Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

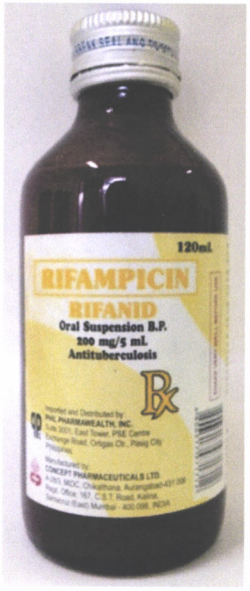
03 NOV 2015

FDA ADVISORY
No. 2015-081

SUBJECT: **Product Recall of Specific Batches of Rifampicin 200 mg/5 mL Suspension (Rifanid)**

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

REGISTRATION NUMBER	**DR-XY30945**
BATCH NUMBER / EXPIRY DATE	**C40001 / JANUARY 2017** **C40002 / JANUARY 2017**
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 analyses conducted by FDA, it was found that the impacted product batches did not conform to the specifications of physical appearance. A pharmaceutical suspension should settle slowly and should readily redisperse upon gentle shaking. However, caking was observed in the affected batches 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 batches of the drug product present 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 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 affected product batches of Rifampicin (Rifanid) 200 mg/5 mL Suspension presents safety risks and are non-pharmaceutically aesthetic. Therefore, distributors, hospitals, retailers or pharmacies that have the affected batches 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 batches.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product batches in the market, appropriately seal discovered stocks of the affected batches 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.

Consumers may contact Phil. Pharmawealth, Inc. at telephone numbers +632 683 0053 to 57 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any suspected adverse reaction experienced from the use of the aforementioned product batches 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.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20150914111800
[1]Pursuant to DPO 2015-1845