LAO PEOPLE'S DEMOCRATIC REPUBLIC
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

Form No3

Checklist of Requirements for the Re-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) - Certificate of Product Registration (Valid original Certificate of Product Registration)		
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 - Stability Studies a/ Real time-at least 12 month data, minimum of 2 batches at 30°C ± 2°C/75% RH ± 5% RH 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		
5	Sample in market or commercial presentation for laboratory analysis		

Head of TMHS Division **Evaluators**