Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 September 2014

FDA Advisory
No. 2014-078

SUBJECT: PRODUCT RECALL OF LOT SPECIFIC RIFAMPICIN 450 MG CAPSULE (PICINAF)

The public is hereby warned by the Food and Drug Administration (FDA) that the following lot of Rifampicin 450 mg capsule (Picinaf) is being recalled from the market. The details of the product are as follows:

REGISTRATION NUMBER	**DRP-833**
LOT NUMBER	**BK3503**
EXPIRY DATE	**JULY 2015**
MANUFACTURER NAME AND ADDRESS	**J.M. TOLMANN LABORATORIES, INC. - #95 NORTH ZUZUARREGUI ST., DILIMAN QUEZON CITY**
DISTRIBUTOR NAME AND ADDRESS	**THE GENERICS PHARMACY, INC. – 459 QUEZON AVENUE, QUEZON CITY**

Based on the results of laboratory analysis conducted by the FDA, it was found that the label claim of lot BK3503 of Rifampicin 450 mg capsule (Picinaf) is below the required potency.

The above specific lot of Rifampicin 450 mg capsule (Picinaf) presents a safety risk and adverse health consequences as it potentially exposes patients to suboptimal dose of Rifampicin therapy.

Rifampicin 450 mg capsule (Picinaf) is used for the treatment of pulmonary and extra-pulmonary tuberculosis. The product is packed in a blister packaging containing ten (10) capsules each (Box of 100's).

The distributors, retailers, hospitals, pharmacies, or clinics that have the affected lot of Rifampicin 450 mg capsule (Picinaf) are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected products.

All field Food and Drug Regulation Officers are ordered to monitor the availability of the product batches in the market.

Consumers may contact The Generics Pharmacy, Inc. at telephone number +632 821-1111or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

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Acting Director General