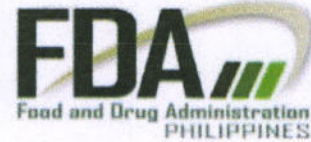




Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



30 JUL 2015

FDA Advisory  
No. **2015-059**

**SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON ALL LOTS OF ERYTHROMYCIN 40 mg/g (4%) GEL (SANSACNE 4)**

This is to inform the public that the Product Recall Order (PRO) issued on all lots of Erythromycin (Sansacne 4) 40 mg/g (4%) Gel is hereby terminated by the Food and Drug Administration (FDA). This product with registration number DR-XY17733 was manufactured by Laboratories Galderma in France and imported by Galderma Philippines, Inc.

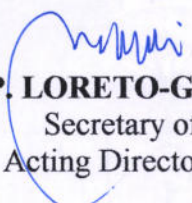
As stated in the FDA Advisory No. 2015-014 dated 27 March 2015, FDA ordered the recall of all lots of the subject product due to the determination of the Center for Drug Regulation and Research (CDRR) that all lots present safety risks for these do not guarantee to deliver a product of good quality.

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, Galderma Philippines, Inc., to recall and properly destroy all product lots in accordance with Bureau Circular No. 8, s. 2001, 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 findings of any violation of existing laws, rules and regulations.

All Field Regulatory Operations Office (FROO) Officers are ordered to appropriately seal discovered stocks of all lots of the subject product affected batches of the product, and 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 via e-mail at [info@fda.gov.ph](mailto: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<sup>1</sup>

DTN: 20150714102110

<sup>1</sup>Pursuant to DPO 2015-1845

