Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 NOV 2015

FDA ADVISORY
No. 2015-076

SUBJECT: **Public Health Warning Against the Use of Counterfeit Clarithromycin (Klaricid) 250 mg/5 mL Granules for Pediatric Suspension in Fruit Punch Flavor**

The Food and Drug Administration advises the public against the use of counterfeit Clarithromycin (Klaricid) 250 mg/5 mL Granules for Pediatric Suspension in Fruit Punch Flavor manufactured by Abbott Laboratories Limited- Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, S16 4XE, UK.

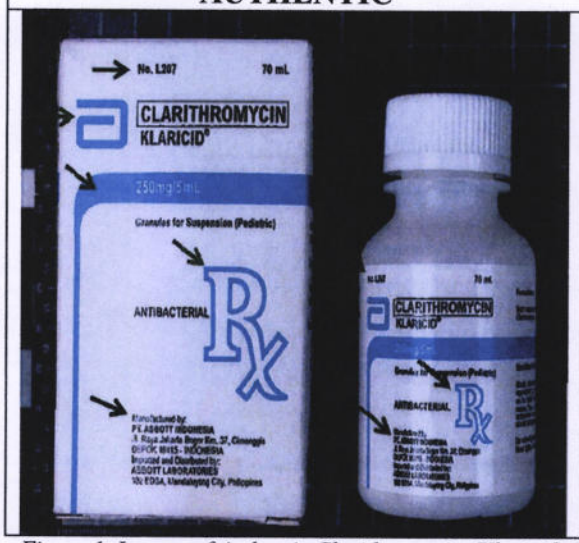
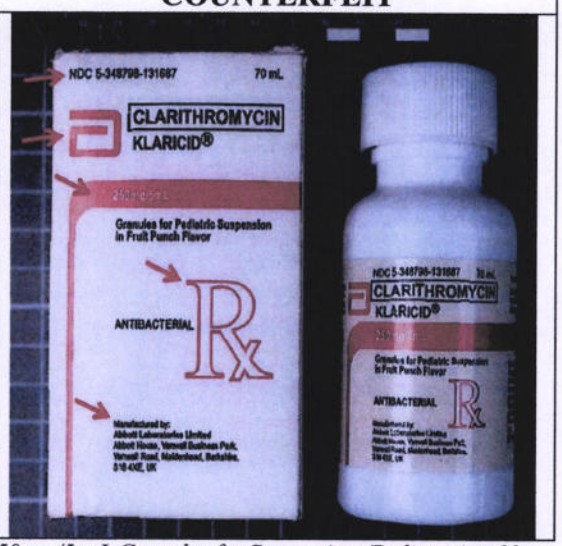
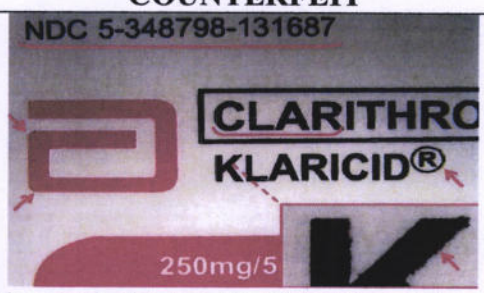
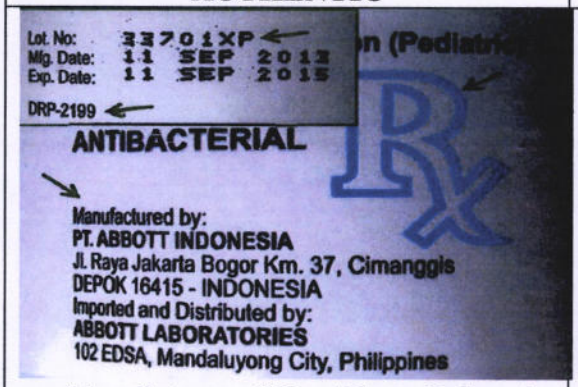
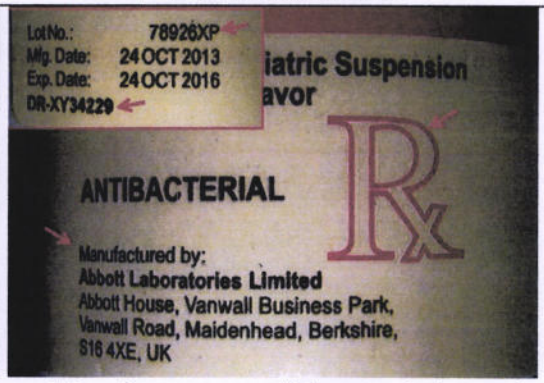
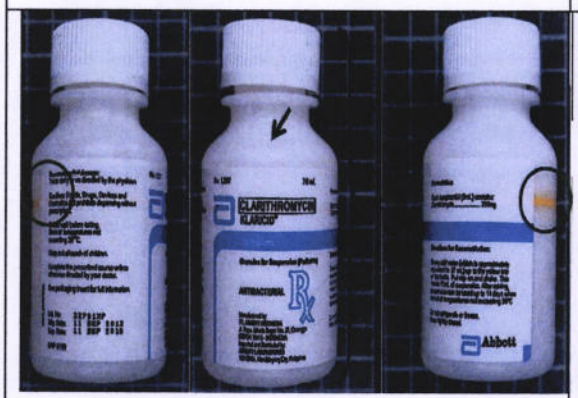
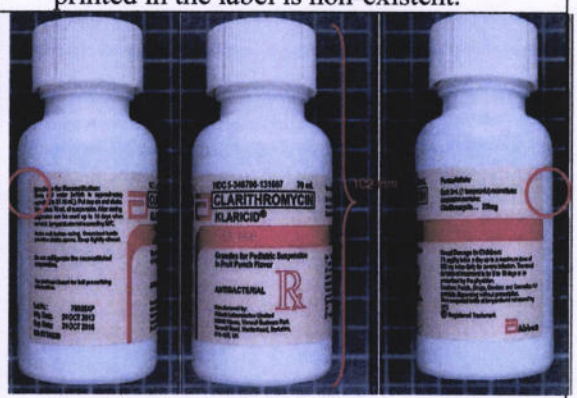
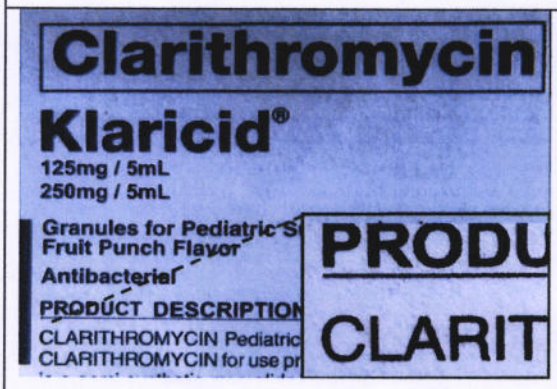
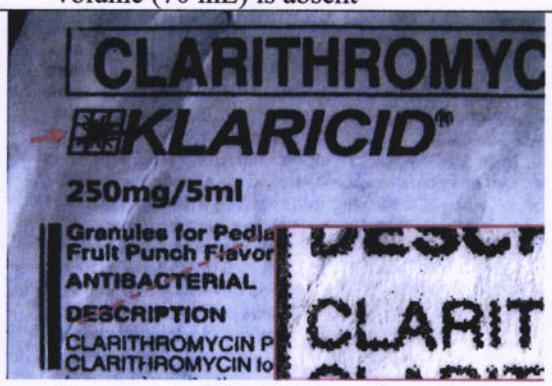
AUTHENTIC	COUNTERFEIT
	

Figure 1. Images of Authentic Clarithromycin (Klaricid) 250 mg/5 mL Granules for Suspension (Pediatric) in blue label design and Counterfeit Clarithromycin (Klaricid) 250 mg/5 mL Granules for Pediatric Suspension in Fruit Punch Flavor in magenta label design

The Food and Drug Administration and the Marketing Authorization Holder of the registered product, Abbott Laboratories, have confirmed that the product is counterfeit. The following are the differences of the authentic registered product with the counterfeit product:

AUTHENTIC	COUNTERFEIT
	
	The text in the label is printed in a different font style and the printing quality is poor

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

AUTHENTIC	COUNTERFEIT
	
• Manufacturer: PT. Abbott Indonesia- Indonesia • Importer and Distributor: Abbott Laboratories- Philippines • FDA Registration Number: DRP-2199	• Manufacturer: Abbott Laboratories Limited- UK • No importer and distributor licensed by FDA Philippines • Lot details (Lot No. and Exp. Date) are invalid • The registration number (DR-XY34229) printed in the label is non-existent.
	 • Text in the label is different and *Caution* statement is not printed • Yellow ribbon to indicate the correct volume (70 mL) is absent
	 • Paper material of the package insert is different • Quality of printing is poor

Moreover, laboratory analysis of the counterfeit product revealed that it does not contain the active ingredient Clarithromycin.

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned counterfeit drug product. This poses potential danger or injury to the consuming public.

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Officers of the Field Regulatory Operations Office (FROO) are hereby ordered to seize the aforementioned unregistered drug product found in the market.

Likewise, all local government units and law enforcement agencies are requested to ensure that this product is not sold or offered for sale in their localities or area of jurisdiction.

All drug establishments and outlets are hereby warned that importation, distribution, or sale of any counterfeit product are subject to sanctions and penalties stipulated in Republic Act No. 8203, otherwise known as "Special Law on Counterfeit Drugs".

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration and testing are measures that the government undertakes to ensure the quality, safety and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please email us at info@fda.gov.ph. To report sale or distribution of counterfeit or unregistered health products, kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN:20151013092526

[1] Pursuant to DPO 2015-1845