ANNEX A

Letter of Request for Post-approval Change/s

DTN	
Date:	

FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Attention: Licensing and Registration Division
Center for Drug Regulation and Research

Sir/Madam,

We would like to submit our application for Post-approval Change/s, *(type of Post Approval Change as per PVGB)* for the following product/s:

Product Name/Strength and Form	CPR Validity/Drug Registration Number	Current	Proposed Change/s	Classification/ Specific Type of PAC/s

We, *(company name)*, declare that there is/are no other change/s to the drug product registration aside from what is/are specified above.

For your approval.

Very truly yours,

(Company representative name and signature)
(Position)

DECLARATION

In support of our post-approval change/s application, 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 Letter of Request for Post-Approval Change/s (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 letter of request meets all the legal requirements and conforms to existing standards and specification requirements applicable to the said product, and that the proposed change/s has/have been checked in reference to the currently approved data in the system.
3. All conditions for the post-approval changes have been fulfilled and all required supporting documents are submitted.
4. The particulars given in this application are true and all data and information of relevance in relation to the request have been supplied and that the documents enclosed are authentic or true copies.
5. I agree that the approval of the variation/s 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 variation and explicit misdeclaration of the applied changes as variation; 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. All the conditions.
    b. 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.
    c. Notify FDA of any reported adverse drug reactions consistent with the requirements of pharmacovigilance.
    d. Respond to and cooperate fully with Food-Drug Regulation Officers (FDROs) regarding any subsequent post-marketing activity initiated by FDA.
    e. 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 certification, at the manufacturing level.
8. I understand that our company or establishment cannot place reliance on the acceptance of the post-approval change 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.

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 met hat 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. _____
Page No. _____
Book No. _____
Series of _____