Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

VARIATION-TURNED-INITIAL APPLICATION

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

Fees to be Paid : **FDA Circular No. 2014-008, Annex D**
Payment shall be on a per product, per change basis
Variation-turned-Initial:
Branded: PHP 15,000.00 + 1% LRF
Unbranded: PHP 10,000.00 + 1% LRF
Monitored Release Status: PHP 20,000.00 + 1% LRF (for three years) + PHP 20,000.00 + 1% LRF (for additional two years as per FDA Circular No. 2013-004)

CHECKLIST OF REQUIREMENTS

- **FDA Circular No. 2014-008: Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products**
- **ASEAN Variation Guidelines**

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 documentary requirements based on the ASEAN Variation Guidelines and FDA Circular No. 2014-008

END