Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY

No. 2019-151

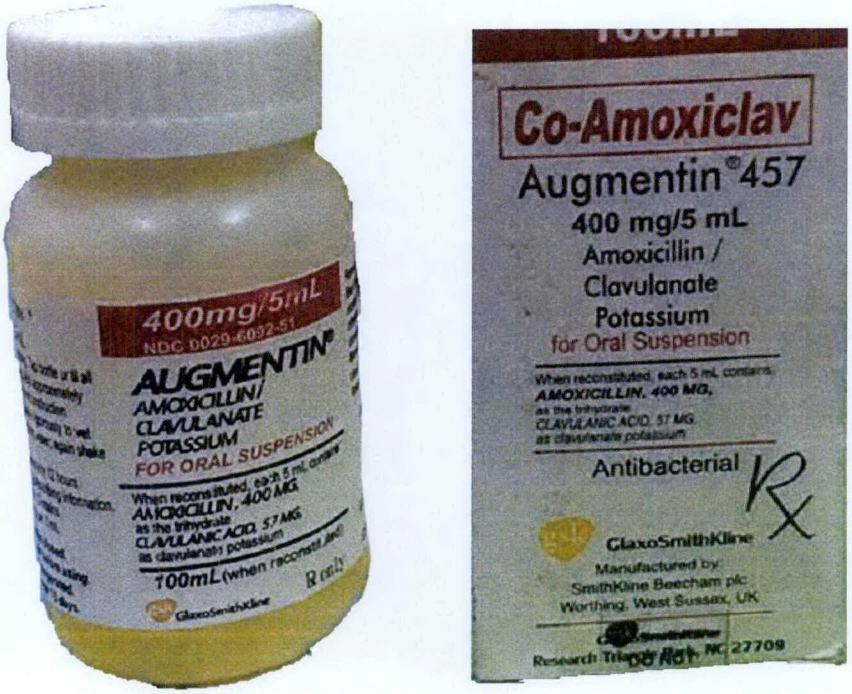
30 MAY 2019

TO: **ALL HEALTHCARE PROFESSIONALS, LOCAL HEALTH CENTERS, HEALTH INSTITUTIONS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Version of Drug Product Co-Amoxiclav (Augmentin) Powder for Oral Suspension.**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit version of drug product Co-Amoxiclav (Augmentin) Powder for Oral Suspension.

Counterfeit product



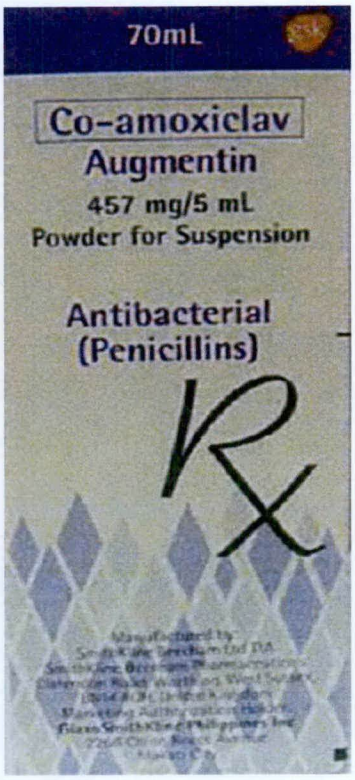
Claimed to be
"Manufactured by: **SmithKline Beecham Pharmaceuticals Worthing, West Sussex, UK"**

Figure 1. Verified counterfeit product Co-Amoxiclav (Augmentin 457) 400 mg/5 mL for Oral

The FDA, together with the Marketing Authorization Holder (MAH), GlaxoSmithKline (GSK) Philippines, Inc., have verified that the above mentioned product in Figure 1 is counterfeit.

The Batch No. 217883A having the expiry date Dec. 2020 was not imported by GSK.

Authentic product



Manufactured by: **SmithKline Beecham Pharmaceuticals**
Clarendon Road, Worthing, West Sussex, BN14 8QH, United Kingdom
Marketing Authorization Holder: **GlaxoSmithKline Philippines Inc.**
2266 Chino Roces Avenue, Makati City

Figure 2. Authentic product Co-Amoxiclav (Augmentin) 457 mg/5 mL Powder for Suspension

	Authentic	**Counterfeit**
Brand name:	AUGMENTIN	AUGMENTIN 457
Container:	Colorless Glass bottle	Plastic bottle
Dosage strength & dosage form reflected on label:	457mg/mL Powder for Suspension	400mg/5mL for Oral Suspension
Pack sizes:	35mL and 70mL	100mL
Logo:	New GSK Logo	Old GSK logo

All healthcare professionals, local health centers, health institutions and the general public are hereby warned of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers, distributors and retailers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing this verified counterfeit drug product with the foregoing features. The importation, selling or offering for sale, brokering, donating or possession without proof of legitimate purchase of such is in direct violation of Republic Act No. 9711, or the Food and Drug Administration Act of 2009, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs, therefore a penalty shall be imposed.

The Bureau of Customs is urged to restrain the importation or entry of this counterfeit product.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is not sold, made available or used in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered or counterfeit health products, kindly e-mail us via **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research at telephone number **(02)809-5596**. 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.

Dissemination of the information to all concerned is requested

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

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