ANNEX B

A. REQUIREMENTS FOR INITIAL LICENSE TO OPERATE APPLICATION

1. **eApplication Form through the FDA eServices Portal System**

   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 C

   c. For RONPD establishments with a pharmacist handling multiple RONPDs, list of all outlets including the Name of Establishment, Address, plotted Geolocation, Day, and Time of shift and LTO number.

2. **Proof of Business Name Registration and FDA-Regulated Activity**
   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 and FDA-regulated activity issued by the Department of Trade and Industry (DTI);

   b. For Corporation, Partnership and other Juridical Person, the Certificate of Incorporation or License to transact business in the Philippines issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation/Partnership shall specify the activity relating to health product/s (e.g. manufacturing, distribution [importation, exportation, wholesaling], retail selling in case of drugs or medical devices) applied for shall be reflected in the primary or secondary purposes;

   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 or other requirements, deemed suppletory to the application.

   Note: 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.

   If the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.

3. For MSMEs, Certification from the Department of Trade and Industry as proof of their level of categorization. Non-submission of the required certification for MSMEs shall treat the applicant as a large establishment and be levied the corresponding fees for large establishment.

4. **Risk Management Plan (RMP)** for the following establishments:

    a. Manufacturers of foods, drugs, medical devices, health-related devices such as equipment or devices used for treating sharps, pathological, and infectious wastes, and water purification treatment devices and/or systems, cosmetics, and household urban hazardous substances (HUHS) including household/urban pesticides (HUPs) and toys and childcare articles (TCCAs);

    b. Traders and Distributors (importers, exporters, and/or wholesalers) of foods, drugs, medical devices, health-related devices such as equipment or devices used for treating sharps, pathological, and infectious wastes, and water purification treatment devices and/or systems, cosmetics, and HUHS including HUPs and TCCAs;

    c. Drug outlets including Drugstores

    d. *Copy of the applicant shall also be presented during inspections.*

5. **Site Master File (SMF)** for the following establishments:

    Manufacturers including packers and repackers of foods, drugs, medical devices, health-related devices such as equipment or devices used for treating sharps, pathological, and infectious wastes, and water purification treatment devices and/or systems, cosmetics, and HUHS including HUPs and TCCAs;

    For Drug Manufacturers, the SMF to be submitted shall follow the PIC/s PE 008-04 Explanatory Notes Pharmaceutical Manufacturers On the Preparation of a Site Master File and its Revisions

    Copy of the applicant shall also be presented during inspections.

6. **List of Sources and Authorized Suppliers/Clients for Manufacturers including Packers/Repackers, Traders, and Distributors (Importers, Exporters, Wholesalers)**

    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.

    The list shall identify the name of source, address, and product list(categories) whether local or imported.

    Copy(ies) of the Contract of Agreement(s) of the applicant shall be presented during inspections.

7. Payment of appropriate fees.

B. REQUIREMENTS FOR REGULAR RENEWAL LICENSE TO OPERATE APPLICATION

1. eApplication Form through the FDA eServices Portal System

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

2. For Manufacturers including Packers/Repackers, a copy of valid GMP Certificate;

3. For MSMEs, Updated Certification from the Department of Trade and Industry as to level of classification. Non-submission of the required certification for MSMEs shall treat the applicant as a large establishment and be levied the corresponding fees for large establishment; and

4. Payment of appropriate fees