

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



26 February 2014

FDA Advisory No2014-015

SUBJECT: RECALL OF ALL PRODUCTS MANUFACTURED (FROM JANUARY 2012 UP TO THE PRESENT) BY COMPACT PHARMACEUTICALS CORP.

The public is hereby warned by the Food and Drug Administration (FDA) that all products manufactured by Compact Pharmaceuticals Corp. from January 2012 up to the present are being recalled from the market.

Critical and major deficiencies in the manufacturing facility of the said establishment were noted by the regional field inspectors. FDA has recommended the recall of all products due to poor compliance to current Good Manufacturing Practice (GMP), which indicates that there is no assurance that the manufactured products are of good quality.

The affected products present a safety risk and potential adverse health consequences. Therefore, Compact Pharmaceuticals Corp. has been ordered to stop the manufacture of any drug product. All traders and distributors are hereby ordered to discontinue the distribution of all the affected products. All drug retail outlets are also ordered to discontinue from selling or offering these products for sale to the consumers. All consumers are advised not to purchase or use the affected products.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report any concern regarding health products, including adverse reactions, kindly email us at report@fda.gov.ph.

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