Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2015-089

03 NOV 2015

SUBJECT: Termination of the Product Recall Order (PRO) Issued to Lot Specific Rifampicin 450 mg Capsule (Picinaf)

This is to inform the public that the Product Recall Order (PRO) issued on affected lot (BK3503) of Rifampicin 450 mg Capsule with brand name Picinaf is hereby terminated by the Food and Drug Administration (FDA). This product is manufactured by J.M. TOLMANN LABORATORIES, INC.

As stated in the FDA Advisory No. 2014-078 dated 29 September 2014, FDA informed the public of the recall of the impacted lot (BK3503) which was analyzed and was found to have a potency below the required specification.

After due and thorough evaluation of the submitted documents by the Marketing Authorization Holder (MAH), FDA has determined that reasonable efforts had been made by the MAH, J.M. TOLMANN LABORATORIES, INC., to recall and properly destroy the impacted product lot in accordance with Bureau Circular No. 8, s. 2011, known as the Guidelines to be Observed on the Implementation of Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be any violation of existing laws, rules and regulations.

All Field Regulatory Operations Office (FROO) Officers are ordered to appropriately seal discovered stocks of the affected lot of the product, and to instruct the concerned establishment to give back the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA representative.

Consumers may contact FDA at telephone number +632 857-1900 or e-mail us at info@fda.gov.ph for any questions or additional information regarding this recalled product.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20151014112156

[1]Pursuant to DPO 2015-1845