Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

19 APR 2022

FDA ADVISORY
No. 20220906

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Counterfeit Human Tetanus Immunoglobulin Tetagam® P 1 ml (250 IU) Solution for Injection

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The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit Human Tetanus Immunoglobulin Tetagam® P 1 ml (250 IU) Solution for Injection:

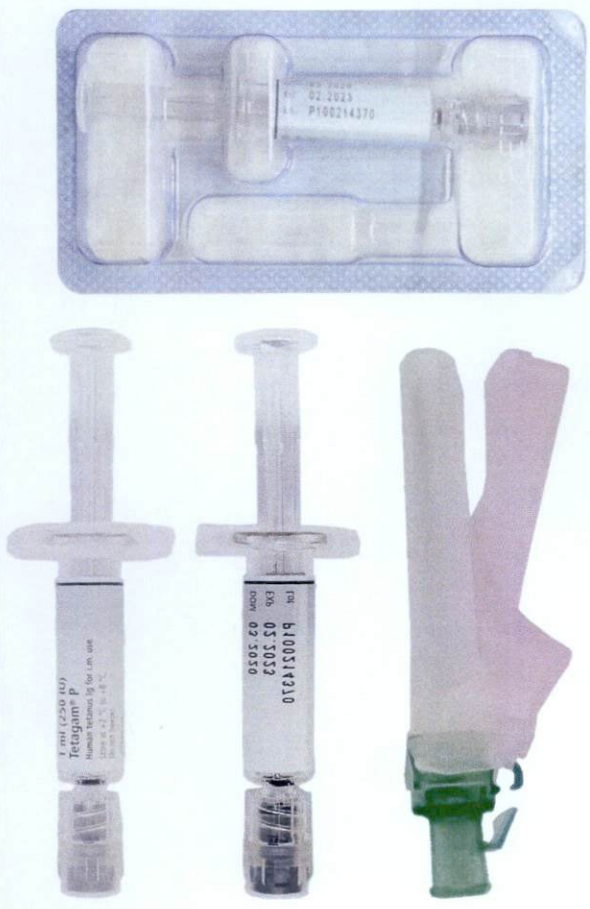
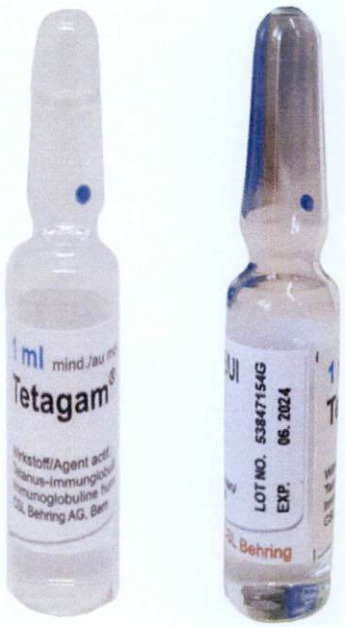
Authentic	Counterfeit
	

Figure 1. Comparison between the Authentic and Verified Counterfeit Human Tetanus Immunoglobulin Tetagam® P 1 ml (250 IU) Solution for Injection (Lot No. 53847154G)

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

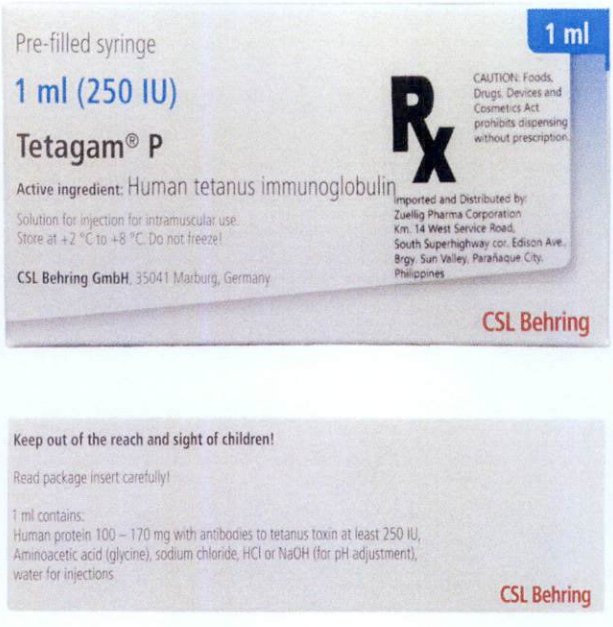
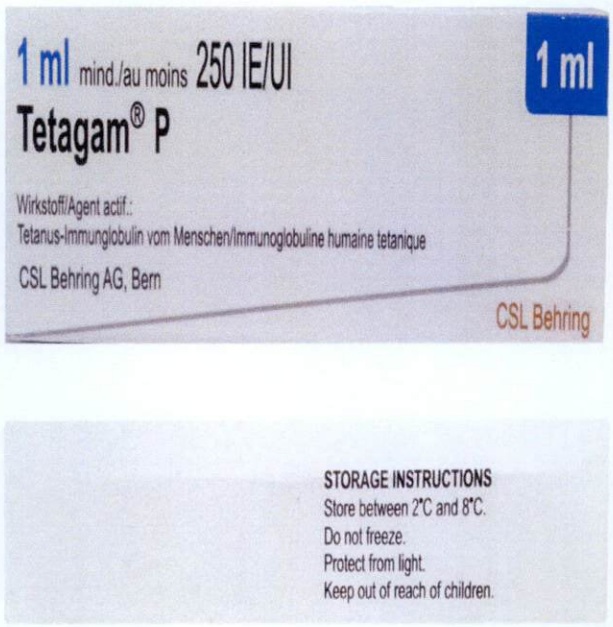
Authentic	Counterfeit
	

Figure 2. Comparison between the Authentic and Verified Counterfeit Human Tetanus Immunoglobulin Tetagam® P 1 ml (250 IU) Solution for Injection (Lot No. 53847154G)

The FDA together with the Marketing Authorization Holder (MAH), Zuellig Pharma Corporation, 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. The registered Tetagam P in the Philippines is packed in pre-filled syringe (PFS).	1. Product presentation is ampoule with blue scored point
2. Content of the front panel of the box: Pre-filled syringe; 1 ml (250 IU); Tetagam® P; Active ingredient: Human tetanus immunoglobulin; Solution for injection for intramuscular use.; Store at +2 °C to +8 °C. Do not freeze!; CSL Behring GmbH, 35041 Marburg, Germany; CSL Behring	2. Content of the front panel of the box: 1ml mind./au moins 250 IE/UI; Tetagam® P; Wirkstoff/Agent actif.: Tetanus-Immunglobulin vom Menschen/Immunglobuline humaine tetanique; CSL Behring AG, Bern; CSL Behring

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 counterfeit drug product aforementioned. 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.

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

DTN: 20220407163605