Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 November 2013

FDA Advisory
No. 2013-060

SUBJECT: PRODUCT RECALL OF CLARITHROMYCIN (CLARIE DS 250) 250mg/5mL POWDER FOR ORAL SUSPENSION

The public is hereby warned by the Food and Drug Administration (FDA) that Clarithromycin (Clarie DS 250) 250mg/5mL Powder for Oral Suspension, manufactured by Ind-Swift Limited – India, is being recalled from the market.

Based on the result of laboratory analysis conducted by FDA, the aforementioned antibiotic product with batch number CQSIC302E, failed to meet the specification based on the laboratory analysis following the direction for reconstitution stated on the label.

Clarithromycin (Clarie DS 250) being offered for sale presents a safety risk and adverse health consequences due to above limit content following the direction for reconstitution on the label of the aforementioned antibiotic product.

Ambica International Trading Corp., the importer, distributor and license holder, are hereby ordered to hold all batches of Clarithromycin (Clarie DS 250). All drug retail outlets carrying all batches of Clarithromycin (Clarie DS 250) are ordered to discontinue from selling or offer for sale to the consumers. All prescribers are warned against prescribing these products and all consumers are advised not to purchase and use the said antibiotic product.

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any report about establishments dealing illegally with sale or offer for sale of unregistered health products should be reported immediately to FDA at report@fda.gov.ph.

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