LAO PEOPLE'S DEMOCRATIC REPUBLIC
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

Form No 1

Checklist of Requirements for the Registration of Import Traditional Medicine Product in Lao PDR

Item	REQUIREMENTS	Yes	No
Part I	**ADMINISTATIVE DATA**		
1	Letter of Application		
2	FDD Application Form No. 1		
3	Letter of Authorization or Application Nomination Agreement between the manufacturer & trader/distributor/exporter - 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) Original Certificate of Pharmaceutical Product from the country of manufacture (Issued at least 1 years from the date the application for registration was filed) - Certificate of Product Registration (Valid original Certificate of Product Registration) For countrires not issuing CPP, the following may be accepted: a/ Government Certificate Licence of the Manufacturer or GMP Certificate b/ Certificate of Free Sale from the country of origin For Products not freely sold in the country of origin: - Original CPP from a country where the product is freely sold shall be summitted - Free Sale Certificate (CFS) (From country of the origin issued by the Health regulatory authority of the manufacturing country or exporting country) Remark: For Imported Product (All official document must be English)		
4	Unit Dose and Batch Formulation		
Part II	**TECHNICAL DATA**		
	QUALITY		
5	Technical Specification of ALL Raw Materials a/ From the supplier of the Active Raw Material (if applicable) b/ From the Manufacturer of the finished product c/Certification of Authenticity of Plant Specimen from the authorized government agency in the country of origin(if any)		
6	Technical Specifications of Finished Product		
7	Certificate of Analaysis of Finish Product(From the same batch or lot of the representative sample submitted)		
8	Stability Studies a/ Accelerated-at least 6 months data, minium of 2 batchs at 40°C ± 2°C/75% RH ± 5% RH b/ Real time-at least 12 month data, minium of 2 batches at 30°C ± 2°C/75% RH ± 5% RH c/ For products intended to be stored in a refrigerator 1. Acelerated-at least 6 month data, minium of 2 batches, 25°C ± 2°C/60% RH ± 5% RH 2. Real time-at leaset 12 month data, minium of 2 batches 5°C ± 3°C		
	SAFETY AND EFFICACY/CLAIM SUBSTANTIATION		
9	Evidence of Safety and Efficancy a/ Claim: (Refferring to efficacy of raw and finished product Requirement) b/ No-Adverse-Effect Level/Dose and Toxidrome c/ Pharmacologic Effects in Animal both in Vivo and in Vitro Studies d/ Non-Mutagenicity-including Ames Test and Micronucleus Test e/ Subchronic Chronic Toxicity Test f/ Phase I Clinical Trial (for galenical products) g/ Phases I,II,III Clinical Trical (For products in pharmaceutical dosage form)		
10	Labeling Materials a/ Facsimile labels with actual color text(3 copies) b/Package Insert Lao language/English		
11	Representative Sample in market or commercial presentation(at least 1 year before expiry)		

Head of TMHS Division **Evaluators**