



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



22 JUN 2016

**FDA CIRCULAR**

No. 2014-008-A

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

**SUBJECT : 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**

To facilitate the processing of applications for minor variations-notifications (MiV-N) of registered drug products, Section IV, C, D and E of FDA Circular No. 2014-008 is hereby amended.

In using the new form, please be reminded that all fields must be **completely filled-out**; for items that are not applicable, kindly write "NA" and after the last entry in the Table of Changes, indicate "NOTHING FOLLOWS". Also, please take note of the additional undertakings in the Declaration section, specifically items 6d and 6e regarding the (1) exhaustion period of the existing labeling materials bearing the old product information, and (2) commitment to submit commercial sample consistent with the submitted notified change.

The scanned copy of the signed and notarized form must be included in the application dossier. **Two (2)** original copies of the new form must be submitted through the Public Assistance, Information and Receiving (PAIR) on **Tuesdays and Wednesdays, from 8:00 am to 12:00 noon, without the need for prior appointment.**

Upon receipt of PAIR, a Document Tracking Slip (DTS) shall be issued and the Notification for Minor Variation form shall be stamped and signed by the receiving officer with the Notification Number (NN) on each page, which shall serve as proof of acknowledgement that the Notification has been received and that FDA has been duly notified of the change.

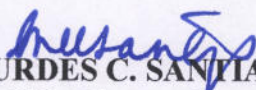
Lastly, any MiV-N with accompanying major variation (MaV) or minor variation - prior approval (MiV-PA) applications shall not be processed in the abovementioned scheme and shall be filed separately.





All other stipulations stated in the FDA Circular 2014-008 dated 28 February 2014 shall remain in full force and effect.

This FDA Circular is effective 1 July 2016.

  
MARIA LOURDES C. SANTIAGO, MSc, MM  
OIC, Director General

