

ANNEX C

LIST OF REQUIREMENTS FOR SPECIFIC VARIATION IN THE LTO

1. Major Variation for Local Manufacturers

Type of Variation	Requirement
<p>Transfer of Location of Manufacturing/Packing/Repacking Plant</p> <p>Physical transfer of the establishment (and may entail changes in the previously approved address)</p>	<ol style="list-style-type: none"> 1. Application Form 2. Proof of business address reflecting the new plant location: <ol style="list-style-type: none"> a. For Single Proprietorship: Business Permit/Mayor’s Permit or Barangay Business Permit/Clearance reflecting the new plant location; b. For SEC-registered establishments: <ul style="list-style-type: none"> - Amended Articles of Incorporation (if transferred from one city/municipality/province); or - Updated General Information Sheet (GIS) from SEC (if transferred from one city/municipality/province) <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.</p> <ol style="list-style-type: none"> 3. Updated Site Master File 4. Updated floor plan or plant lay-out 5. Payment of appropriate fees.
<p>Expansion of Manufacturer/Packer/Repacker and/or Additional Product Line; or Change of Manufacturing Activity</p> <ul style="list-style-type: none"> • Expansion shall refer to expansion made which is adjacent to the existing location of the establishment • Additional product line refers to additional type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.) 	<ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File and Floor Plan showing the expansion made to be presented upon inspection 3. Payment of appropriate fees. <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"> Change in manufacturing activity shall refer to an additional activity that a manufacturer engages in (e.g., LTO as Manufacturer-Repacker to Manufacturer-Packer) 	
---	--

2. Minor Variation

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

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

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

	<ul style="list-style-type: none"> i. Deed of Sale or Assignment or Transfer of Rights/Ownership; ii. Memorandum of Agreement (MOA); iii. Notarized Affidavit of the owner, proprietor, chairman or CEO of the establishment validating the transfer. <p>3. Payment of appropriate fees</p>
<p>Zonal Change in Address</p> <p>Change of the name/number of the street/building without physical transfer of the establishment</p>	<ul style="list-style-type: none"> 1. Application Form 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 3. Payment of appropriate fees
<p>Change of Qualified Person</p> <p>Change in the identified qualified person initially registered with the FDA</p>	<ul style="list-style-type: none"> 1. Application Form 2. Valid PRC ID 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. <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>Change of Authorized Person</p> <p>Change in the authorized person initially registered with the FDA</p>	<ul style="list-style-type: none"> 1. Application Form 2. Valid government issued ID 3. Payment of appropriate fees.
<p>Addition/Deletion of Sources and Products</p> <p>Addition/deletion of source(s) and product(s) in the previous/existing list</p>	<ul style="list-style-type: none"> 1. Application Form 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) 3. Payment of appropriate fees.