

ANNEX A

Requirements for License to Operate Application

1. Application Form

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 creates 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 or Barangay Certificate with complete business address (e.g., Mayor's Permit).

4. Proof of Capitalization for Manufacturers and Traders

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. Risk Management Plan and Site Master File for Manufacturers which shall be presented during inspection.

6. Certificate of Compliance with technical requirements after a satisfactory inspection from a pre- or post-licensing inspection.

7. For Drug establishments, list of all RONPDs handled by the Pharmacist (for pharmacists handling multiple RONPDs, include the Name of Establishment, Address, Day, and Time of shift and LTO Number)

8. Payment of appropriate fees.