Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

ANNEX B

NOTIFICATION FORM FOR MINOR VARIATION/S OF REGISTERED PHARMACEUTICAL PRODUCT

Date:			**DOCUMENT TRACKING NUMBER (DTN)**	
FOOD AND DRUG ADMINISTRATION			**TO BE FILLED OUT BY FDA**	
Civic Drive, Filinvest Corporate City			**Received by:**	
Alabang, Muntinlupa City			**Signature:**	
			Date:	
			PAYMENT DETAILS	
			Amount Paid:	
			OR No.:	
			OR Date Issued:	

Sir/Madam:

In accordance with Administrative Order No. 2013-0021 and related issuances, we wish to apply and notify FDA of our intention to make Minor Variation/s to our pharmaceutical product described below:

PRODUCT PARTICULARS

Details should be consistent with the current CPR/CLIDP.

Generic Name	
Dosage Strength and Form	
Brand Name	

Approved Shelf-life	
Storage Condition	
Packaging/Presentation	

FDA Registration No.		**Validity**		
Registration Status				*State the validity or the DTN of the renewal application, if the CPR/CLIDP has not yet been renewed*

COMPANY PARTICULARS

Details should be consistent with the current CPR/CLIDP. Complete name/s and address/es of the involved establishment/s should be reflected.

Manufacturer	
Trader	
Importer	
Distributor	
Packer/Repacker	

DTN	
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POST-APPROVAL CHANGES PARTICULARS

Table of Changes		
Current	**Proposed Changes**	**Specific Type of Variation** *For BMiV-N17, indicate the original variation code applied for the PCPR, e.g. BMiV-N17 (BMaV-15)*

***** NOTHING FOLLOWS *****

DTN	
Received by:	

DECLARATION

In support of our notification, I, the undersigned, hereby declare under oath that:

1. I am duly authorized to bind the establishment I represent pursuant to the authority attached to this Notification Form for Minor Variation/s of Registered Pharmaceutical Product (Board Resolution in case of corporation and Special Power of Attorney in all other cases both of which should be duly notarized).
2. On behalf of my company, the pharmaceutical product identified in the notification form meets all the legal requirements, and conforms to existing standards and specification requirements applicable to the said product.
3. All conditions for the variations have been fulfilled and all required supporting documents are submitted.
4. The particulars given in this notification are true and all data and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.
5. I agree that the acknowledgement of this notification shall not preclude the Food and Drug Administration (FDA) in imposing appropriate regulatory actions in the event that there is/are outright negligence on the conditions for minor variation – notification and explicit misdeclaration of the applied changes as notification; lacking and deficient documentary requirements as stipulated in existing policies on Post-Approval Changes; subsequent findings of misrepresentation in any of the data indicated in the required documents or any of the said documents is subsequently found to be falsified or fraudulently filed; and/or in case the samples of the identified pharmaceutical product collected through post marketing surveillance shall be found not to conform to the product's registered specifications or approved labeling.
6. The company I represent shall automatically cease and desist from further distributing the identified pharmaceutical product subject of revocation upon receipt of the notice of revocation and pending any administrative proceeding until further notice from FDA.
7. I, or my company undertake to:
   a) Ensure the identified pharmaceutical product's technical and safety information is made readily available to FDA anytime when requested, and to keep records of the distribution of the products for inspection, product recall, and other purposes that may be deemed necessary.
   b) Notify FDA of any reported adverse drug reactions consistent with the requirements of pharmacovigilance.
   c) Respond to and cooperate fully with Food-Drug Regulation Officers (FDROs) with regard to any subsequent post-marketing activity initiated by FDA.
   d) Exhaust the remaining stocks **of labeling materials and products** bearing the old product information up to a maximum of one (1) year from the date of receipt of the notification, at the manufacturing level.
8. I understand that our company or establishment cannot place reliance on the acceptance of the notification by FDA in any legal proceedings concerning the above product, in the event that the identified product has failed to conform to any standards or specifications previously declared to FDA.
9. There is/are no other change/s made to/proposed for the drug product aside from what is/are specified in the Post-Approval Changes Particulars of this Notification Form.

DTN	
Received by:	

HEAD OF REGULATORY AFFAIRS OFFICE		COMPANY PHARMACIST	
Signature:		**Signature:**	
Name:		**Name:**	
Designation :		**Designation :**	
Date:		**Date:**	

SUBSCRIBED AND SWORN TO BEFORE ME this personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued

Known to me and to me known to be the same persons who executed the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed.

WITNESS MY HAND AND SEAL on the date and place first above written.

Doc No.	
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