Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016 015

05 FEB 2016

SUBJECT: **Product Recall of Batch Number C30003 of Rifampicin 200 mg/5 mL Oral Suspension (Rifanid)**

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

REGISTRATION NUMBER	**DR-XY30945**
BATCH NUMBER / EXPIRY DATE	**C30003 / MAY 2016**
MANUFACTURER NAME AND ADDRESS	**CONCEPT PHARMACEUTICALS LTD. – NO. 167, C.S.T. ROAD, INDIA**
IMPORTER/DISTRIBUTOR (MAH)	**PHIL. PHARMAWEALTH, INC. – SUITE 3001, EAST TOWER, PSE CENTER, EXCHANGE RD., ORTIGAS CENTER, PASIG CITY**

Based on the results of the laboratory analyses conducted by FDA, it was found that the affected product batch did not conform to the specifications of pH and physical appearance. A pharmaceutical suspension should settle slowly and should readily redisperse upon gentle shaking. However, caking was observed in the concerned batch which made the suspension not readily redispersable upon shaking and also prevented the suspension to be readily poured from the container. The suspension was homogenized only upon the exertion of extra effort in shaking the bottle through the help of a mechanical device. The stated batch of the drug product presents safety risks if the suspension is not homogenized before administration to the patient. Some parts will have low potency and other parts will have high doses of the active ingredient. Erratic potency of doses unknowingly taken by the patient may possibly cause either therapeutic failure or toxicity.

Rifampicin (Rifanid) 200 mg/5 mL Oral 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.

Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batch of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batch and may contact Phil. Pharmawealth, Inc. at telephone numbers +632 683 0053 to 57 loc. 118 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product batch in the market, appropriately seal discovered stocks of the affected batch of the product, and instruct the concerned establishment to return 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 aforementioned product batch should be reported immediately to the FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General

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