

## ANNEX C

### LIST OF REQUIREMENTS FOR SPECIFIC VARIATION IN THE LTO

#### 1. Major Variation for Local Manufacturers

Type of Variation	Requirement
<p><b>Transfer of Location of Manufacturing/Packing/Repacking Plant</b></p> <p>Physical transfer of the establishment (and may entail changes in the previously approved address)</p>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Proof of business address reflecting the new <b>plant</b> location:               <ol style="list-style-type: none"> <li>a. For Single Proprietorship: Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new <b>plant</b> location;</li> <li>b. For SEC-registered establishments:                   <ul style="list-style-type: none"> <li>- Amended Articles of Incorporation (if transferred from one city/municipality/province); or</li> <li>- Updated General Information Sheet (GIS) from SEC (if transferred from one city/municipality/province)</li> </ul> </li> </ol> </li> </ol> <p>If the establishment address is different from the address indicated in the SEC Registration, provide <b>Business Permit/Mayor’s Permit</b> or <b>Barangay Business Permit/Clearance</b> reflecting the new <b>plant</b> location.</p> <ol style="list-style-type: none"> <li>3. Updated Site Master File</li> <li>4. <b>Updated floor plan or plant lay-out</b></li> <li>5. Payment of appropriate fees.</li> </ol>
<p><b>Expansion of Manufacturer/Packer/Repacker and/or Additional Product Line; or Change of Manufacturing Activity</b></p> <ul style="list-style-type: none"> <li>• Expansion shall refer to expansion made which is adjacent to the existing location of the establishment</li> <li>• Additional product line refers to additional type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.)</li> </ul>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Updated Site Master File and Floor Plan showing the expansion made to be presented upon inspection</li> <li>3. Payment of appropriate fees.</li> </ol> <p>For drug and food products, satisfactory laboratory analysis of not more than one (1) year from the issuance shall also be presented</p>

<ul style="list-style-type: none"> <li>Change in manufacturing activity shall refer to an additional activity that a manufacturer engages in (e.g., LTO as Manufacturer-Repacker to Manufacturer-Packer)</li> </ul>	
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## 2. Minor Variation

<p><b>Transfer of Location of Offices</b></p> <p>Physical transfer of the office of the establishment</p>	<p><b>Proof of business address reflecting the new office location:</b></p> <ol style="list-style-type: none"> <li>Application Form</li> <li><b>For Single Proprietorship</b> Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new office location;</li> <li><b>For SEC-registered establishments</b> <ol style="list-style-type: none"> <li>Amended Articles of Incorporation (if transferred from one city/municipality/province); or</li> <li>Updated General Information Sheet (GIS) from SEC (if transferred <a href="#">within the same city/municipality</a>)</li> </ol> </li> <li>PEZA Certificate reflecting the new office address, if applicable</li> <li><a href="#">Notarized Contract of Lease or any proof of ownership of the new office location</a></li> <li>Payment of appropriate fees.</li> </ol> <p>If the establishment address is different from the address indicated in the SEC Registration, provide LGU/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new office location.</p>
<p><b>Transfer of Location of Drug Retailers</b></p> <p>Physical transfer of the drug retailer establishment</p>	<p><b>Proof of business address reflecting the new location of drug retailer:</b></p> <ol style="list-style-type: none"> <li>Application Form</li> <li><b>For Single Proprietorship</b> Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new office location;</li> </ol>

	<p>Permit/Clearance reflecting the new location of drug retailer;</p> <p><b>3. For SEC-registered establishments</b></p> <p>d. Amended Articles of Incorporation (if transferred from one city/municipality/province); or</p> <p>e. Updated General Information Sheet (GIS) from SEC (if transferred <a href="#">within the same</a> city/municipality)</p> <p><b>4. Payment of appropriate fees.</b></p> <p>If the establishment address is different from the address indicated in the SEC Registration, provide LGU/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new location of drug retailer.</p>
<p><b>Change of Distributor Activity</b></p> <p>Shall refer to an additional/deletion of/change in activity that the distributor engages in.</p>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Contract Agreements showing change in activity</li> <li>3. Payment of appropriate fees.</li> </ol>
<p><b>Transfer/Addition of Warehouse</b></p> <p>Physical transfer and addition of the warehouse of the establishment</p>	<ol style="list-style-type: none"> <li>1. Application form</li> <li>2. Business permit/Mayor’s permit/Barangay Clearance reflecting the new address</li> <li>3. Contract of Lease including the warehouse address</li> <li>4. PEZA certificate reflecting the new warehouse address, if applicable</li> <li>5. Payment of appropriate fees</li> </ol>
<p><b>Additional Drugstore Activities</b></p>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Additional Credentials of Pharmacist, as applicable</li> <li>3. Other documents related or specific to the additional activity, such as but not limited to: <ol style="list-style-type: none"> <li>a. Adult vaccination <ol style="list-style-type: none"> <li>i. Standard Operating Procedure (SOP) for the cold chain management following FDA Circular 2021-003 (Revised Guidelines on the Cold Chain Management for</li> </ol> </li> </ol> </li> </ol>

	<ul style="list-style-type: none"> <li>Pharmaceutical Products and Establishments)</li> <li>ii. SOP for the vaccination/immunization activities</li> <li>iii. Certification as a Certified Immunizing Pharmacist</li> <li>b. Dispense Vaccines and Biologicals <ul style="list-style-type: none"> <li>i. SOP for the cold chain management following FDA Circular 2021-003</li> </ul> </li> <li>c. Mobile Pharmacy <ul style="list-style-type: none"> <li>i. SOP for the conduct of mobile pharmacy activities</li> <li>ii. Image/Picture with description of the mobile pharmacy vehicle</li> <li>iii. Credentials of the supervising pharmacist of the mobile pharmacy</li> </ul> </li> <li>d. Online Ordering and Delivery <ul style="list-style-type: none"> <li>i. SOP for the online ordering and delivery activities</li> <li>ii. Website link</li> <li>iii. Website screenshot showing the ordering system and the placement of LTO details</li> <li>iv. Other documents as required in separate issuance for e-Pharmacy</li> </ul> </li> <li>e. Sterile Compounding and Non-Sterile Complex Compounding <ul style="list-style-type: none"> <li>i. SOP for the compounding activities.</li> </ul> </li> </ul> <p>4. Payment of appropriate fees.</p> <p><b>NOTE: The establishment shall be inspected for GMP clearance prior approval of the variation.</b></p>
<p><b>Expansion of Office Establishments and Drug Retailers</b></p> <p>Shall refer to expansion made which is adjacent to the existing location of the establishment</p>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Current floor plan</li> <li>3. Expansion floor plan</li> <li>4. Payment of appropriate fees</li> </ol>
<p><b>Change in ownership of the establishment</b></p> <p>Change only in the business name of the establishment</p>	<ol style="list-style-type: none"> <li>1. Business name registration reflecting new ownership;</li> <li>2. Any proof of the transfer of ownership such as any of the following;</li> </ol>

	<ul style="list-style-type: none"> <li>i. Deed of Sale or Assignment or Transfer of Rights/Ownership;</li> <li>ii. Memorandum of Agreement (MOA);</li> <li>iii. Notarized Affidavit of the owner, proprietor, chairman or CEO of the establishment validating the transfer.</li> </ul> <p>3. <a href="#">Payment of appropriate fees</a></p>
<p><b>Zonal Change in Address</b></p> <p>Change of the name/number of the street/building without physical transfer of the establishment</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Certificate of Zonal Change from the Local Government Unit or Business Permit/Mayor's Permit/Barangay Clearance stating that there is no actual transfer of the establishment</li> <li>3. Payment of appropriate fees</li> </ul>
<p><b>Change of Qualified Person</b></p> <p>Change in the identified qualified person initially registered with the FDA</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Valid PRC ID</li> <li>3. Proof of termination of employment, if previously connected with another pharmacy/establishment or Notarized Waiver of Liability/ Sworn Statement stating the QP is effectively resigned from the previous employer.</li> </ul> <p>For Pharmacists handling multiple RONPDs: List of all RONPDs handled by the Pharmacist (to include, Name of establishment, Address, Day and Time of shift and LTO Number)</p> <p>4. Payment of appropriate fees.</p>
<p><b>Change of Authorized Person</b></p> <p>Change in the authorized person initially registered with the FDA</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Valid government issued ID</li> <li>3. Payment of appropriate fees.</li> </ul>
<p><b>Addition/Deletion of Sources and Products</b></p> <p>Addition/deletion of source(s) and product(s) in the previous/existing list</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Notarized Valid Contract Agreement; For foreign source(s), a copy of the contract agreement duly authenticated by the host government of the country of origin (legalized by the Philippine Embassy/Consulate if from a non-Apostille country)</li> <li>3. Payment of appropriate fees.</li> </ul>