Annexure #1

Central Drug Standard Control Organization

Directorate General of Health Services

Office of Drugs Controller General (India)

(Biological Division)

Checklist for Pre Screening of Applications for variations under Post approval changes as per CDSCO Guidance for Industry.

Name of the firm: _____ **Date:** _____

TR-6 challan (if applicable) no:_____ **Date:**_____ **Ref.no:**_____

S.no.	Information and Documents	Status	
		Yes	No
1	Covering Letter-Purpose should be clearly mentioned with page number and Index.		
2	Whether change in Drug Substance or Drug Product along with **Description of change.**		
3	Change category: Supplement/Notifiable/Annual notification as per CDSCO Guidance for Industry.		
4	Copy of Market Authorization and other permissions/approvals for subject's product.		
5	Undertaking or satisfactory statement to fulfill conditions of proposed change as per CDSCO Guidance for industry.		
6	Side by side comparison of previously approved and changed information and declaration that other information is not changed or no change as a result of variation if applicable.		
7	Whether information as per CDSCO Guidance for industry for proposed variation is submitted.		
8	For imported products certified copy of approval from NRA of country of origin and from EMEA, USFDA etc. along with list of countries where proposed variation is approved.		
9	In case of annual notification declaration stating that supporting data for Level III change should be submitted on annual basis or within 15days whenever required by DCGI.		
10	Statements & evidences about effect of change on quality, stability, validation, animal toxicity & clinical (safety & efficacy) status of the product.		
11	For label change, Package insert change, extension in shelf life or change in specifications not mentioned in Indian pharmacopoeia one additional set of literature (hard & soft copy).		

Accepted/Returned due to incomplete application

Signature of the Reviewer

Signature of firm representative

Annexure #2

ANNUAL REPORT FORM (MINOR CHANGES)

January_____ to December_____

1	MANUFACTURING SITE (S) OR AREA (S) INVOLVED	
2	PRODUCTS INVOLVED	
3	DESCRIPTION OF CHANGE	
4	RATIONALE OF CHANGE	
5	REFERENCE TO CDSCO GUIDELINES PAC/1108/1.1	Conditions:
6	IMPLEMENTATION DATE	
7	CROSS REFERENCE TO VALIDATION PROTOCOLS AND/OR SOPS/STPS/SPEC'S (IF RELEVANT)	
8	RELEVANT DATA FROM STUDIES AND TESTS PERFORMED (IMPACT OF CHANGE ASSESSED)	

Submitted by: