

ANNEX A

A. REQUIREMENTS FOR INITIAL LICENSE TO OPERATE APPLICATION

1. eApplication Form through the FDA Available Online Application Platforms

Among other information, the applicant shall provide the following information:

- a. Global Positioning System (GPS) coordinates
- b. Name of the Qualified Person, depending on the type of health product establishment as specified in Annex B

2. Proof of Business Name Registration

Any one of the following shall be submitted as proof of business name registration (in pdf):

- a. For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
- b. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;
- c. For Cooperative, the Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation; or
- d. For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter.

3. When the business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit/Mayor's Permit, or Barangay Certificate with complete business address.

4. Proof of Capitalization for Manufacturers, Traders, CROs, and Sponsors

Proof of Capital Investment such as the latest audited Financial Statement with Balance Sheet (in pdf) or duly notarized Statement/Certification of Initial Capitalization, for those newly-opened establishments shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fees.

5. The following documents shall be presented during inspection for examination or review, when required:

- a. **Risk Management Plan (RMP)** for the following establishments:
 - i. Manufacturers of drugs, medical devices, cosmetics, and household urban hazardous substances (HUHS) including household/urban pesticides (HUPs) and toys and childcare articles (TCCAs);
 - ii. Medium and large food manufacturers;
 - iii. Traders and Distributors (importers, exporters, and/or wholesalers) of drugs, medical devices, foods, cosmetics, and HUHS including HUPs and TCCAs

- b. **Site Master File (SMF) and floor plan/plant layout** for the following establishments:
 - i. Manufacturers including packers and repackers of drugs, medical devices, cosmetics, and HUHS including HUPs and TCCAs;
 - ii. Medium and large food manufacturers;
- 6. For RONPD establishments with a pharmacist handling multiple RONPDs, list of all outlets including the Name of Establishment, Address, Day and Time of shift and LTO number.
- 7. For Food Business Operators and Medical Device Retailers, Notarized Contract of Agreement/Appointment or Authorization Letter/Distributorship Agreement and Notarized Franchise Agreement provided that the following conditions are met:
 - a. Notarized Franchise Agreement – The business name of the establishment reflected in the LTO shall be based on the trade name indicated in the Franchise Agreement. In addition, it must be consistent with the business name registration.
 - b. Notarized Contract of Agreement – For appropriate determination of activity that shall be indicated in the LTO, a copy of the Contract of Agreement is recommended to be submitted. The basis for the LTO activity shall depend on the legally binding contract agreement between the establishment and its client/supplier.
- 8. Payment of appropriate fees.

B. REQUIREMENTS FOR RENEWAL LICENSE TO OPERATE APPLICATION

1. eApplication Form through the FDA Available Online Application Platforms

Among other information, the applicant shall provide the following information:

- a. License Number and its validity date
 - b. Security code as provided in the QR Code of current LTO Certificate or a sequence number located at the bottom right corner of the LTO Certificate.
 - c. Contact Information
- 1. For Food Business Operators, Financial Statement
 - 2. Payment of appropriate fees