Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. **2016-017**

0 3 OCT 2016

TO : **ALL DRUG ESTABLISHMENTS AND OTHER CONCERNED STAKEHOLDERS**

SUBJECT : **Additional Post-Approval Changes for Pharmaceutical Products**

To further facilitate the processing of applications for post-approval changes (PACs) of registered pharmaceutical products, reclassification and inclusion of other minor variations with minimal/no significant impact on the aspects of safety, efficacy, and quality are necessary.

The following MINOR VARIATIONS are hereby reclassified from PRIOR APPROVAL to NOTIFICATION:

VARIATION	CONDITION/S
MiV-PH3 [Change of marketing authorization holder (MAH)]	*as per country-specific variations provided under FDA Circular 2014-008*
MiV-PA2* [Change of product labeling (in accordance to country specific labeling requirement)]	Shall include a)-b) of MiV-PA2, such as: 1. change/s in packaging design (no change in text) 2. change/s in layout (positioning of graphic designs) 3. printing of product information inside the carton 4. conversion of package insert to product information leaflet [for Over-the-Counter (OTC) products] 5. inclusion of product information leaflet (for OTC products) 6. addition of Global Product Identification Number (GPIN) New variation code is **MiV-PH-N1.** Those under c)-f) shall follow appropriate variation classification.

MiV-PA18 (Deletion of the solvent/diluent for the drug product)	*as per the ASEAN Variation Guideline for Pharmaceutical Products under FDA Circular 2014-008*
MiV-PA31 (Change of outer carton pack sizes for a drug product)	
MiV-PA32 [Change in any part of the (primary) packaging material not in contact with the finished product formulation such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)]	

**Compliance to Administrative Order No. 2016-0008 shall be processed as a prior approval variation*

In addition, the following MINOR VARIATIONS are hereby included to the list of MINOR VARIATION NOTIFICATION:

VARIATION	CONDITION/S
MiV-PH-N2 [Change/addition of QC/Stability testing site/s (different from the batch release site]	no change in the manufacturer of the drug product / drug substance / excipient
MiV-PH-N3 [Change/inclusion of distributor (for Principal Certificate of Product Registration, PCPR)]	no change in MAH
MiV-PH-N4 (Addition/change of supplier of drug substance / excipient)	1. no change in the manufacturer of the drug substance / excipient 2. no change in the specification of the drug substance / excipient
MiV-PH-N5 (Addition/change of supplier of packaging materials)	1. no change in the qualitative and quantitative composition, and type of container 2. no change in the specification of the packaging materials
MiV-PH-N6 (Administrative changes affecting entities other than the MAH)	1. no change in the manufacturer of the drug product 2. no change in the distributor [for Certificate of Listing of Identical Drug Products (CLIDP)]
MiV-PH-N7 (Addition of pack size for non-sterile drug product)	1. no change in the qualitative and quantitative composition, and type of container 2. no change in the specification of the packaging materials

The following are the requirements to be submitted:

1. Two (2) original hard copies of notarized Annex B;
2. Portable Document Format (PDF) copy of the signed integrated application form;
3. Integrated Application Form (IAF) in excel format;
4. Electronic copy of the complete documentary requirements and pertinent evidences supporting the change/s;
5. Declaration, signed by the Head of the Regulatory Office, that there is/are no other change/s except for the proposed variation.
6. For CLIDP, copy of PCPR variation approval.

The reclassified/additional variation types shall be submitted following the notification submission scheme as per FDA Circular No. 2014-008-A (Amendment to Annex B, Notification for Minor Variation of FDA Circular No. 2014-008 entitled "Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products", specifically on Section IV, C, D, and E for Minor Variation-Notification).

This FDA Circular shall take effect immediately.

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