

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



16 December 2013

FDA Advisory No.2013- 060-A

SUBJECT:

CLARIFICATION ON RECALLED CLARITHROMYCIN

(CLARIE DS 250) 250 MG/5ML POWDER FOR ORAL

SUSPENSION

The Food and Drug Administration (FDA) is clarifying the Recall Advisory for the antibacterial drug Clarithromycin (Clarie DS 250) 250mg/5 mL Powder for Oral Suspension. On November 28, 2013, FDA Advisory 2013-060 was issued, stating that the aforementioned product, manufactured by Ind-Swift Limited-India and imported and distributed by Ambica International Trading Corp, is being recalled from the market because batch number CQSIC302E of Clarie DS 250 failed to meet the specification based on laboratory analysis following the direction for reconstitution as stated on the label.

The public is hereby informed that the product recall issued does not include all batches of Clarithromycin (Claire DS 250) 250mg/5 mL Powder for Oral Suspension. The recall advisory is batch specific for a particular marketing authorization holder and it is only for batch number COSIC302E.

For more information and inquiries, please email us at info@fda.gov.ph.

RTIGAN-GO, MD g Director General





