Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 June 2015

FDA Advisory
No. 2015-048

SUBJECT: RECALL OF ALL DRUG PRODUCTS MANUFACTURED BY ALLIED PHARMACEUTICAL LABORATORIES, INC. FROM JANUARY 2014 UP TO THE PRESENT

The public is hereby warned by the Food and Drug Administration (FDA) that all drug products manufactured by Allied Pharmaceutical Laboratories, Inc. from January 2014 up to the present are being recalled from the market.

Critical and major findings of non-conformance to Pharmaceutical Inspectorate Cooperation Scheme-Good Manufacturing Practice (PIC/s-GMP) were noted during inspection of the said manufacturing facility which indicated that there is no assurance that the manufactured products are of good quality.

The affected products present safety risk and potential adverse health consequences. Therefore, Allied Pharmaceutical Laboratories, Inc. has been ordered to discontinue their manufacturing operations. All distributors, retailers, hospitals, pharmacies, or clinics are instructed to discontinue further distribution, sale and use of the affected drug products which were manufactured from January 2014 up to the present. All consumers are likewise advised not to purchase or use these products and to contact Allied Pharmaceutical Laboratories, Inc. at telephone number (02) 741-8737 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All Field Regulatory Operations Office (FROO) Officers are ordered to monitor the availability of the affected products in the market, appropriately seal discovered stocks of the affected products, and instruct the concerned establishment to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the affected drug products should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

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Secretary of Health
Acting Director General[1]

DTN: 20150513100741
[1]Pursuant to DPO 2015-1845

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