VARIATION APPLICATION
(EXCEPT TURNED-INITIAL VARIATION)

Who May Avail : All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products

Fees to be Paid : **FDA Circular No. 2014-008, Annex D**

Payment shall be on a per product, per change basis

1. Regular PACs, including change of capsule color : PHP 500.00 + LRF
2. With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement: PHP 500.00 + LRF
3. With FDA Clinical Review for additional indication: PHP 2,500.00 + LRF
4. With Subsequent Labeling Amendment per product strength: + PHP 500.00 + LRF
5. Change or addition of brand name: PHP 2,500.00 + LRF + PHP 510.00 (for each brand name proposed)
6. Shelf life extension/reduction: PHP 1,000.00 + LRF
7. Equivalent to Initial Registration, including Additional Route of Administration
   Unbranded: PHP 10,000.00 + LRF
   Branded: PHP 15,000.00 + LRF
   Monitored Release Status: PHP 20,000.00 + LRF (for Three years) + PHP 20,000.00+ LRF (for additional two years as per FDA Circular No. 2013-004)
8. Reclassification: PHP 3,000.00 + LRF

CHECKLIST OF REQUIREMENTS

- **FDA Circular No. 2014-008: Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products**
- **ASEAN Variation Guidelines**
- **AO No. 47-a, series of 2001: Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products**

1. Duly accomplished and notarized Integrated Application Form (IAF) [PDF]
2. IAF in Microsoft Excel format
3. Proof of Payment based on Annex D of FDA Circular No. 2014-008
4. Letter of Request for Post-Approval Changes (Annex A) [A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.]
5. Copy of valid Certificate of Product Registration and/or proof of CPR renewal
6. Copy of previously approved PACs (if not yet incorporated in the current CPR, if

applicable)

7. For Certificate of Listing of Identical Drug Product (CLIDP), a copy of Principal CPR (PCPR) variation approval (where applicable)
8. Complete List of Documentary Requirements based on Annex C of FDA Circular No. 2014-008 and ASEAN Variation Guidelines (attached as annexure to this document)
9. Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable)

END