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CENTER FOR COSMETICS REGULATION AND RESEARCH

CHECKLIST OF REQUIREMENTS FOR THE ISSUANCE OF LICENSE TO OPERATE FOR COSMETIC ESTABLISHMENTS

I. INITIAL/OPENING APPLICATIONS

A. GENERAL REQUIREMENTS

- ☐ Completely accomplished and notarized Integrated Application Form with ID picture of both the Owner/Incorporator/General Manager and the Authorized Person (Refer to FDA Circular No. 2014-003) (only for NCR and CHD IV-A)
- ☐ Notarized Accomplished Petition Form with 2 x 2 ID picture of Owner/Incorporator/Authorized Representative (see Annex A) (except for NCR and CHD IV-A)
    - Notarized Secretary's Certificate/Special Power of Attorney (if the Authorized Representative is not the owner in the DTI business registration or one of the incorporators in the SEC)
- ☐ **Proof of Business Registration:**
    - Valid certificate of business name registration with the Department of Trade and Industry (DTI), (for single proprietorship)
    - Valid registration with the Securities and Exchange Commission (SEC) and Articles of Incorporation or Partnership (for corporation or partnership)
        - 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)"
    - certificate of Cooperative Development Authority (CDA), (for cooperatives),

  Note: If the business address in the DTI business registration and SEC is different from the declared office address, provide a valid Mayor's Permit/Barangay Clearance
- ☐ **Proof of Occupancy (Office, Manufacturing Plant and Warehouse):**
    - Transfer Certificate of Title (TCT) as proof of ownership.
    - Notarized Certificate of Occupancy, if owned by one of the incorporators.
    - Notarized valid contract of lease/sublease, if the space/building being occupied is not owned,
    - Valid Clearance from Homeowner's Association (HOA) / Condominium/Building Administration, if within a residential area/ condominium,
    - Valid notarized warehousing agreement for third party logistics,
- ☐ **Other requirements**
    - Floor plan/lay-out in meters and proper identification of areas (office and warehouse)
    - Blueprint for manufacturing plant
    - Vicinity/Location map with landmarks (i.e. google map, sketch of the area)
- ☐ **Pertinent Documents for Authorized Person (Pharmacist or any Allied Health Science Professional with relevant trainings):**
    - Notarized Joint Affidavit of Undertaking with 2 x 2 ID picture of Authorized Person (see Annex B) (except NCR and CHD IV-A)
    - PRC Board Certificate

- Valid PRC ID
- Current Professional Tax Receipt (PTR)
- Duties and responsibilities signed by the authorized person and the immediate supervisor
- Certificate of Attendance to "Qualified Person in Industry Regulatory Affairs (QPIRA)" for CCRR or promissory letter to attend with proof of scheduled day of attendance and payment
- Certificate of Attendance to"Training on the 13 ASEAN Cosmetic GMP Modules" or promissory letter to attend with proof of scheduled day of attendance and payment (only for traders and manufacturers)

B. SPECIFIC REQUIREMENTS

1. FOR COSMETIC DISTRIBUTOR

- List of products indicating the name and address of source/supplier/manufacturer, country of origin (if imported) following the format below:
  *Specify the cosmetic product type (Example: lipstick, lotion, creams, eye liner, foundation, masks, scrub, etc.)

Source Name & Address	Manufacturer Name & Address	Country of Origin	Complete Product List*
OR			

IMPORTER:

- Valid Foreign Agency Agreement (FAA) or any form of authorization from each source/supplier duly authenticated by the Territorial Philippine Consulate
- If the source/supplier has appointed another logistic/invoicing company, any of the following:
  - Valid Supply Agreement between the foreign source/supplier and manufacturer
  - Valid Tripartite Agreement duly authenticated by the Territorial Philippine Consulate
- **Proof of GMP Compliance of Manufacturer (any of the following):**
  - Valid GMP Certificate of manufacturer issued by the government agency or accredited business association (WHO, ECC/EU, COLIPA) in the country of origin
  - Self-declaration of compliance to GMP if manufacturer is from an ASEAN Member State
  - Certificate of Free Sale issued by the government agency (National Regulatory Authority or Chamber of Commerce) in the country of origin
  - ISO Certificate in compliance to GMP
  - Valid manufacturer's license

- **FOR WHOLESALER**
  - Duly notarized valid distribution agreement with the FDA-licensed supplier

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- **FOR EXPORTER**
  - Duly notarized valid distribution agreement with the local supplier reflecting the country where the products are to be exported
  - List of products to be exported with their corresponding notification numbers and validities

2. **FOR COSMETIC TRADER**
   - Photocopy of the Financial statement notarized/received by the Bureau of Internal Revenue (BIR) or notarized certification of initial capital invested
   - Duly notarized valid contract manufacturing agreement with the FDA-licensed Cosmetic Manufacturer stipulating the following:
     - That the trader owns the formulation
     - That the trader and manufacturer are jointly responsible for the quality of the product/s
     - List of products to be manufactured by the toll manufacturer
   - **FOR EXPORTER OF OWN FINISHED PRODUCTS:**
     - Duly notarized valid distribution agreement with the supplier in the country where the products are to be exported
     - List of products to be exported with corresponding notification numbers and validities

3. **FOR COSMETIC MANUFACTURER**
   - Photocopy of the Financial statement notarized/received by the Bureau of Internal Revenue (BIR) or notarized certification of initial capital invested
   - Site Master File (see Annex C)
   - List of products to be manufactured
   - **FOR EXPORTER OF OWN FINISHED PRODUCTS/FINISHED BULK:**
     - Duly notarized valid distribution agreement with the supplier in the country where the products are to be exported
     - List of products to be exported with notification numbers and validity

- **FOR REPACKER:**
  - Duly notarized valid contract/agreement with the manufacturer of the product/s to be repacked with stipulation that both the manufacturer and repacker are jointly responsible for the quality of the product
  - List of products to be repacked
  - List of repacking and quality control equipment and facilities
- **FOR TOLL MANUFACTURER:**
  - Duly notarized valid contract manufacturing agreement with the FDA-licensed Cosmetic Trader stipulating the following:
    - That the trader owns the formulation
    - That the trader and manufacturer are jointly responsible for the quality, efficacy and safety of the product/s placed in the market
    - List of products to be manufactured by the toll manufacturer

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C. FEES AND CHARGES (LTO valid for 1 year)

Proof of payment of fees as prescribed by the current FDA regulations.

II. RENEWAL APPLICATIONS (can be filed at least 3 months before LTO expiry date)

A. AUTOMATIC RENEWAL

- Completely accomplished and notarized Integrated Application Form (Refer to FDA Circular No. 2014-003) (only for NCR and CHD IV-A)
- Duly notarized Affidavit of Undertaking for Automatic Renewal (except for NCR and CHD IV-A)
- Photocopy of the current Financial statement notarized/received by the Bureau of Internal Revenue (BIR) or notarized certification of initial capital invested (for traders and manufacturers only)
- Original LTO (scanned copy only for NCR and CHD IV-A)

B. REGULAR RENEWAL

- Completely accomplished and notarized Integrated Application Form (Refer to FDA Circular No. 2014-003) (only for NCR and CHD IV-A)
- Letter of request for the renewal of the LTO and the changes in the status of business since the last issuance of LTO (except NCR and CHD IV-A)
- Photocopy of the Financial statement notarized/received by the Bureau of Internal Revenue (BIR) or notarized certification of initial capital invested (for traders and manufacturers only)
- Original LTO (scanned copy only for NCR and CHD IV-A)

C. FEES AND CHARGES (LTO valid for 2 years)

Proof of payment of fees as prescribed by the current FDA regulations

III. AMENDMENT/CHANGE OF CIRCUMSTANCES

A. ADDITION OF ACTIVITY AND SOURCE (IMPORTER, EXPORTER, WHOLESALER, TOLL MANUFACTURER, REPACKER)

- Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (for NCR and CHD IV-A)
- Letter of intent stating the change/amendment applied for
- Original LTO (scanned copy only for NCR and CHD IV-A)
- Required document stated in I B (Specific Requirements)

B. DELETION OF ACTIVITY AND SOURCE

- Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (for NCR and CHD IV-A)
- Letter of intent stating the change/amendment applied for
- Original LTO (scanned copy only for NCR and CHD IV-A)
- Proof of cancellation/deletion of supplier or notarized termination agreement

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C. CHANGE IN BUSINESS NAME AND ADDRESS OF SOURCE AND/OR MANUFACTURER:

- ☐ Valid Foreign Agency Agreement (FAA) or any form of authorization from each source/supplier duly authenticated by the Territorial Philippine Consulate reflecting the new business name or address
- ☐ If the source/supplier has appointed another logistic/invoicing company, any of the following:
  - Valid Supply Agreement between the foreign source/supplier and manufacturer reflecting the new business name or address
  - Valid Tripartite Agreement duly authenticated by the Territorial Philippine Consulate reflecting the new name or address
- ☐ Proof of GMP compliance of manufacturer under the new business name or address

D. ADDITION/DELETION OF PRODUCT

- ☐ Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (for NCR and CHD IV-A)
- ☐ Letter of request
- ☐ Original LTO (scanned copy only for NCR and CHD IV-A)
- ☐ If distributor/wholesaler, amendment in the distribution agreement with the FDA-licensed supplier
- ☐ If distributor/importer, amendment in the Foreign Agency Agreement (FAA) or any form of authorization with the source/supplier duly authenticated by the Territorial Philippine Consulate
- ☐ If trader, amendment in the manufacturing agreement with the FDA-licensed mannufacturer
- ☐ If manufacturer, letter of request for inspection

E. CHANGE OF BUSINESS NAME

- ☐ Completely accomplished and notarized Integrated Application Form (Refer to FDA Circular No. 2014-003) (only for NCR and CHD IV-A)
- ☐ Letter of request
- ☐ Original LTO (scanned copy only for NCR and CHD IV-A)
- ☐ Notarized Accomplished Petition Form with 2 x 2 ID picture of Owner/Incorporator/Authorized Representative (except for NCR and CHD IV-A)
- ☐ Notarized Joint Affidavit of Undertaking with 2 x 2 ID picture of Authorized Person (except for NCR and CHD IV-A)
- ☐ Proof of Business Registration with amended business name
- ☐ Amended agreement with each source/supplier reflecting the new business name

F. CHANGE OF OWNERSHIP/ MERGING/ BUY-OUT

- ☐ Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (only for NCR and CHD IV-A)
- ☐ Letter of request

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- ☐ Original LTO (scanned copy only for NCR and CHD IV-A)
- ☐ Deed of Sale or Transfer of Rights
- ☐ All the required documents applied for initial/opening application (for distributor only)

G. TRANSFER OF OFFICE/WAREHOUSE ADDRESS (Distributor & Trader)

- ☐ Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (only for NCR and CHD IV-A)
- ☐ Letter of request
- ☐ Original LTO (scanned copy only for NCR and CHD IV-A)
- ☐ Proof of business registration (DTI or SEC) reflecting the new address
- ☐ All required documents for proof of occupancy

H. TRANSFER OF MANUFACTURING SITE

- ☐ Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (only for NCR and CHD IV-A)
- ☐ Letter of request
- ☐ Original LTO (scanned copy only for NCR and CHD IV-A)
- ☐ All the required documents applied for initial/opening application

I. CHANGE OF AUTHORIZED PERSON

- ☐ Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (for NCR and CHD IV-A)
- ☐ Letter of request
- ☐ Original LTO (scanned copy only for NCR and CHD IV-A)
- ☐ Notarized Joint Affidavit of Undertaking with 2 x 2 ID picture of Authorized Person (see Annex B) (except NCR and CHD IV-A)
- ☐ PRC Board Certificate (Pharmacist or any Allied Health Science Profession)
- ☐ Valid PRC ID
- ☐ Current Professional Tax Receipt (PTR)
- ☐ Duties and responsibilities signed by the authorized person and the immediate supervisor
- ☐ Certificate of Attendance to "Qualified Person in Industry Regulatory Affairs (QPIRA)" for CCRR or promissory letter to attend with proof of scheduled day of attendance and payment
- ☐ Certificate of Attendance to "Training on the 13 ASEAN Cosmetic GMP Modules" or promissory letter to attend with proof of scheduled day of attendance and payment (for traders and manufacturers only)
- ☐ Resignation letter of former and newly-hired authorized persons duly signed by the employer

J. FEES AND CHARGES

Proof of payment of fees as prescribed by the current FDA regulations

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IV. OTHERS

A. RE-ISSUANCE OF LOST/DILAPIDATED LTO

- Completely accomplished Integrated Application Form (Refer to FDA Circular No. 2014-003) (for NCR and CHD IV-A)
- Letter of request
- Original LTO(scanned copy only for NCR and CHD IV-A)(if lost, submit an affidavit of loss)
- *Proof of payment of fees as prescribed by the current FDA regulations*

B. CLOSURE OF BUSINESS ACTIVITY

- Letter of request
- Original LTO (if lost, submit an affidavit of loss)
- Over the counter submission at PAIR Unit

NOTES:

1. If activity only deals with manufacturing, trading and distribution of cosmetic raw materials, please refer to FDA Circular 2013-015 entitled "**Deregulation of Bulk Industrial Chemicals Used as Raw Materials in Cosmetic Products and Household Products Considered as Urban Hazardous Substances"**
2. For applicant establishments in NCR and CHD IV-A, all documentary requirements should be in electronic copies stored in a USB flash drive and submitted in FDA Main Office in Alabang, Muntinlupa City following the guidelines in **FDA Circular 2014-003 (Link: http://www.fda.gov.ph/issuances-2/others-laws-and-regulations-not-applicable-to-the-above-categories/others-fda-circular/145645-fda-circular-no-2014-003)**
3. For applicant establishments in other regions, all documentary requirements should be filed in an orange folder with electronic copies saved in a DVD-R and submitted in respective FDA Regional Offices or CHDs in each region.