



**LAO PEOPLE'S DEMOCRATIC REPUBLIC  
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY**

**Form No 2**

**Application for Health Supplement Registration**

<b>GATALOGUE</b>	<b>PART I</b>			<b>Application Information</b> <small>(see requirement#1)</small>
<i>Name</i>				
<i>Address</i>				
<i>Telephone</i>				
<i>Fax</i>				
<i>Contact person</i>				
<b>GATALOGUE</b>	<b>PART II</b>			<b>Manufacturer Information</b> <small>(see requirement#2)</small>
<i>Name</i>				
<i>Address</i>				
<i>Telephone</i>				
<i>Fax</i>				
<i>Contact person</i>				
<b>LAOS CDR DATABASE</b>	<b>PART III</b>			<b>Product Information</b> <small>(see requirement#3)</small>
<i>Brand name</i>				
<i>Active ingredients</i>				
<i>Name</i>	<i>Quantity</i>	<i>Name</i>	<i>Quantity</i>	
1.		3.		
2.		4.		
<i>Inactive ingredients</i> <small>(see package insert)</small>				
<i>Name</i>	<i>Quantity</i>	<i>Name</i>	<i>Quantity</i>	
1.		5.		
2.		6.		
3.		7.		
4.		8.		
<i>Dosage Form</i>	<small>(see package insert)</small>			
<i>Rout</i>	<small>(see package insert)</small>			
<i>Storage Condition</i>	<small>(see package insert)</small>			
<i>Shelf Life</i>	<small>(see package insert)</small>			
<i>Primary Packaging</i>				
<i>Packaging Size</i>	<small>(see package insert)</small>			
<i>Dispensing category</i>	<input type="checkbox"/> OTC		<input type="checkbox"/> Prescription	
<i>Therapeutic Code(if any)</i>				
<i>Level of Health Claim</i>	<input type="checkbox"/> General Level of Evidence (General or Nutritional) <input type="checkbox"/> Medium Level of Evidence (Functional) <input type="checkbox"/> High Level of Evidence (Other Risk Reduction)			
<i>Descriptions</i>				
<i>Indications/Usage</i>				
<i>Contraindications</i>				
<i>Side effects</i>				
<i>Manufacturing Unit price (USD)</i>				
<b>LAOS CDR DATA BASE</b>	<b>PART IV REGISTRATION INFORMATION (IN CASE OF IMPORTATION)</b>			
<i>Country of origin</i>				
<i>Registration No</i>				
<i>Date of registration</i>				
<i>Free Sale No</i>				

At.....Date.....  
Authorized signature



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**Form No3**

**Checklist of Requirements for the Re-Registration of Import  
 Health Supperment Product in Lao PDR**

Item	PARTICULARS	Yes	No
<b>Part I.</b>	<b>ADMINISTATIVE DATA</b>		
<b>1</b>	Letter of Company		
<b>2</b>	FDD Application Form No. 2		
<b>3</b>	Letter of Authorization or Application Nomination Certified by the Manufacturer of the Product <ul style="list-style-type: none"> <li>- Letter of authorization of product owner</li> <li>- Letter of appointment of contract manufacturer and/ or repacked</li> <li>- Letter of acceptance as contract manufacturer and/ or repacked</li> <li>- Certificate Of Pharmaceutical Product (CPP),</li> <li>- Free Sale Certificate (CFS) (From country of the origin issued by the Health regulatory authority of the manufacturing country or exporting country)</li> <li>- Certificate of Product Registration (Valid original Certificate of Product Registration)</li> </ul>		
<b>Part II</b>	<b>TECHNICAL DATA</b>		
<b>4</b>	<b>QUALITY</b>		
	For manufacturing “under-license” <ul style="list-style-type: none"> <li>- Good Manufacturing Practice (GMP)</li> <li>- Attachment of Protocol Analysis</li> <li>- Finished Product Quality Control (FPQC)</li> <li>- Limit Test for Heavy Metals</li> <li>- Disintegration Test (for tablets, capsules and pills) Disintegration time</li> <li>- Test for Uniformity of Weight (tablets and capsules only)</li> <li>- Tests for Microbial Contamination</li> <li>- Technical Specification:               <ol style="list-style-type: none"> <li>1. Certificate of analysis of active raw material</li> <li>2. Technical specifications of Health Supplement product</li> <li>3. Certificate of analysis of finished product</li> </ol> </li> <li>- Stability Studies               <ul style="list-style-type: none"> <li>a/ Real time-at least 12 month data, minimum of 2 batches at 30°C ± 2°C/75% RH ± 5% RH</li> <li>b/ For products intended to be stored in a refrigerator Real time-at least 12 month data, minimum of 2 batches 5°C ± 3°C</li> </ul> </li> </ul>		
<b>5</b>	Sample in market or commercial presentation for laboratory analysis		

**Head of TMHS Division**

**Evaluators**