Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2015-083

03 NOV 2015

SUBJECT: **Product Recall of Specific Batches of Tolnaftate 10 mg/mL Solution (Tinactin)**

The public is hereby warned by the Food and Drug Administration (FDA) that the following batches of Tolnaftate (Tinactin) 10 mg/mL Solution are being recalled from the market due to a non-compliance to the approved labeling reported by the Marketing Authorization Holder (MAH), Organon Philippines In corporated. The generic name of the drug product was printed erroneously as "Tolnafate" instead of "Tolnaftate" in the generic outline box and on the cartonsert (summary of product characteristics printed on the carton itself). The details of the product are as follows:

REGISTRATION NUMBER	**DR-1774**
BATCH NUMBERS / EXPIRY DATE	**A1241 / MARCH 2016** **A34601 / JULY 2016**
MANUFACTURER NAME AND ADDRESS	**SCHERING PLOUGH** **HEROUVILLE-ST-CLAIR, FRANCE**
IMPORTER/DISTRIBUTOR	**ORGANON PHILIPPINES INCORPORATED –** **26/F PHILAMLIFE TOWER, 8767 PASEO DE ROXAS, MAKATI CITY**

Tolnaftate (Tinactin) 10 mg/mL Solution is used for the treatment of tinea flava, body ringworm, athlete's foot, and other types of fungus infection. The product is packed in 15 mL HDPE bottle (Box of 1's).

The affected product batches present safety risks and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batch of Tolnaftate (Tinactin) 10 mg/mL Solution 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 Organon Philippines Incorporated at telephone numbers (02) 817 7638 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: 20150914115617

[1]Pursuant to DPO 2015-1845