NATIONAL MEDICINES REGULATORY AUTHORITY, SRI LANKA

120, Norris Canal Road, Colombo 10, Sri Lanka.

Telephone: +94 011 2698896/7 Fax: +94 011 2689704 email: info@nmra.gov.lk

Application form for submission/notification of variation

For office use only		
Confirmed variation type		Payment required: Yes/No
		Payment receipt No.:
Listed documents have been attached	Yes/NO Remarks:	
Checking pharmacist	…… Signature	Date:
Pharmacist for detailed review		Assigned by: …… Head of MRD

To be filled by the applicant:

Remark: *Please complete each section of this application form electronically as a signed Word document or a text-selectable PFD document. Please ensure that the printed application form accompany with the submission.*

SECTION 1: APPLICANT DETAILS AND CURRENT REGISTRATION

Dossier No.		Registration number	
Registration Type	Full/~~PR for one year/PR for two years~~	Valid till	
Name of the applicant company (MAH)	Yaden International (Pvt) Ltd	Date of submission	
Address of the MAH	No. 67, Norris Canal Road, Colombo 10	Email:	
		Tel:	
		Fax:	
Name of the product	Chondroitin Sulphate Sodium 4.0 % w/v and Sodium Hyaluronate 3.0 % w/v Ophthalmic Solution	Brand name (if applicable)	

Name of the manufacturer			
Address of the manufacturer			

SECTION 2: VARATION DETAILS AND CHECKLIST

Variation type: (tick all applicable options) ☐ Major ☐ Minor for prior approval ☑ Minor for notification

Grouping of variations: ☐ Single ☐ Grouped

Proposed change(s)	1. Inclusion of additional pack size 1 ml PFS		
	1.		
	2.		
	3.		
List of supporting documents attached	1. Description of the change(s)		Yes/No
	2. Summary of changes		Yes/No
	3. Justification(s)		Yes/No
	4. Other NRA approvals (if applicable)		Yes/No
	5. Copy of existing certificate of registration		Yes/No
	6. Stability data		Yes/No
	7. PM specification, MoA & CoAs, Artwork and PIL		Yes/No
	8. Revised API specification, Method of Analysis and CoAs		Yes/No
	9. CEP of API		Yes/No
Reference authority if proposed change(s) has been approved	-	Date(s) of approval	-
Additional comments/remarks			

SECTION 3: DECLARATION BY THE RESPONSIBLE PHARMACIST

(Please check all declarations that are applicable)

I declare that:

√	There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied separately.

The | √ | information contained herein and in supporting documents is true and accurate

Name: .

Designation .

Signature: . Date: .

NB: 1. Details/supporting documents/specimens (e.g. amended labels) should be attached
2. NMRA reserves the right to re-route the variation type, split unrelated changes or request for additional information during course of screening/evaluation