



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



29 FEB 2016

**FDA ADVISORY**

No. **2016-021**

**TO: GENERAL PUBLIC**

**SUBJECT: Termination of Product Recall Order (PRO) on Lot Specific Clarithromycin 250 mg/5 mL Granules for Suspension (Clarithroid)**

This is to inform the public that the Product Recall Order (PRO) issued on lot number 150947 of Clarithromycin 250 mg/5 mL Granules for Suspension (Clarithroid) is hereby terminated by the Food and Drug Administration (FDA). The product lot was manufactured by EL Laboratories, Inc.

As stated in the FDA Advisory No. 2015-093 dated 03 November 2015, FDA informed the public on the voluntary recall of the affected lot due to its failure in the assay test conducted by the Central Laboratory of FDA.

After due and thorough evaluation of the documents submitted by The Cathay Drug Company, Inc., the Marketing Authorization Holder (MAH), FDA has determined that reasonable efforts had been made to recall and properly destroy the affected product lot 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 Officers of the Field Regulatory Operations Office (FROO) are ordered to inventory and seal any discovered stocks of the affected lot of the subject product, and to instruct the concerned establishment to return 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 the recalled product.

Dissemination of the information to all concerned is requested.

By Authority of the Secretary of Health

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Officer-in-Charge, Director General

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