

## ANNEX D

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

#### A. Major Variation

Type of Variation	Requirement
<p><b>Transfer of Location of Manufacturing/Packing/Repacking Plant, Medical Device/Drug Retailer</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. Payment of appropriate fees;</li> <li>3. Proof of business address reflecting the new plant location: and               <ol style="list-style-type: none"> <li><b>a. For Single Proprietorship</b> Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new office location</li> <li><b>b. For SEC-registered establishments</b> <ol style="list-style-type: none"> <li>i. Amended Articles of Incorporation (if transferred from one city/municipality/province); or</li> <li>ii. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality)</li> </ol> </li> </ol> </li> </ol> <p>If the establishment address is different from the address indicated in the SEC Registration, provide Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new plant location or PEZA certificate, if applicable</p> <p><i>If the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.</i></p> <ol style="list-style-type: none"> <li>4. Updated Site Master File</li> </ol>
<p><b>Expansion/Reduction of Manufacturer/Packer/Repacker and/or Additional Product Line; or Change of Manufacturing Activity</b></p>	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees; and</li> </ol>

<ol style="list-style-type: none"> <li>1. Expansion shall refer to expansion made to the existing location of the establishment.</li> <li>2. Additional product line refers to additional type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, parametric, etc.)</li> <li>3. Change in manufacturing activity shall refer to an addition/deletion of activity that a manufacturer engages in (e.g., LTO as Manufacturer-Repacker to Manufacturer-Packer)</li> </ol>	<ol style="list-style-type: none"> <li>3. Updated Site Master File (including previous and expanded floor plan)</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>
<p><b>Transfer/Addition/Deletion of Warehouse handling drug, food, cosmetic, household/urban hazardous substances, and medical device products</b></p> <p>Physical transfer and addition of the warehouse of the establishment</p>	<ol style="list-style-type: none"> <li>1. Application form; and</li> <li>2. Payment of appropriate fees</li> <li>3. Business permit reflecting new warehouse</li> </ol> <p><i>In case of transfer or addition, if the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.</i></p>
<p><b>Additional Drugstore Activities</b></p>	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees; and</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. <b>Adult vaccination</b> <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 Pharmaceutical Products and Establishments);</li> </ol> </li> </ol> </li> </ol>

	<ul style="list-style-type: none"> <li>ii. SOP for the vaccination/immunization activities; and</li> <li>iii. Certification as a Certified Immunizing Pharmacist</li> </ul> <p><b>b. Dispense Vaccines and Biologicals</b> SOP and compliance with the requirements for the cold chain management following FDA Circular 2021-003 and its amendment or revision, and the applicable rules on GDSP.</p> <p><b>c. Online Ordering and Delivery</b></p> <ul style="list-style-type: none"> <li>i. SOP for the online ordering and delivery activities;</li> <li>ii. Official Website link of the Drugstore; and</li> <li>iii. Website screenshot showing the ordering system and the placement of LTO details</li> </ul> <p><b>d. Compounding of drugs not categorized as sterile or non-sterile complex drug</b> SOP for the compounding activities. <i>*Note: For Sterile and Non-Sterile Complex drugs the rule on GMP Compliance shall apply</i></p> <p>NOTE: The establishment shall be inspected for GMP clearance prior approval of the variation.</p>
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**B. Minor Variation**

<p><b>Transfer of Location of Offices (Not considered as Manufacturing Plant or Medical Device/Drug Retailer)</b></p> <p>Physical transfer of the office of the establishment</p>	<ul style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees;</li> <li>3. <b>Proof of business address reflecting the new office location:</b> <ul style="list-style-type: none"> <li><b>a. For Single Proprietorship</b> Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new office location</li> </ul> </li> </ul>
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	<p><b>b. For SEC-registered establishments</b></p> <ul style="list-style-type: none"> <li>i. Amended Articles of Incorporation (if transferred from one city/municipality/province); or</li> <li>ii. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality)</li> </ul> <p>4. PEZA Certificate reflecting the new office address, if applicable; and</p> <p>5. Notarized Contract of Lease or any proof of ownership of the new office location, if applicable</p> <p>If the establishment address is different from the address indicated in the SEC Registration, provide Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new office location.</p>
<p><b>Expansion/extension of Office Establishments and Medical Device/Drug Retailer</b></p> <p>In case of office establishments, it shall refer to area expansion made to the existing location of the establishment within the same building.</p> <p>In case of Medical Device/Drug Retailer, it shall refer to area expansion made to the existing location only.</p>	<ul style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees;</li> <li>3. Current floor plan; and</li> <li>4. Expansion floor plan</li> </ul>
<p><b>Change in ownership of the establishment</b></p>	<ul style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees;</li> <li>3. Business name registration reflecting new ownership;</li> <li>4. Proof of the transfer of ownership such as any of the following:</li> </ul>

	<ul style="list-style-type: none"> <li>a. Deed of Sale or Assignment or Transfer of Rights/Ownership;</li> <li>b. Memorandum of Agreement (MOA); or</li> <li>c. Notarized Affidavit: <ul style="list-style-type: none"> <li>i. Previous owner, chairman or CEO (covered by appropriate board resolution) of the previously licensed establishment validating the transfer; or</li> <li>ii. In case of transfer to heirs due to death of previous owner, affidavit of the authorized heir</li> </ul> </li> </ul>
<b>Change in the business name of the establishment</b>	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees; and</li> <li>3. Business name registration reflecting the new business name</li> </ol>
<b>Change of Distributor Activity</b>  Shall refer to an addition in/deletion of/change activity that the distributor previously engaged in.	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees; and</li> <li>3. Appropriate Contract Agreements showing change in activity</li> </ol>
<b>Zonal Change in Address</b>  Change of the name/number of the street/building without physical transfer of the establishment	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees; and</li> <li>3. 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> </ol>
<b>Addition or Change of Qualified Person (QP)</b>  Addition or change in the identified qualified person initially registered with the FDA	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees;</li> <li>3. Valid PRC ID, if applicable; and</li> <li>4. Proof of termination of employment, if previously connected with another pharmacy/establishment or Notarized</li> </ol>

	Waiver of Liability/ Sworn Statement stating the QP is effectively resigned from the previous employer.
<b>Addition or Change of Pharmacist for Drug Establishment</b>  <b>Addition or Change of Optometrist for Medical Device Optical Product-Dispensing Establishment</b>	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees;</li> <li>3. Valid PRC ID;</li> <li>4. In case of change of pharmacist or optometrist, proof of termination of employment/resignation of the additional/new pharmacist or optometrist if previously connected with another establishment except for cases of activities involving pharmaceutical products covered by Section 31.b of RA No. 10918; and</li> <li>5. For Pharmacists handling multiple RONPDs: List of all RONPDs (to include Name of establishment, Address, plotted geolocation, Day, and Time of shift and LTO Number)</li> </ol>
<b>Change on the Details of Qualified Person/Pharmacist/Optometrist</b>  Updates/changes, but not limited to the following: <ol style="list-style-type: none"> <li>1. Validity of the government-issued ID</li> <li>2. Change and/or corrections in the details of the submitted government-issued ID (e.g., marital status, print errors)</li> </ol>	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees;</li> <li>3. For profession with board exam: PRC ID (back-to-back) with signature at the back panel of the ID;</li> <li>4. For non-board: Valid government-issued ID (e.g., passport, driver's license, SSS, etc.); and</li> <li>5. Other evidence corresponding to the update/change not mentioned</li> </ol>
<b>Change of Authorized Person</b>  Change in the authorized person initially registered with the FDA	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees; and</li> <li>3. Valid government issued ID</li> </ol>
<b>Addition or Deletion of Medical Device Retailer Activity such as but not be limited to the following:</b>	<ol style="list-style-type: none"> <li>1. Application Form; and</li> <li>2. Payment of appropriate fees</li> </ol>

<ol style="list-style-type: none"> <li>1. Retail stores for medical devices;</li> <li>2. Clinics that sell products classified as medical devices except those that are covered by the DOH One Stop Shop Licensing System;</li> <li>3. Sellers using online shopping website, social media platforms and/or TV shopping companies in selling or offering to sell medical device directly to the general public;</li> <li>4. Operator of medical device vending machine;</li> <li>5. Optical shops; and</li> <li>6. Drug outlets, such as drugstores, or boticas, and retail outlets for non-prescription drugs (RONPD) that also sell or offer to sell medical device</li> </ol>	
<p><b>Change of official e-mail address of the establishment</b></p>	<ol style="list-style-type: none"> <li>1. Application Form;</li> <li>2. Payment of appropriate fees; and</li> <li>3. Request Letter signed by the owner/CEO/President</li> </ol>
<p><b>Addition/Deletion of Sources and Products for medical device, household/urban hazardous substances, cosmetic, and drug establishments</b></p> <p>Addition/deletion of source(s) and product(s) in the previous/existing list</p> <p><i>Note:</i> Notarized Valid Contract Agreement; or</p> <p>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</p>	<ol style="list-style-type: none"> <li>1. Application Form; and</li> <li>2. Payment of appropriate fees</li> </ol>

Embassy/Consulate if from a non-Apostille country shall be available during inspection of the establishments.	
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