Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2015-086

03 NOV 2015

SUBJECT: Product Recall of Batch Specific Orlistat 120 mg Capsule (Reducin)

The public is hereby warned by the Food and Drug Administration (FDA) that the following batch of Orlistat (Reducin) 120 mg Capsule is being recalled from the market. The Central Laboratory (CL) of FDA tested the specific batch and was found negative for the presence of the Active Pharmaceutical Ingredient (API), Orlistat. The details of the product are as follows:

REGISTRATION NUMBER	**DR-XY40428**
BATCH NUMBER / EXPIRY DATE	**RD-TTI / AUGUST 2016**
MANUFACTURER NAME AND ADDRESS	**SHANXI SHUGUANG PHARMACEUTICAL CO., LTD. NO. 1, KANGLE ST., QI COUNTRY, JINGZHONG, SHANXI, CHINA**
IMPORTER/DISTRIBUTOR	**GOLDEN DALE PHARMA CORP. G/F AARON BLDG., 20 G ARANETA AVE., STO. DOMINGO, QUEZON CITY**

Orlistat (Reducin) 120 mg Capsule is used together with dietary modification in the management of obesity. The product is packed in Alu/Clear PVC Blister Pack of 10's boxes of 20 and 30 capsules.

The affected product batch present safety risks and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batch of Orlistat (Reducin) 120 mg Capsule 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 Golden Dale Pharma Corp. at telephone numbers (02) 291 8816 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All field Food Drug Regulation Officers are ordered to monitor the availability of the product batch in the market, to seal the discovered stocks of the affected batch of the product, and to instruct the concerned establishment to give back 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 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: 20150914113724

[1]Pursuant to DPO 2015-1845