Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

MINOR VARIATION - NOTIFICATION

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
Regular PACs: PHP 500.00 + LRF

CHECKLIST OF REQUIREMENTS

- **FDA Circular No. 2014-008-A**

1. Hard copy:
   a. Two (2) copies of notarized Annex B (see attached sample Annex B)
   b. Original copy of the Official Receipt
2. Soft copy:
   a. Notarized latest Notification Form for minor variation (Annex C)
   b. Portable document format (PDF) copy of signed integrated application form (IAF);
   c. IAF in Microsoft Excel format
   d. Copy of Certificate of Product Registration (CPR) and/or proof of renewal
   e. Copy of previously approved PACs (if not yet incorporated in the current CPR) (if applicable)
   f. For Certificate of Listing of Identical Drug Product (CLIDP), a copy of Principal CPR (PCPR) variation approval (where applicable)
   g. Complete documentary requirements based on the ASEAN Variation Guidelines, FDA Circular No. 2014-008, FDA Circular No. 2014-008-A, and FDA Circular No. 2016-017 and pertinent evidence supporting change/s

END