CHECKLIST OF REQUIREMENTS FOR THE RE - REGISTRATION OF IMPORT DRUG PRODUCT

Item	PARTICULARS	#Copies	FDD Use Only
1	**FDD Application Form**	1	
2	**Applicant nomination** note certified by the manufacturer	1	
3	**Manufacturer Information**		
3.1	**GMP Certificate** (issued by the drug regulatory authority of the manufacturing country)	1	
3.2	**Certificate of free sale** (From the country of origin issued by the drug regulatory authority of the manufacturing country or exporting country	1	
3.3	**The previous of origin certificate** of drug registration in Lao PDR.	1	
4	**Technical Specification**		
4.1	**Certificate of analysis** of active raw material :		
	a. from manufacturer of raw material	1	
	b. from manufacturer of the finished product	1	
4.2	**Technical specifications** of the finished product	2	
4.3	**Certificate of analysis** of the finished product	2	
4.4	**Assay method** and other test procedures for the finished product	2	
5	**Sample** in market or commercial presentation for laboratory analysis		

Remark : Certificate of Pharmaceutical Product in accordance with the WHO Certification Scheme on the Quality of Pharmaceutical products Moving in International Commerce is highly acceptable in lieu of Requirement No.3.1 and 3.2

APPLICATION FOR RE-REGISTRATION

Lao Peoples Democratic Republic

CATALOGUE	PART I.	APPLICANT INFORMATION
Name		(see requirement 1.1)
Address		
Telephone		
Fax		
Contact person		

CATALOGUE	PART II.	MANUFACTURER INFORMATION
Name		(see requirement 1.1)
Address		
Telephone		
Fax		
Contact person		

LAO CDR DATABASE	PART III.	PRODUCT INFORMATION
Brandname		(see requirement 1.4)

Active ingredients

Name	*Qty*	*Name*	*Qty*
1.		4.	
2.		5.	
3.		6.	

Inactive ingredients (see package insert)

Name	*Qty*	*Name*	*Qty*
1.		4.	
2.		5.	
3.		6.	

Dosage Form	(see package insert)
Storage Condition	(see package insert)
Shelf Life	(see package insert)
Primary packaging	
Packing Size	(see package insert)
Dispensing category	☐ *OTC* ☐ *Prescription*
ATC Classification	
Pharmacologic Classification.	
Is in Lao PDR.?	☐ *Yes* ☐ *No*
Description	
Indications	
Contraindications	
Side effects	
Manufacturing Unit price (USD)	

LAO CDR DATABASE	PART IV.	REGISTRATION INFORMATION (IN CASE OF IMPORTATION)
Country of origin		
Registration No.		
Date of registration		(dd/mm/yy)
The previous number and date of registration in Lao PDR		(dd/mm/yy)

At .....Date.....

Authorized signature