Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

27 March 2015

FDA Advisory
No. 2015-013

SUBJECT: PRODUCT RECALL OF BATCH SPECIFIC RIFAMPICIN 200 mg/5 mL SUSPENSION (RIFANID)

The public is hereby warned by the Food and Drug Administration (FDA) that the following batch of Rifampicin (Rifanid) 200 mg/5 mL Suspension is being recalled from the market. The details of the product are as follows:

REGISTRATION NUMBER	**DR-XY30945**
BATCH NUMBER / EXPIRY DATE	**C30005 / JULY 2016**
MANUFACTURER NAME AND ADDRESS	**CONCEPT PHARMACEUTICALS LTD. NO. 167, C.S.T. ROAD, INDIA**
IMPORTER/DISTRIBUTOR	**PHIL. PHARMAWEALTH, INC. SUITE 3001, EAST TOWER, PSE CENTER, EXCHANGE RD., ORTIGAS CENTER, PASIG CITY**

Based on the result of the laboratory analysis conducted by FDA, it was found that the label claim of batch number C30005 of Rifampicin (Rifanid) 200 mg/5 mL Suspension is below the required potency.

The above specific batch of Rifampicin (Rifanid) 200 mg/5 mL Suspension presents a safety risk and adverse health consequences as it potentially exposes patients to suboptimal dose of Rifampicin therapy.

Rifampicin (Rifanid) 200 mg/5 mL Suspension is used for the treatment of tuberculosis, leprosy, methicillin resistant staphylococcocal infections, serious staphylococcocal infections, meningococcal carriers and other infections. The product is packed in a 120 mL Amber bottle.

The distributors, retailers, hospitals, pharmacies or clinics that have the affected batch of Rifampicin (Rifanid) 200 mg/5 mL Suspension are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batch.

All field Food and Drug Regulation Officers are ordered to monitor the availability of the product batch in the market.

Consumers may contact Phil. Pharmawealth, Inc. at telephone numbers 683 0053 to 57 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product batch should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

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