

ANNEX C
LIST OF REQUIREMENTS FOR SPECIFIC VARIATION

CATEGORY I

I. Major Variation (Local and Foreign)

Type of Variation	Requirement
Transfer of manufacturing site address	<ol style="list-style-type: none"> 1. Application form; 2. Payment of fee equivalent to initial application; and 3. Same requirement with initial application (reflecting the new manufacturing site address)
Additional product line, and or Additional manufacturing operations	<ol style="list-style-type: none"> 1. Application form; 2. Payment of fee equivalent to initial application; and 3. Same requirement with initial application <ol style="list-style-type: none"> a. Acceptable GMP Evidence reflecting the requested additional product line, and/or manufacturing operations b. Updated GMP Contract Agreement covering the additional product line, and/or manufacturing operations

II. Minor Variation (Local and Foreign)

Type of Variation	Requirement
Change of Manufacturer's Name	<ol style="list-style-type: none"> 1. Application form; 2. Payment of Variation fee; and 3. Proof of Change of Manufacturer's Name

	<p>a. For local Updated License to Operate of the Manufacturer reflecting the new Manufacturer's name</p> <p>b. For foreign Acceptable GMP Evidence reflecting the new Manufacturer's Name</p>
<p>Zonal Change of manufacturing site address</p>	<ol style="list-style-type: none"> 1. Application form; 2. Payment of Variation fee; and 3. Proof of Change of manufacturing site address <p>a. For local Updated License to Operate of the Manufacturer reflecting the new Manufacturing site address</p> <p>b. For foreign Certification from Local authority stating that there is no actual transfer of the establishment</p>
<p>Change in Qualified Person (Pharmacist)</p>	<ol style="list-style-type: none"> 1. Application form; 2. Payment of Variation fee; 3. Affidavit of Undertaking of the new Qualified Person 4. Proof of change of Qualified Person <p>a. For local Updated License to Operate of the Manufacturer reflecting the new Qualified Person</p>

	<p>b. For foreign</p> <p>Updated License to Operate of the Importer reflecting the new Qualified Person, and A</p>
<p>Change in Key Personnel (Production Manager/Head, Quality Assurance Manager/Head, Quality Control Manager/Head, and Authorized Person for Batch Release)</p>	<ol style="list-style-type: none"> 1. Application form; 2. Payment of Variation fee; 3. Updated Site Master File reflecting the changes 4. For profession with board exam: PRC ID (back-to-back) with signature at the back panel of the ID; and 5. For non-board: Valid government issued ID (e.g., passport, driver's license, SSS, etc.)
<p>Change of business name (Importer) applicable for foreign</p>	<ol style="list-style-type: none"> 1. Application form 2. Payment of Variation fee; and 3. Updated License to Operate of Importer reflecting the new Business Name
<p>Change in ownership of the manufacturer, applicable for local</p>	<ol style="list-style-type: none"> 1. Application form 2. Payment of Variation fee; and 3. Updated License to Operate of Importer reflecting the owner