Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Advisory
No. 2015 -090

SUBJECT: **TERMINATION OF PRODUCT RECALL ORDER ISSUED TO ALL PRODUCTS MANUFACTURED BY ALLIED PHARMACEUTICAL LABORATORIES, INC. FROM JANUARY 2014 UP TO 24 JUNE 2015**

This is to inform the public that the Product Recall Order (PRO) issued on all drug products manufactured by Allied Pharmaceutical Laboratories, Inc. from January 2014 up to 24 June 2015 is hereby terminated by the Food and Drug Administration (FDA).

As stated in the FDA Advisory No. 2015-048 and further amended by FDA Advisory No. 2015-048-A with the latest posting dated 31 July 2015, Allied Pharmaceutical Laboratories, Inc. was found with critical and major non-conformances to Pharmaceutical Inspectorate Cooperation Scheme-Good Manufacturing Practice (PIC/s-GMP). However, appropriate compliance has been made as determined by the Field Regulatory Operations Office (FROO), thus, found capable to engage again in manufacturing activities starting from 25 June 2015.

After due and thorough evaluation of the submitted documents by the Marketing Authorization Holder (MAH), FDA has determined that reasonable efforts had been made by Allied Pharmaceutical Laboratories, Inc. to recall and properly destroy the impacted batches of all drug products manufactured from January 2014 up to 24 June 2015 in accordance with Bureau Circular No. 8 s. 2001, known as the Guidelines to be Observed on the Implementation of Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of existing laws, rules and regulations.

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All Officers of the Field Regulatory Operations Office (FROO) are ordered to appropriately seal additional discovered stocks of all drug products of Allied Pharmaceutical Laboratories, Inc. with date of manufacture of January 2014 up to 24 June 2015, and instruct the concerned establishment to give back the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA representative.

Consumers may contact FDA at telephone number +632 857-1900 or via e-mail at info@fda.gov.ph for any questions or additional information regarding the recalled products.

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Secretary of Health
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DTN: 20150824104958

[1]Pursuant to DPO 2015-1845