LAO PEOPLE'S DEMOCRATIC REPUBLIC
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

Form No 1

Checklist of Requirements for the Registration of Import Health Supplement Product in Lao PDR

Item	PARTICULARS	Yes	No
Part I.	**ADMINISTATIVE DATA**		
1	Letter of Company		
2	FDD Application Form No. 2		
3	Letter of Authorization or Application Nomination Certified by the Manufacturer of the Product - Letter of authorization of product owner - Letter of appointment of contract manufacturer and/ or repacked - Letter of acceptance as contract manufacturer and/ or repacked - Certificate Of Pharmaceutical Product (CPP), - Free Sale Certificate (CFS) (From country of the origin issued by the Health regulatory authority of the manufacturing country or exporting country)		
Part II	**TECHNICAL DATA**		
4	**QUALITY**		
	For manufacturing "under-license" - Good Manufacturing Practice (GMP) - Attachment of Protocol Analysis - Finished Product Quality Control (FPQC) - Limit Test for Heavy Metals - Disintegration Test (for tablets, capsules and pills) Disintegration time - Test for Uniformity of Weight (tablets and capsules only) - Tests for Microbial Contamination - Technical Specification: 1. Certificate of analysis of active raw material 2. Technical specifications of Health Supplement product 3. Certificate of analysis of finished product - Certificate for Stability Data stamps by Pharmaceutical industries • Storage Conditions with type of Container Closure System/Stability Data • Report of Stability Studies shall provide detail of the batch placed under study (a minimum of 2 batches are required)		
5	**SAFETY**		
	- Negative list active ingredient - Restricted list active ingredient - Restricted list Excipient - Maximum Level of Vitamin and Mineral (HS) - Limit of Microbial Contamination, Use of additives and excipients, - Limit of Pesticides, Minimizing the Risk of transmission of transmissible spongiform encephalopathy (TSE Risks) - Safety Substantiation.		
6	**EFFICACY/CLAIM SUBSTANTIATION**		
	Referrence of Claim, Clinical Trial (referring to efficacy of finish Product) - Claims: (Referring to efficacy of raw and finished product Requirement) - Labeling: (Labeling Requirement), Package Insert Lao language/English		
7	Sample in market or commercial presentation for laboratory analysis		

Head of TMHS Division **Evaluators**