Borderline Product Submission Form

1.Name of the Borderline Product			
Brand Name			
Authorization letter addressed to CEO / NMRA by the Manufacturer / Distributer	(Original)		
Copy of Sample Import License (Please "√")			
Copy of Whole Sale License (Please "√")			
Registration status: (Please "√")	New	RR	
Have already submitted a dossier to other regulatory body in Sri Lanka	Yes/No	If "Yes" mentioned the details	
Status of the applicant (Plcase "√")	Manufacturer	Importer	
Route of administration:		Dosage form (If applicable only)	
Type of product: (Please "√")	Medicine and Food	Medicine and Medical Device	Medicine and Cosmetic

2. Details of the Marketing Authorization holder (Applicant) in Sri Lanka	
Name of the applicant	
Address of the applicant	
Telephone no.	
Email / web	
Note: Overseas manufactures should forward their application only through a local agent in Sri Lanka	

3. Details of the Manufacturer (Please "√" where needed)			
Name			
Actual manufacturer	Contract manufacturer	Other	
Address of the Actual Manufacturing Site		Any other address	
Product is registered and marketed in the	Registered	Marketed	

country of manufacture		
Classification in country of manufacture		
Borderline Product		
Medical Device		
Health supplement		
Listed product		
Cosmetic Product		
Traditional Medicines		
Other		
If it is a Device		
Does this product require dedicated instrumentation?	If Yes	Details
Availability of User Manual	Yes	No
Justification for not submitting		

4. Please provide documents, if registered or marketed in the following countries	
Country	Product Classification
i. Australia	
ii. Canada	
iii. European Union (EU)	
iv. Japan	
v. New Zealand	
vi. Singapore	
vii. UK	
viii. USA	
ix. Malaysia	
x. Thailand	
xi. India	
Justification for not submitting	

5. Please provide the following information on finished product	
5.1 Certificate of Pharmaceutical Product (COPP)	
5.2 Copy of Certificate of Free Sale (CFS) (Applicable if COPP is not available)	
5.3 Certificate of Good Manufacturing Practice (GMP) / ISO Certificate	
Justification for not submitting	
5.4 Approved Master formula issued by the NMRA when classifying	
5.4.1 Manufacturing formula with batch size	
5.4.2 Validated testing procedures for finished product	

5.4.3 Validation report	
5.4.4 Manufacturing process or Flow diagram	
Justification for not submitting	

5.5 Please provide the Certificate of Analysis (COA) and Stability Report for finished product
Please "√" the following details accordingly

	COA	Stability Report
Appearance		
Chemical Assay for active ingredients		
Limits for heavy metals		
Limits for microbial contamination		
Disintegration test		
Any other specific test		

*Complete real time stability data should be submitted at least for two commercial batches after 2 years of the product registration. Failure on submission will cause the product to be suspended until the complete documents are submitted; the registration of the product will be terminated if the complete documents still cannot be produced upon renewal of product registration.

Justification for not submitting	

6. Please provide efficacy data if available
Published reports
Detail Clinical trial report for the product

7 .Composition per dosage form

Each Tablet/ Capsule/ 5ml/.....) contains:

Name of the ingredient	Botanical name (if available)	Amount Unit: g/IU, etc	Function
i.			
ii.			
iii.			
iv.			
v.			
vi.			
vii.			
viii.			
ix.			
x.			
xi.			
xii.			
xiii.			
xiv.			
xv.			

xvi.			
xvii.			
xviii.			
xix.			
xx.			
xxi.			
xxii.			
xxiii.			
xxiv.			
xxv.			
Justification for not submitting			

8 .Instrument with standard accessories and spare parts (If applicable)		
Name of the accessory / spare part	Catalogue number	Function
Justification for not submitting:		

9.Please provide the following documents	
9.1 PIL	
9.2 Packaging materials (primary and secondary) / Art work	
9.3 Promotional materials	
Justification for not submitting	

Declaration

I'm responsible for the safety, quality & effectiveness of the product and any possible hazardous effects caused by the use of this borderline product.

I declare that the particulars given in this application (page1-4) are true and that the supporting documents enclosed are authentic or true copies.

Signature:.....

Name:.....

Designation:.....

Date:..... Approved by Director General (National Medicines Regulatory Authority)