

ANNEX A
Guidance LTO Application

A. The establishment's owner, president, chief executive officer (CEO) or authorized officer and its qualified person shall sign the application form. The authority of the signatories shall be evidenced by any of the following:

1. Single Proprietorship – Power of Attorney when the authorized representative is not the owner of the establishment;
2. Corporation and Cooperative – Secretary Certificate or Board Resolution;
3. Partnership – Partnership Resolution; or
4. Government Agency – Authority from the Head of Agency.

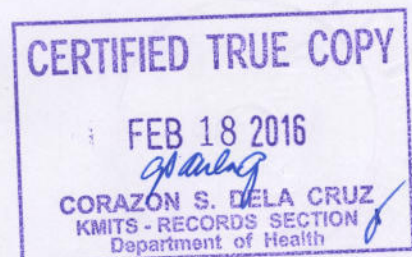
B. The documentary requirements for submission:

1. Accomplished Application Form

Among other information, the application form shall contain the following:

- (a) Declaration and undertaking of the responsibilities of the applicant as a condition for the processing and approval of the LTO;
- (b) The location plan and global position system (GPS) coordinates of the establishment;
- (c) The name of the qualified person per type of establishment, and the relevant credentials (e.g. PRC ID):

| Type of Establishment | Qualified Person | Credentials |
|------------------------------|---|---|
| Drug Establishment: | Pharmacist | <input type="checkbox"/> PRC ID <input type="checkbox"/> Attendance to FDA appropriate Licensing Seminar |
| | Responsible pharmacy assistant (for drugstore and RONPDs) | <input type="checkbox"/> Certificate of Training |
| Food Establishment | Food Safety Compliance Officer or Regulatory Officer | <input type="checkbox"/> Certificate of Attendance to appropriate FDA Licensing Seminar <input type="checkbox"/> Certificate of Attendance to GMP, HACCP, or Food Safety Seminar |
| Medical Device Establishment | Pharmacist or Any Other Qualified Professional | <input type="checkbox"/> PRC ID or any Proof of Qualification <input type="checkbox"/> Attendance to medical device QPIRA |
| Cosmetic Establishment | Pharmacist or Any Other Qualified Professional | <input type="checkbox"/> PRC ID or any Proof of Qualification <input type="checkbox"/> Attendance to QPIRA |



(d) The names of the following personnel shall also be listed:

| Type of Establishment | Other Qualified Person |
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| Drug Manufacturer: | (a) Production Manager/Head (b) Quality Assurance Manager/Head (c) Quality Control Manager/Head (d) Authorized person for batch release (e) Pharmacovigilance Officer |
| Other Drug Establishments | (a) Pharmacovigilance Officer |
| Food Manufacturer | (a) Production Manager/Head (b) Quality Assurance Manager/Head (c) Quality Control Manager/Head (d) Food Safety Officer (e) Any designated senior technical personnel |
| Medical Device Establishment | (a) Production Manager/Head (b) Quality Assurance Manager/Head (c) Quality Control Manager/Head |
| Cosmetic Establishment | (a) Production Manager/Head (b) Quality Control and/or Assurance Manager/Head |

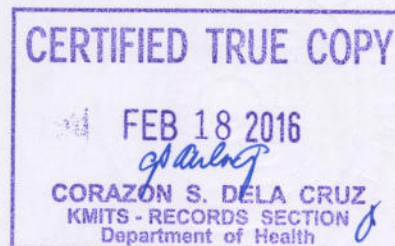
2. Proof of Business Name Registration

The business name/registration must be evidenced by copies of the following:

- (a) For single proprietorship – Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
- (b) For corporation, partnership and other juridical person – Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;
- (c) For cooperative – 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.

The document must indicate the exact and complete address, e.g., unit number, floor, building, lot, block, phase, street, barangay, city/ municipality, province, where applicable.

In case the business address of the applicant is different from the one indicated in its business name registration, the applicant must submit a copy of its valid Business Permit.



3. Site Master File¹ (for manufacturers of drugs, devices and cosmetics except traders)

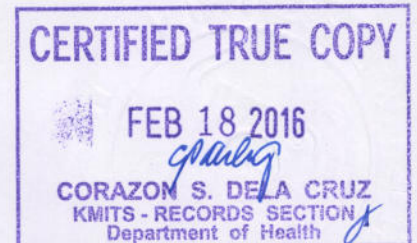
As required by the applicable good manufacturing practice (GMP) for the type of establishment.

4. Risk Management Plan (for manufacturers and distributors of drugs and medical devices establishments, and drugstores and RONPDs)

A general Risk Management Plan (RMP) for the establishment must be submitted. The RMP shall contain details on how to identify, characterize, prevent or minimize risk relating to the products that the establishment is engage with. These shall include post-marketing surveillance activities and interventions to manage the risks.

5. Payment

Proof of payments (e.g., official receipt or authorized bank payment slip) must be attached to the application.



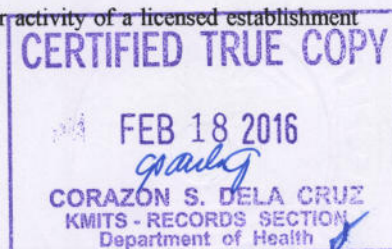
¹ Site Master File refers to a document prepared by the manufacturer and contains specific information about the quality management policies and activities of the site, the production and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. It provides clear information on the manufacturer's GMP related activities that are useful in general supervision and in the efficient planning and undertaking of GMP inspections.

ANNEX B
LIST OF REQUIREMENTS FOR VARIATION
APPLICATIONS FOR ESTABLISHMENTS

A. Major Variation²

| Transfer of Location of Manufacturing Plant and Drug Retailers | |
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| C | <ol style="list-style-type: none"> 1. Physical transfer of the establishment (and may entail changes in the previously approved address). 2. Other variations (e.g. change of pharmacist or qualified personnel, and/or business name) may also be included in the application for variation provided that that same are indicated therein and the corresponding requirements for such changes are included. |
| D | <ol style="list-style-type: none"> 1. Application Form 2. Business permit reflecting the new address 3. Updated Site Master File 4. Payment |
| Expansion of Manufacturer | |
| C | <ol style="list-style-type: none"> 1. Shall refer only to the expansion made which is adjacent to the existing location of the establishment and no additional product line is involved. 2. Expansion shall also include additional floors for production. |
| D | <ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File 3. Payment |
| Additional Production Line | |
| C | An additional production line is an added type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.) |
| D | <ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File 3. Payment |
| Change of Manufacturing Activity | |
| C | <ol style="list-style-type: none"> 1. Shall refer to an additional activity that the manufacturer engages in (e.g. LTO as Manufacturer with additional activity as Repacker) 2. Shall also refer to a change of previously licensed activity (e.g. LTO as Manufacturer-Repacker to Manufacturer-Packer). |

² Major variation refers to post-FDA approval changes in the status, condition or activity of a licensed establishment where inspection is required prior to approval of variation.



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| D | <ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File 3. Payment |
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| Transfer/Addition of Warehouse | |
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| C | <ol style="list-style-type: none"> 1. Shall refer to the physical transfer of warehouse. 2. Shall also refer to an addition of warehouse aside from the existing and previously inspected warehouse by FDA. |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Business permit reflecting new warehouse 3. Payment |
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B. Minor Variation ³

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| Transfer of Location of Offices | |
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| C | <ol style="list-style-type: none"> 1. Physical transfer of the office of the establishment (which may also entail changes in the previously approved address). 2. Other variations (e.g. change of pharmacist or key personnel, and/or business name) may also be included in the application for variation provided that that same are indicated therein and the corresponding requirements for such changes are included. |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Business permit reflecting the new address 3. Payment |
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| Change of Distributor Activity | |
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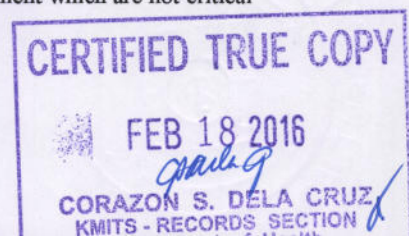
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| C | <ol style="list-style-type: none"> 1. Shall refer to an additional activity that the distributor engages in (e.g. LTO as Distributor-Importer with additional activity as Exporter) 2. Shall also refer to a change from the initially licensed activity (e.g. LTO as Distributor-Importer to Distributor-Exporter). |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Contract Agreements to prove activity 3. Payment |
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| Expansion of Office Establishments and Drug Retailers | |
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| C | <ol style="list-style-type: none"> 1. Shall refer to the expansion made which is adjacent to the existing location of the establishment. 2. Expansion shall also include additional floors where the building is occupied. |
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³ Minor variation refers to changes in the status, condition or activity of a licensed establishment which are not critical to the safety or quality, or in the purity or efficacy, when applicable, of the health product.



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| D | <ol style="list-style-type: none"> 1. Application Form 2. Payment |
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| Additional Drugstore Activity | |
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| C | <ol style="list-style-type: none"> 1. Additional activity shall include online ordering and delivery, sterile compounding and non-sterile complex compounding, mobile pharmacy, carrying of medical devices, and other additional activities that may require appropriate regulation or may be handled on a case to case basis. 2. These additional activities may already be included in the initial application. |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Additional Credentials of Pharmacist (e.g. Certificate of Training, where applicable) 3. Documents related to activity with proof of validation (e.g. SOP, Masterlist of compounding recipes) 4. Payment |
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| Change of Ownership | |
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| C | There is a change of ownership of the licensed establishment. |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Any proof on the transfer of ownership such as any of the following: Deed of sale or assignment or transfer of rights/ownership, Memorandum of Agreement, or notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer 3. Payment |
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| Change of Business Name | |
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| C | <ol style="list-style-type: none"> 1. Change only in the business name 2. No transfer of location or change of ownership. |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Proof of business name registration reflecting the new name |
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| Zonal Change in Address | |
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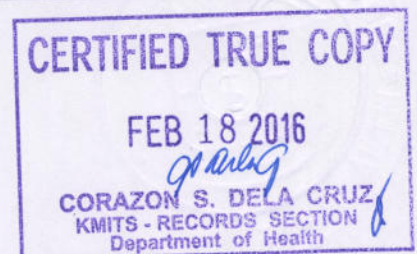
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| C | Shall refer to change of the name/number of the street/building without physical transfer of the establishment. |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Payment |
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| Change of Qualified Personnel | |
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| C | There is a change of the identified qualified person registered with FDA |
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| D | <ol style="list-style-type: none"> 1. Application Form 2. Payment |
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| Deletion of Activity | |
| C | Shall refer to deletion of any approved/added activity. |
| D | <ol style="list-style-type: none"> 1. Application Form 2. Payment |

* C - Condition

** D - Documentary Requirements

