Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

31 JUL 2015

FDA Advisory
No. 2015-048-A

SUBJECT: **AMENDMENT TO FDA ADVISORY NO. 2015-048 TO REFLECT SPECIFIC COVERAGE OF THE PRODUCT RECALL FROM *"ALL PRODUCTS MANUFACTURED BY ALLIED PHARMACEUTICAL LABORATORIES, INC. FROM JANUARY 2014 UP TO THE PRESENT"* TO *"ALL PRODUCTS MANUFACTURED BY ALLIED PHARMACEUTICAL LABORATORIES, INC. FROM JANUARY 2014 UP TO 24 JUNE 2015"***

The Food and Drug Administration (FDA) is informing the public that the products covered by the Product Recall Order (PRO) issued on *"all products manufactured by Allied Pharmaceutical Laboratories, Inc from January 2014 up to the present"* is hereby amended to *"all products manufactured by Allied Pharmaceutical Laboratories, Inc. from January 2014 up to 24 June 2015."*

Critical and major findings of non-conformance to Pharmaceutical Inspection Co-operation Scheme-Good Manufacturing Practice (PICf/s-GMP) were noted during inspection of the said manufacturing facility on 18 to 21 November 2014 which indicated that there is no assurance that the manufactured products are of good quality. In this regard, the establishment has been ordered to discontinue their manufacturing operations during the inspection period. However, during the follow-up inspection on 24 June 2015, Officers of the Field Regulatory Operations Office (FROO) found that the company has sufficiently complied with the noted PIC/s-GMP non-conformances. Hence, the company was found capable to engage in manufacturing activities from the said date.

All consumers are advised 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.

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Secretary of Health
Acting Director General[1]

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