Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

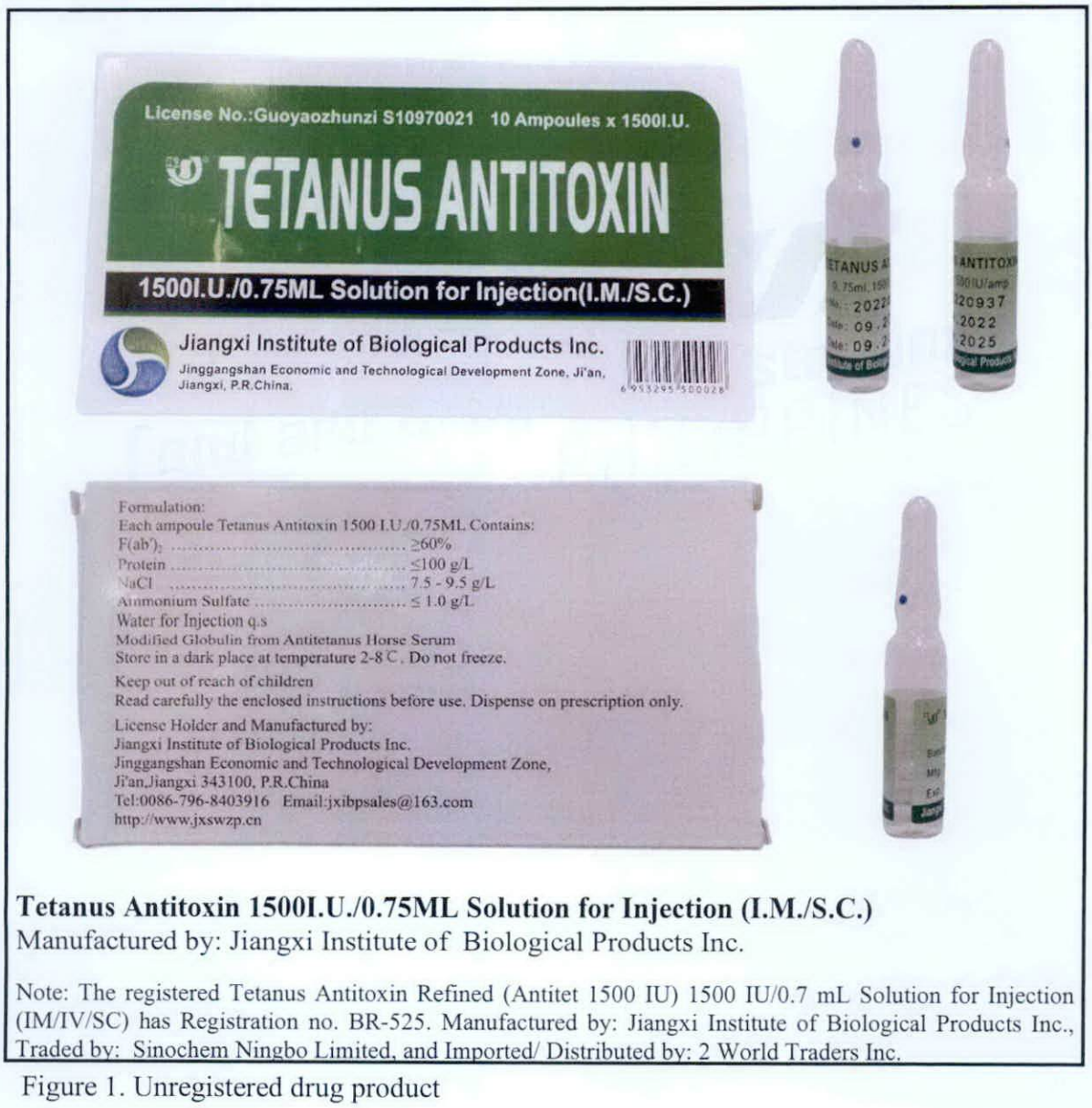
FDA ADVISORY
No. 2024075 4

0 8 MAY 2024

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

SUBJECT : **Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "Tetanus Antitoxin 1500I.U./0.75ML Solution for Injection (I.M./S.C.)"**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug product:



Tetanus Antitoxin 1500I.U./0.75ML Solution for Injection (I.M./S.C.)
Manufactured by: Jiangxi Institute of Biological Products Inc.

Note: The registered Tetanus Antitoxin Refined (Antitet 1500 IU) 1500 IU/0.7 mL Solution for Injection (IM/IV/SC) has Registration no. BR-525. Manufactured by: Jiangxi Institute of Biological Products Inc., Traded by: Sinochem Ningbo Limited, and Imported/ Distributed by: 2 World Traders Inc.

Figure 1. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug product has not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative product may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health product without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the product are registered with the FDA by using the **FDA Verification Portal feature** accessible at **https://verification.fda.gov.ph**.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this 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 health product, kindly e-mail us via **ereport@fda.gov.ph**. 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://bit.ly/FDAPHReportSideEffect** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

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