Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 NOV 2015

FDA ADVISORY
No. 2015-093

SUBJECT: **Voluntary Recall of Lot Specific Clarithromycin 250 mg/ 5 mL Granules for Suspension (Clarithrocid)**

This is to inform the public that The Cathay Drug Company, Inc. is voluntarily recalling the impacted lot of Clarithromycin (Clarithrocid) 250 mg/5 mL Granules for Suspension due to failure of the subject product in the assay test conducted by the Food and Drug Administration-Central Laboratory (FDA-CL). Clarithromycin (Clarithrocid) 250 mg/5 mL Granules for Suspension is used for the treatment of respiratory tract infections, skin and soft tissue infections, leprosy, infections due to *Mycobacterium avium,* protozoal infection and for eradication of *Helicobacter pylori* associated with peptic ulcer. This product is packed in a 10 mL (Physician's sample), 25 mL, 35 mL, 50 mL and 70 mL opaque white HDPE plastic bottle. The details of the affected product lot are as follows:

REGISTRATION NUMBER	**DRP-3634**
LOT NUMBER / EXPIRY DATE	**150947 / SEPTEMBER 2016**
MANUFACTURER NAME AND ADDRESS	**EL LABORATORIES, INC.** **109 NORTH MAIN AVE., LAGUNA TECHNOPARK, BIÑAN, LAGUNA**
TRADER (Marketing Authorization Holder)	**THE CATHAY DRUG COMPANY, INC.** **120 AMORSOLO ST., MAKATI CITY**

Therefore, distributors, hospitals, retailers or pharmacies that have the affected lot of Clarithromycin (Clarithrocid) 250 mg/5 mL Granules for Suspension are instructed to discontinue further distribution, sale and use of this product lot. All consumers are likewise advised not to purchase or use the affected product lot.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product lot in the market, to appropriately seal the discovered stocks of the affected lot of the product, and to instruct the concerned establishments to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Consumers may contact The Cathay Drug Company, Inc. at telephone numbers 892-5936 to 43 & 894-0553 to 56 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

Any suspected adverse reaction experienced from the use of the aforementioned product lot should be reported immediately to the FDA through this link: 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: 20150926104057
[1]Pursuant to DPO 2015-1845