Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-018

05 FEB 2016

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

The public is hereby warned by the Food and Drug Administration (FDA) that a certain batch of Orlistat (Reducin) 120 mg Capsule is being recalled from the market due to the failed assay result from the analysis of the FDA Common Services Laboratory (CSL). The details of the product batch are as follows:

REGISTRATION NUMBER	**DR-XY40428**
BATCH NUMBER / EXPIRY DATE	**RD-TTS/ OCTOBER 2016**
MANUFACTURER NAME AND ADDRESS	**SHANXI SHUGUANG PHARMACEUTICAL CO., LTD. – NO. 1, KANGLE ST., QI COUNTY, JINZHONG, SHANXI, CHINA**
IMPORTER/DISTRIBUTOR (MAH)	**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 10 and 30 capsules.

The affected product batch presents safety risks and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batch 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 +632 291 8816 or +632 516-8888 or mobile no. +63 909 3333333 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

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.

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

DTN: 20151110162039