



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



06 March 2015

FDA CIRCULAR
No. 2013-008 ~ A

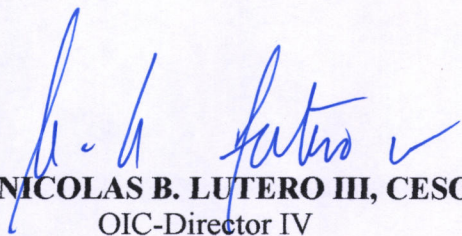
SUBJECT: Amendment to FDA Circular No. 2013-008 on A. Process and Communication under Section IV. Details/Directives

The first two paragraphs of A. Process and Communication, Section IV. Details/Directives under FDA Circular No. 2013-008, "Adoption of the Association of Southeast Asian Nations (ASEAN) Post-Marketing Alert System (PMAS) for Defective or Unsafe Processed Food Products, Pharmaceutical Products, Traditional Medicines and Health Supplements, and Cosmetic and Household Hazardous Products and Devices", dated 22 April 2013 is hereby amended to read as follows:

"Each Center of the Food and Drug Administration shall assign a PMA System focal point or coordinator for each of the product sectors: processed food products, pharmaceuticals, traditional medicine and health supplements, cosmetic products and household hazardous substance and devices. **The PMA System focal point or coordinator shall be responsible for the exchange of PMAS reports with other Member States.**

The Centers of the FDA, through the PMA System focal point or coordinator shall send (email or fax) an alert notification to other Member States using the agreed standardized form of reporting, the PMA form. The validity of the content of the alert notification must be established prior to circulation. The timeline requirement for notification will be subject to individual Member State's regulatory judgement and discretion, to allow for reporting timeline flexibility."

For your information and strict compliance.


ATTY. NICOLAS B. LUTERO III, CESO III
OIC-Director IV
Food and Drug Administration

