Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-067

05 MAR 2018

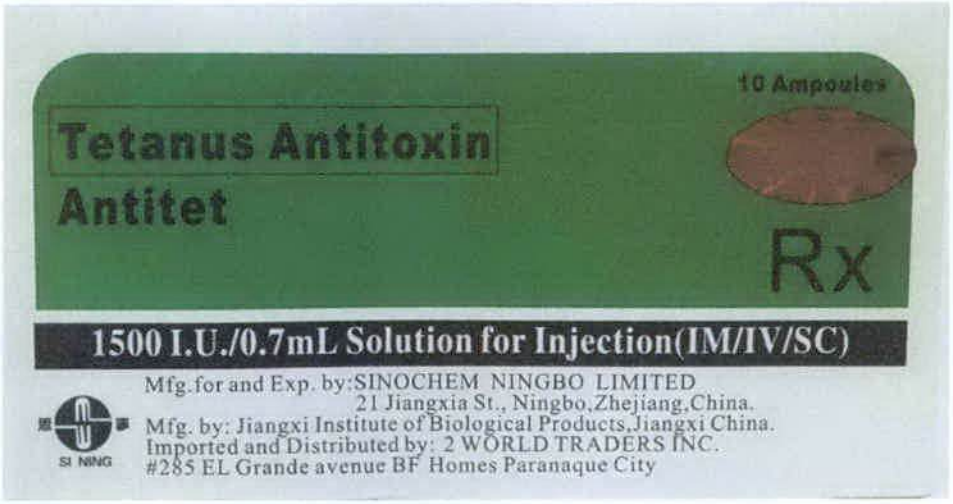
TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Drug Product Tetanus Antitoxin (Antitet) 1500 I.U./0.7 mL Solution for Injection (IM/IV/SC)**

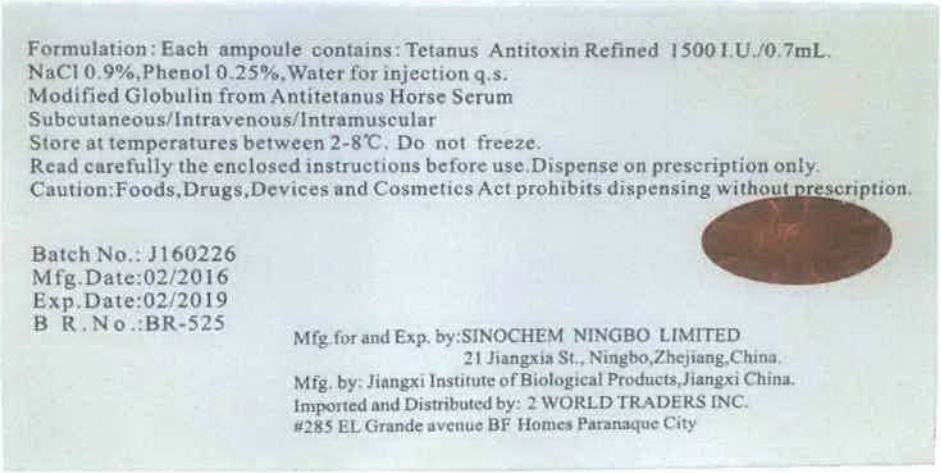
The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Tetanus Antitoxin (Antitet) 1500 I.U./0.7 mL Solution for Injection (IM/IV/SC):

Tetanus Antitoxin (Antitet) 1500 I.U.
Sinochem Ningbo Limited – 21 Jiangxia st., Ningbo, Zheijiang, China

Figure 1. Verified counterfeit/fake Tetanus Antitoxin (Antitet) 1500 I.U.



FRONT



BACK

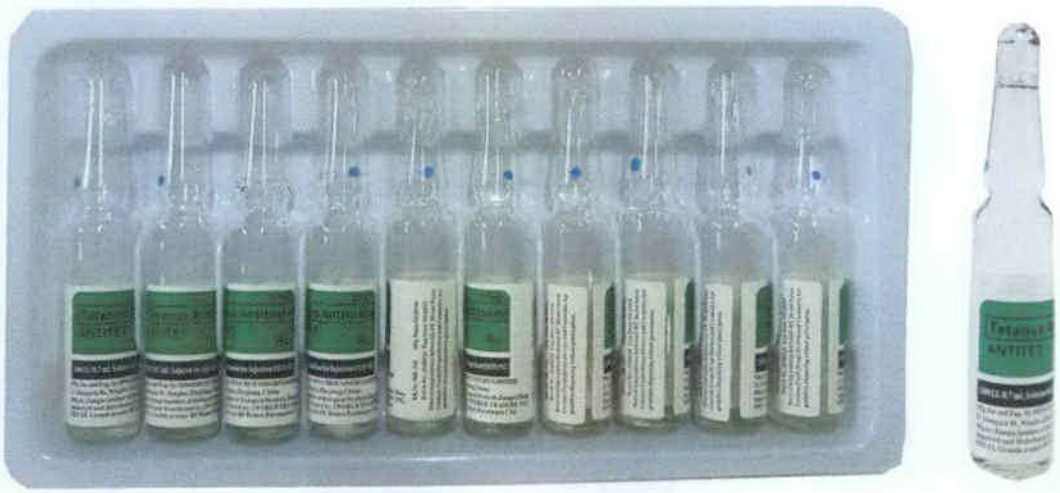


Figure 2. Authentic sample of Tetanus Antitoxin (Antitet) 1500 I.U./0.7 mL Solution for Injection (IM/IV/SC)

The FDA together with the Marketing Authorization Holder (MAH), 2 World Traders, Inc., have verified that the abovementioned sample drug product is counterfeit. The comparisons of the collected product and the registered and authentic one are as follows:

AUTHENTIC	COUNTERFEIT
• Product name is Tetanus Antitoxin (Antitet) 1500 I.U./0.7 mL Solution For Injection (IM/IV/SC)	• Product name is Tetanus Antitoxin (Antitet) 1500 I.U.
• Labeling design is **comparable** to retention sample	• Labeling design is **not comparable** to retention sample
• Generic name **enclosed** in an outline box 	• Generic name is **not enclosed** in an outline box 
• **Correct and complete** dosage strength is printed on the label 	• Dosage strength is **incomplete** 
• **Correct dosage form**, *Solution for Injection (IM/IV/SC)*, **is printed** on the label	• Dosage form is **not printed** on the label
• Registration No. BR-525 is printed on the label	• Registration No. BR-525 is **not printed** on the label

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 verified counterfeit drug product 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, therefore a penalty shall be imposed.

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 unregistered and/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.

NELA CHARADE G. PUNO, RPh
Director General

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