Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 APR 2021

FDA ADVISORY
No. 20210834

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Counterfeit "Augmentin™ Amoxicillin + Clavulanate Potassium 457mg/5ml 70ml syrup in powder form"**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit Augmentin™ Amoxicillin + Clavulanate Potassium 457mg/5ml 70ml syrup in powder form:

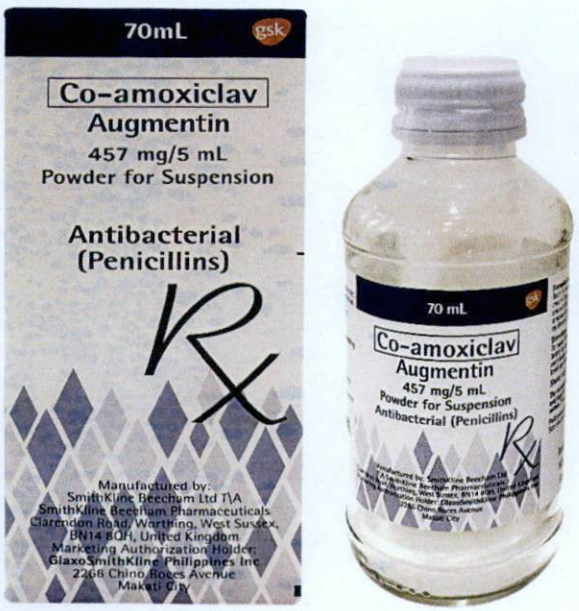
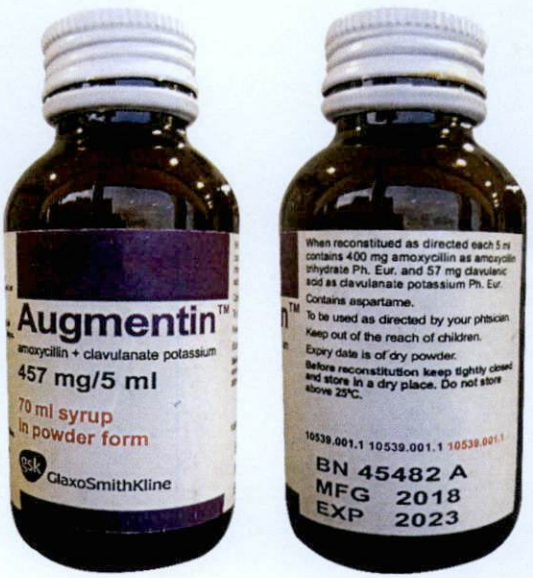
Authentic	Counterfeit
	

Figure 1. Comparison between the Authentic and Verified Counterfeit Augmentin™ Amoxicillin + Clavulanate Potassium 457mg/5ml 70ml syrup in powder form (Batch no. 45482 A)

Civic Drive, Filinvest Corporate 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

The FDA together with the Marketing Authorization Holder (MAH), GlaxoSmithKline Philippines Inc., have verified that the above-mentioned sample drug product is counterfeit. The comparison of the collected counterfeit drug product and the distinguishing feature of the authentic are as follows:

Authentic	Counterfeit
1. Manufacturing Site Reflected on Label: SmithKline Beecham Ltd T\A SmithKline Beecham Pharmaceuticals Clarendon Road, Worthing, West Sussex, BN14, 8QH, United Kingdom 2. Pack size and dosage form: 457 mg/5 mL 70mL Powder for Suspension 3. Compliant to generic labelling requirements 4. Primary container: Clear colorless glass bottle with measuring cup 5. Printed with correct and updated GSK logo	1. Manufacturing Site Reflected on Label: Smithline Beecham plc* Worthing, UK 2. Pack size and dosage form: 457 mg/5 mL 70mL syrup in powder form 3. Not compliant to generic labelling requirements 4. Primary container: Amber glass bottle 5. Printed with old GSK logo

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers 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 of this drug product with the abovementioned features of a counterfeit drug product. The importation, selling or offering for sale 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. Anyone found selling the said counterfeit drug product will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is not sold or made available 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 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) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20210419132030