Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

19 MAY 2022

FDA ADVISORY
No. 2022-1081

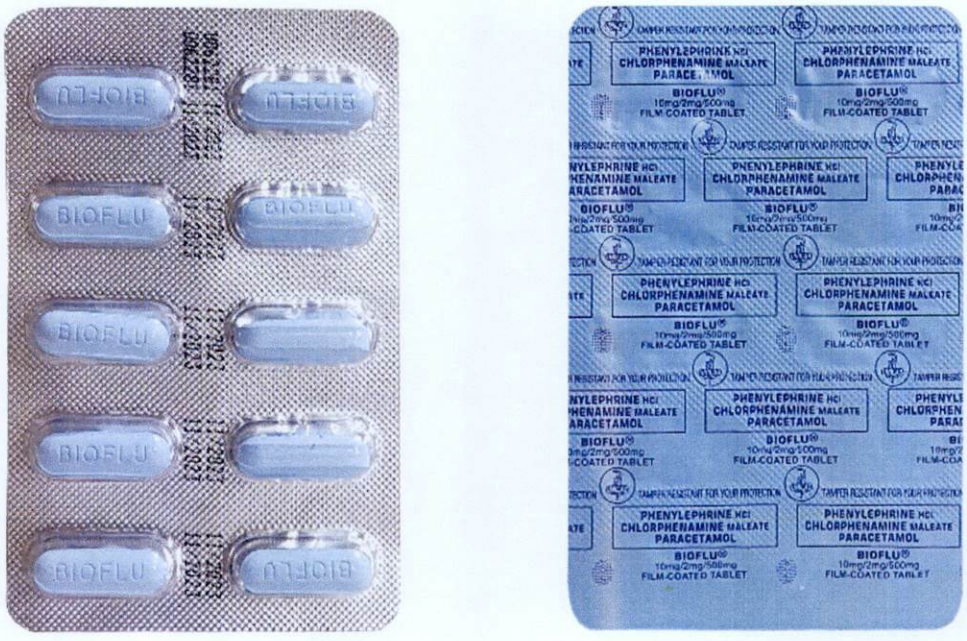
TO : **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT : **Public Health Warning Against the Purchase and Use of the following Verified Counterfeit Drug Products:**

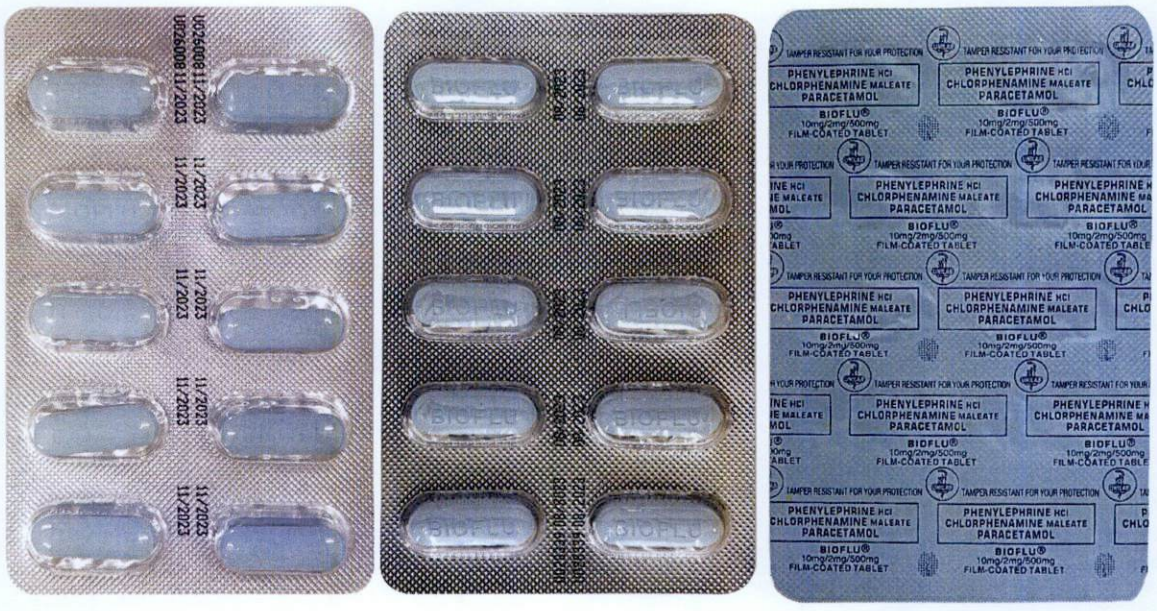
1. **Phenylephrine Hydrochloride + Chlorphenamine Maleate + Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet**
2. **Loperamide (Diatabs®) 2 mg Capsule**
3. **Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule**
4. **Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran®Forte) 15 mg / 25 mg / 325 mg Capsule 100's**
5. **Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen®Forte) 25 mg / 2 mg / 500 mg Tablet 100's**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of the following products:

AUTHENTIC



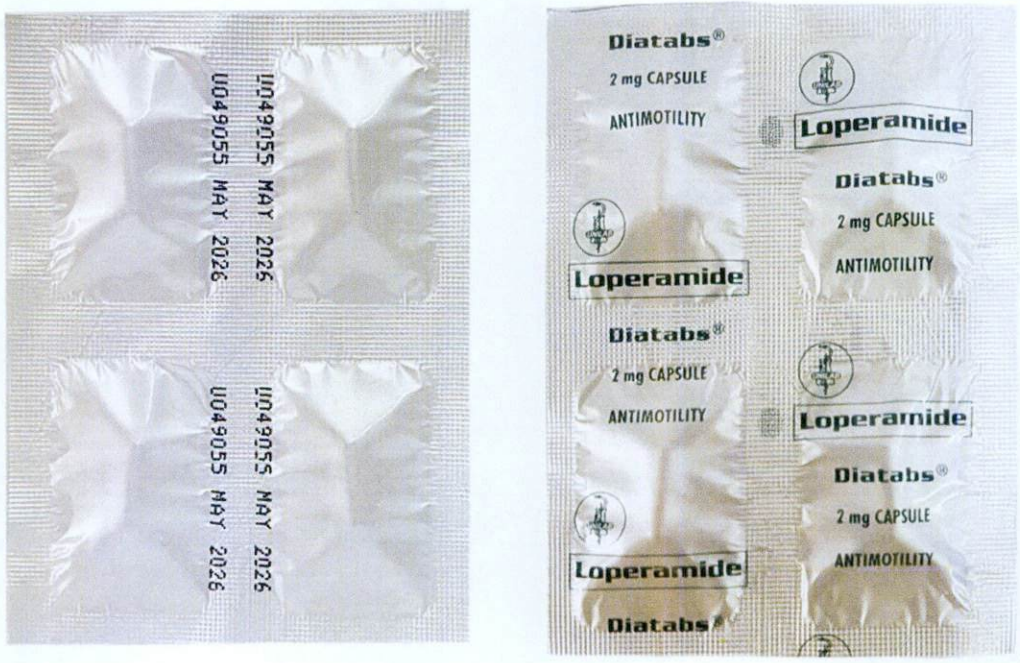
COUNTERFEIT



Counterfeit – The tablet, security mark and print appearance are not comparable with the standard features of the registered product.

Figure 1. Comparison between the Authentic and Verified Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet (Lot No. U028339, U026008)

AUTHENTIC



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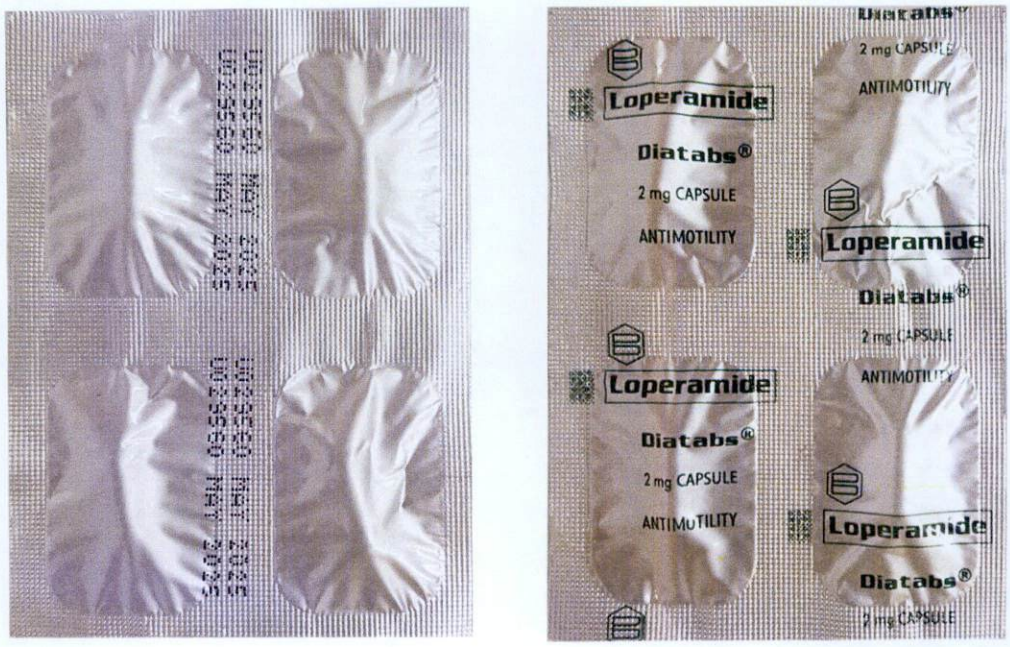
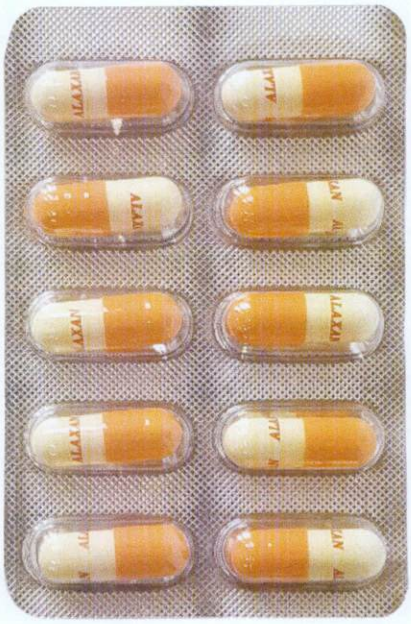


Counterfeit – The knurling, security mark and print appearance are not comparable with the standard features of the registered product.

Figure 2. Comparison between the Authentic and Verified Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot No. U029560)

AUTHENTIC



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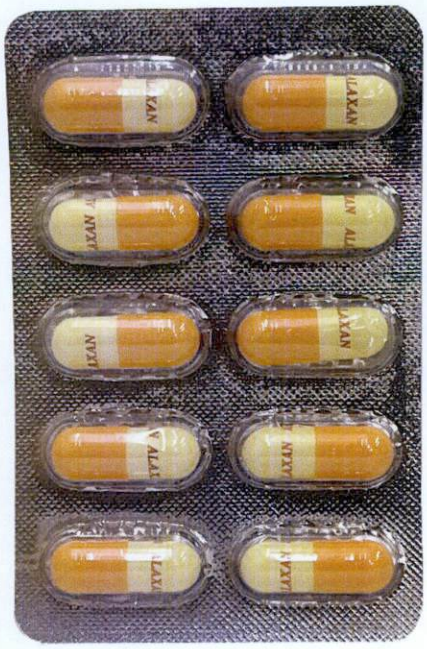
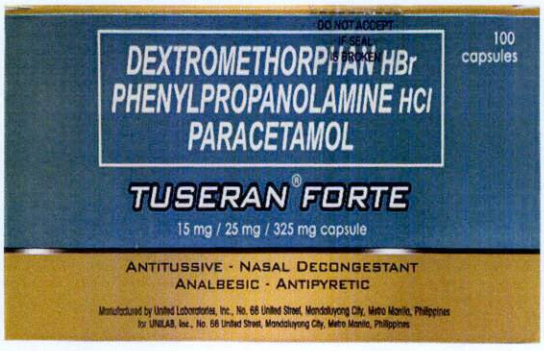


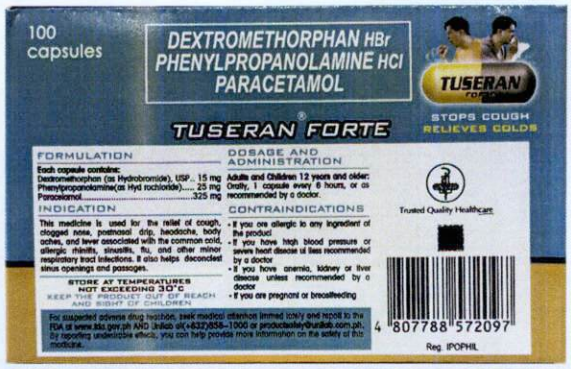
Counterfeit – The capsule, knurling, security mark and print appearance are not comparable with the standard features of the registered product.

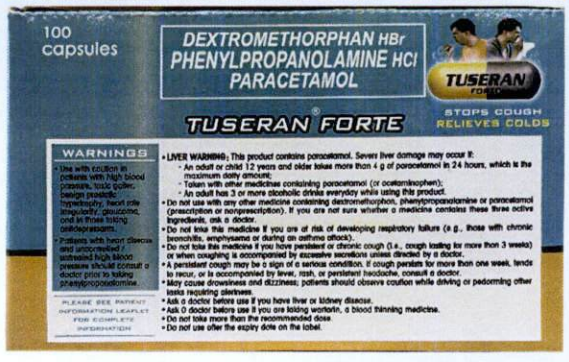
Figure 3. Comparison between the Authentic and Verified Counterfeit Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule (Lot No. 40379275)

AUTHENTIC

COUNTERFEIT



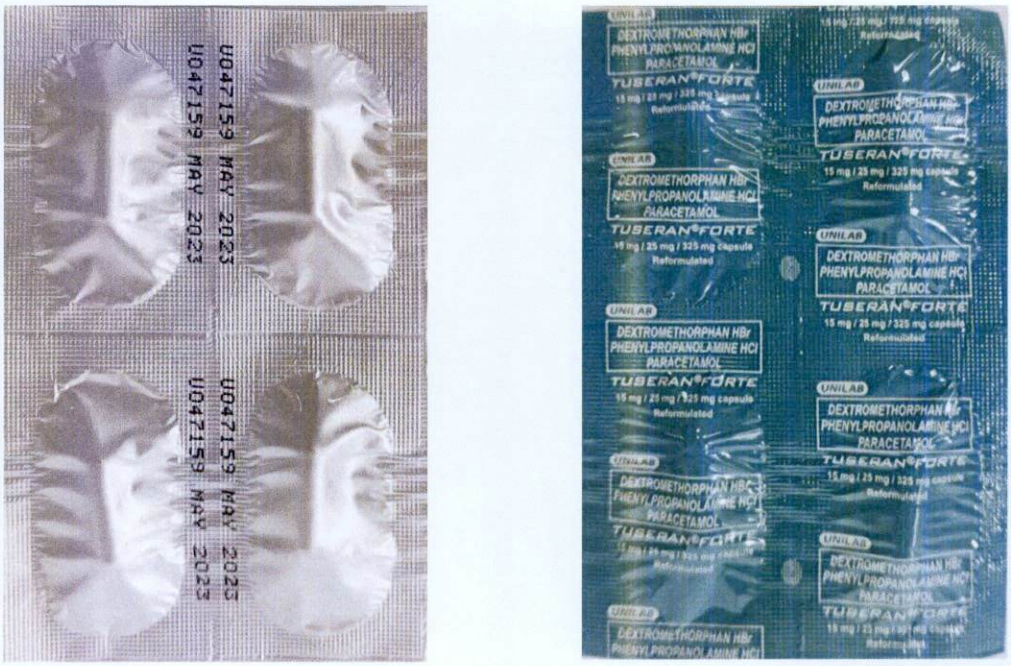




Counterfeit – The box is comparable with the standard features of the registered product.

Figure 4. Comparison between the Authentic and Verified Counterfeit Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran®Forte) 15 mg / 25 mg / 325 mg Capsule 100's (Lot No.U034501)

AUTHENTIC



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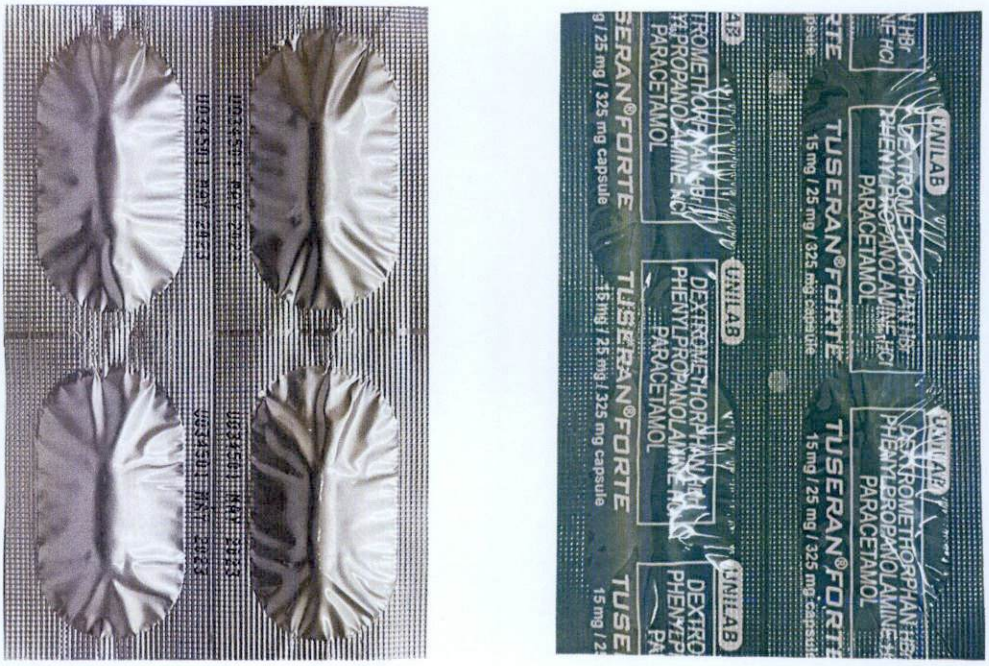
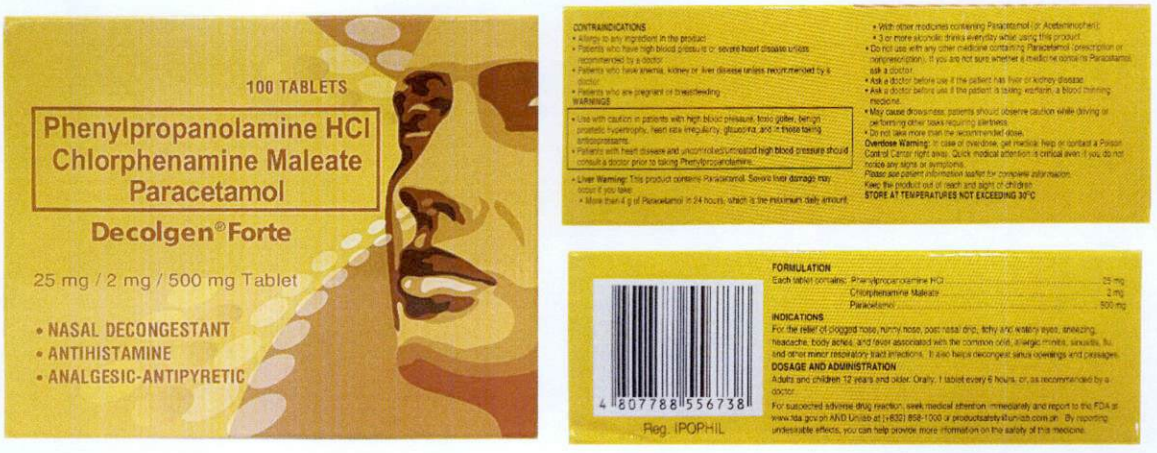


Counterfeit – The knurling, security mark and print appearance are not comparable with the standard features of the registered product.

Figure 5. Comparison between the Authentic and Verified Counterfeit Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran®Forte) 15 mg / 25 mg / 325 mg Capsule 100's (Lot No.U034501)

AUTHENTIC

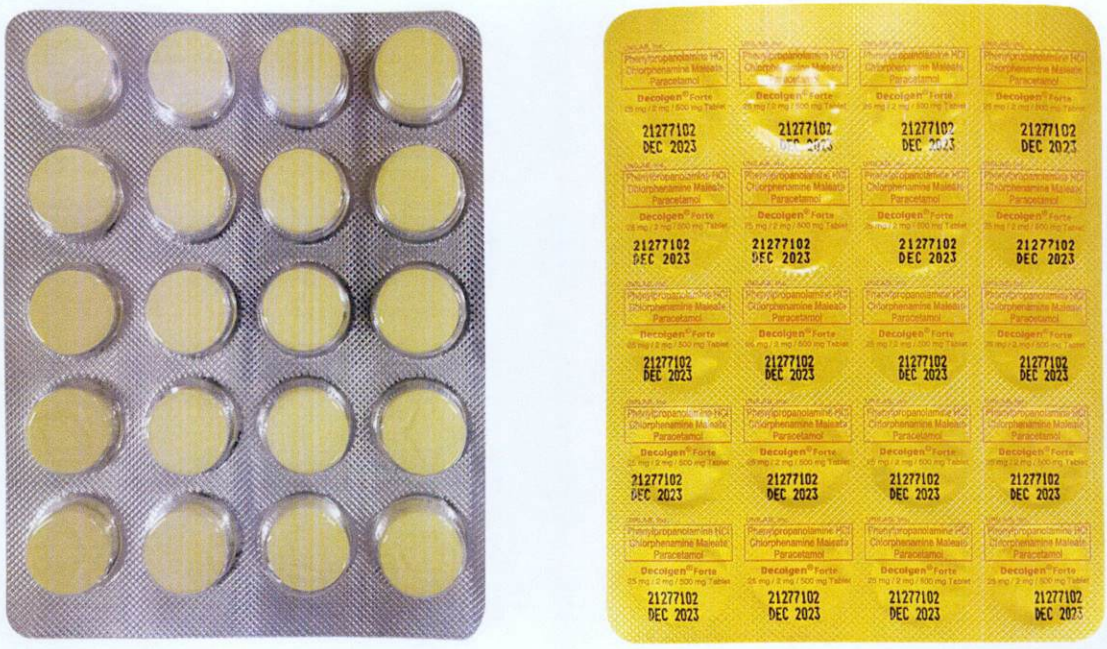
COUNTERFEIT



Counterfeit – The box is comparable with the standard features of the registered product.

Figure 6. Comparison between the Authentic and Verified Counterfeit Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen®Forte) 25 mg / 2 mg / 500 mg Tablet (Lot No. 21507865)

AUTHENTIC



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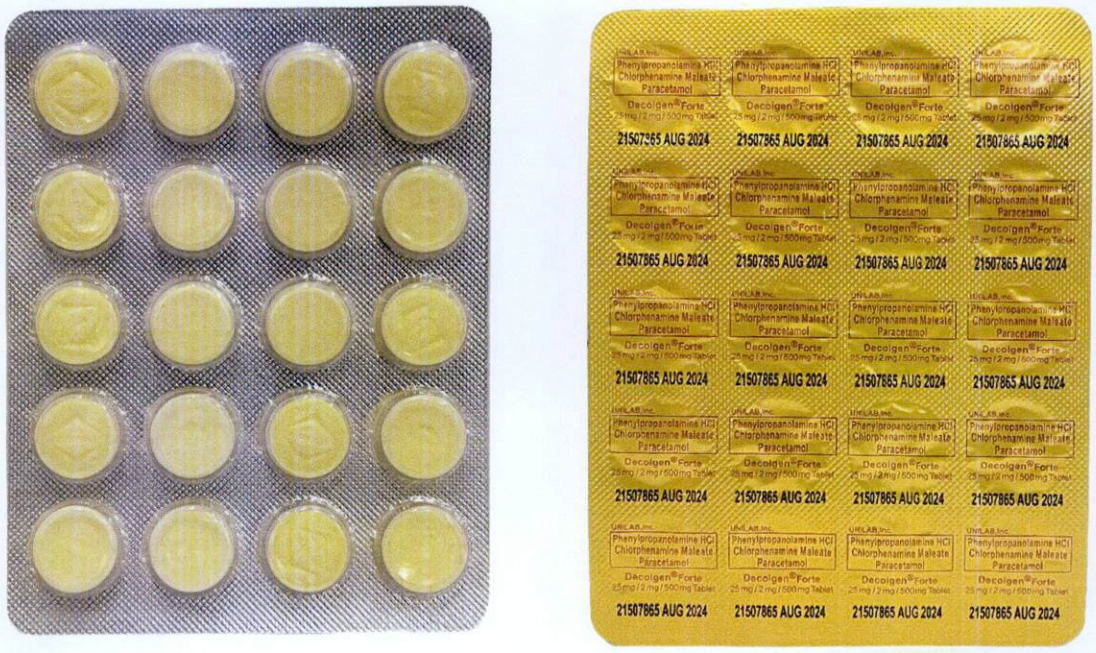

Counterfeit – The tablet, knurling, security mark and print appearance are not comparable with the standard features of the registered product.

Figure 7. Comparison between the Authentic and Verified Counterfeit Phenylpropanolamine HCl/ Chlorphenamine Maleate/ Paracetamol (Decolgen®Forte) 25 mg / 2 mg / 500 mg Tablet (Lot No. 21507865)

All healthcare professionals and the general public are hereby warned as to the availability of these counterfeit drug products in the market which pose 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 the said counterfeit products with the abovementioned features. 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 products will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are 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 unregistered health products, kindly e-mail us via **ereport@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.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN: 20220516152217