Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

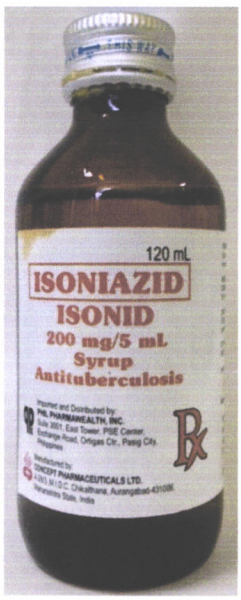
FDA ADVISORY No. 2015-084

03 NOV 2015

SUBJECT: Product Recall of Specific Batches of Isoniazid 200 mg/5 mL Syrup (Isonid)

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

REGISTRATION NUMBER	**DR-XY30788**
BATCH NUMBER / EXPIRY DATE	**C30002 / MAY 2016** **C30003 / MAY 2016** **C30007/ 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 laboratory analyses conducted by FDA, it was found that the product batches mentioned did not conform to the specifications of pH and physical appearance. Syrup should remain physically stable under conditions of varying temperature (resistant to crystallization of precipitation). However, the samples tested were observed with white precipitates and with presence of crystals or precipitates around the cap. Furthermore, the samples ranged from yellow to dark yellow syrup which is non-conforming to the correct specifications of light yellow colored, clear transparent syrup.

Isoniazid (Isonid) 200 mg/5 mL Syrup is used for the primary treatment of pulmonary and extra pulmonary tuberculosis. The product is packed in a 120 mL Amber bottle.

The affected product batches present safety risks and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies

or clinics that have the affected batches of Isoniazid (Isonid) 200 mg/5 mL Syrup are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batches and 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.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product batches in the market, to seal the discovered stocks of the affected batches of the product, and to 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 batches should be reported immediately to FDA by visiting 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: 20150914112428
[1]Pursuant to DPO 2015-1845