of 2001) • Other requirements, refer to particular specific business activity as stated in the general checklist of requirements • Proof of payment	**CHANGE OF BUSINESS NAME** • Letter of Request • Notarized Petition Form & Joint Affidavit of Undertaking • Business Name Registration (DTI/SEC) • Proof of payment
CHANGE OWNERSHIP • Letter of Request • Deed of Sale or Transfer of Rights • Surrender Original LTO • All the required documents applied for initial/opening • Proof of payment	**TRANSFER OF LOCATION (Trader & Distributor)** • Letter of Request • Business Name Registration (DTI/SEC) Reflecting the New Address • Mayor's Permit or Brgy. Business Permit • Contract of Lease/ Proof of Ownership • Floor Plan w/ Dimension • Vicinity Map/Location Plan • Surrender Original LTO • Proof of payment
CHANGE OF MANUFACTURING SITE • Letter of request • The case for change of site of a manufacturer follows the requirements for Opening/Initial application • Surrender Original LTO • Proof of payment	**ADDITION/ DELETION of SOURCE** • Letter of Request • Proof of cancellation/deletion of supplier/notarized termination agreement • If in case addition of source, refer to the Checklist of Requirements • Original LTO • Proof of payment
CHANGE OF AUTHORIZED PERSON (Pharmacist/Allied health Science Profession for Cosmetics only) • Letter of Request • Resignation Letter noted by the employer • Submit Notarized Joint Affidavit of Undertaking • All requirements under the general requirements for Authorized Person • Proof of payment	**RECONSTRUCTION/LOST /DILAPIDATED LTO** • Letter of Request • Affidavit of Lost • Proof of payment
Schedule of fees for change of Circumstances/Amendment : P 500.00 + 1% (LRF) = **P510.00**	In case of closure of business activity: • Letter of request • Surrender LTO If lost, submit Affidavit of Lost