



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



25 JUL 2016

FDA ADVISORY  
No. **2016-081**

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

**SUBJECT: Public Health Warning Against the Use of the Counterfeit Tetanus Antitoxin (Antitet) 1500 IU/0.75 mL Solution for Injection (IM/IV/SC) and 3000 IU/0.95 mL Solution for Injection (IM/IV/SC)**

The Food and Drug Administration (FDA) warns the public against the use of the counterfeit Tetanus Antitoxin (Antitet), 1500 IU/0.75 mL Solution for Injection (IM/IV/SC) and Tetanus Antitoxin (Antitet), 3000 IU/0.95 mL Solution for Injection (IM/IV/SC).

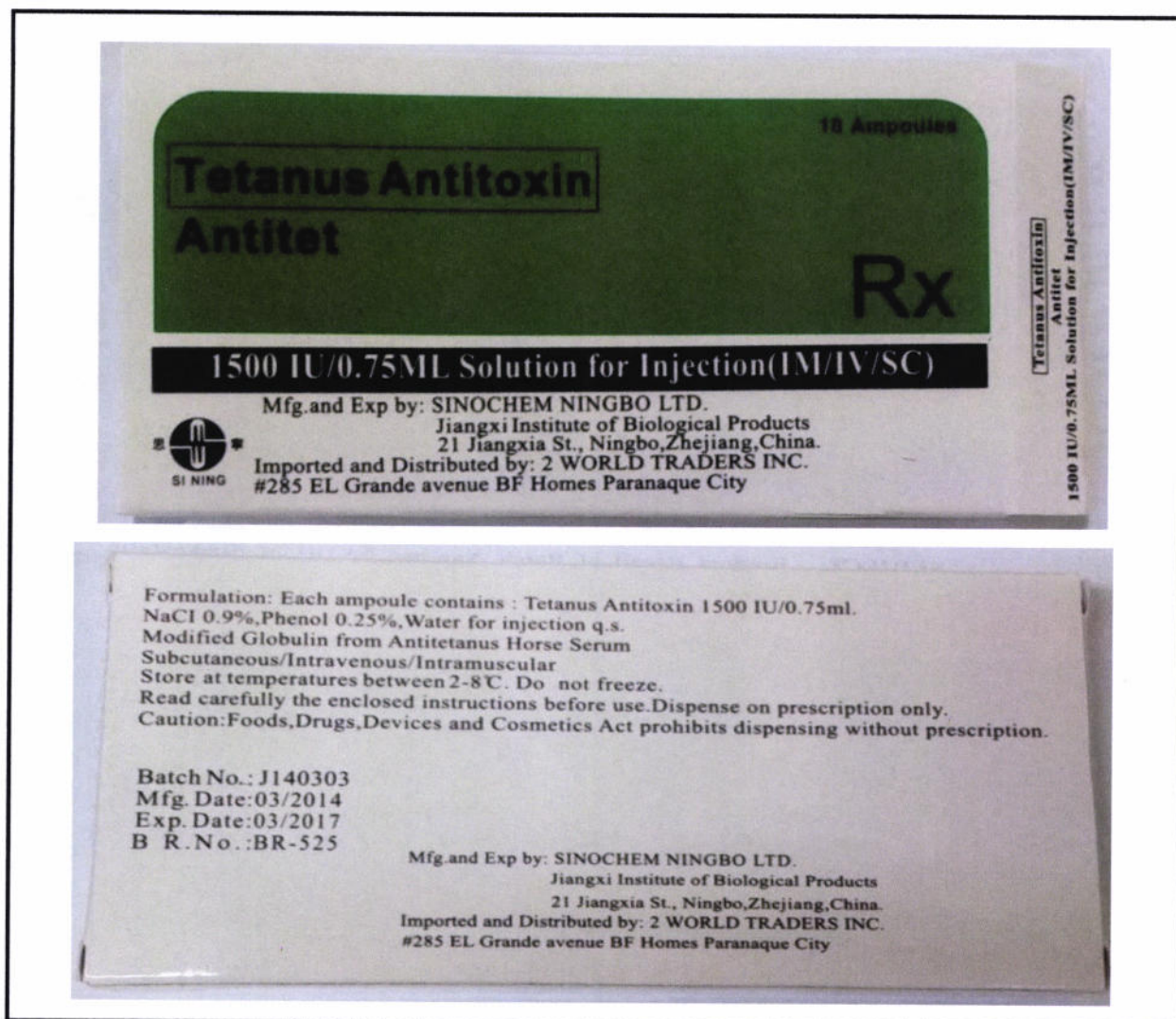


Figure 1. Secondary packaging of the counterfeit Tetanus Antitoxin (Antitet) 1500 IU/0.75 mL Solution for Injection (IM/IV/SC)





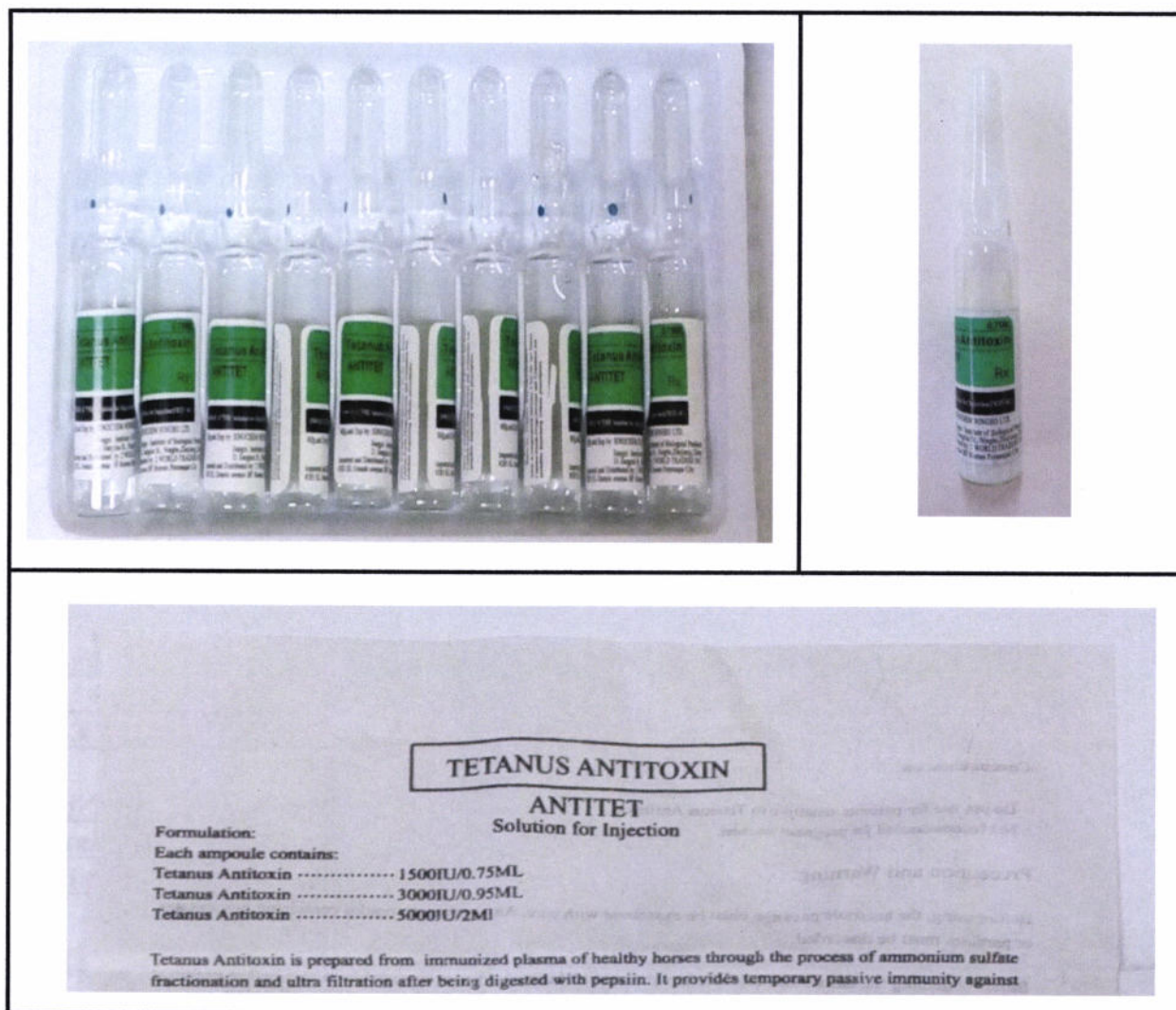


Figure 2. Ampoules and package insert of the counterfeit Tetanus Antitoxin (Antitet) 1500 IU/0.75 mL Solution for Injection (IM/IV/SC)

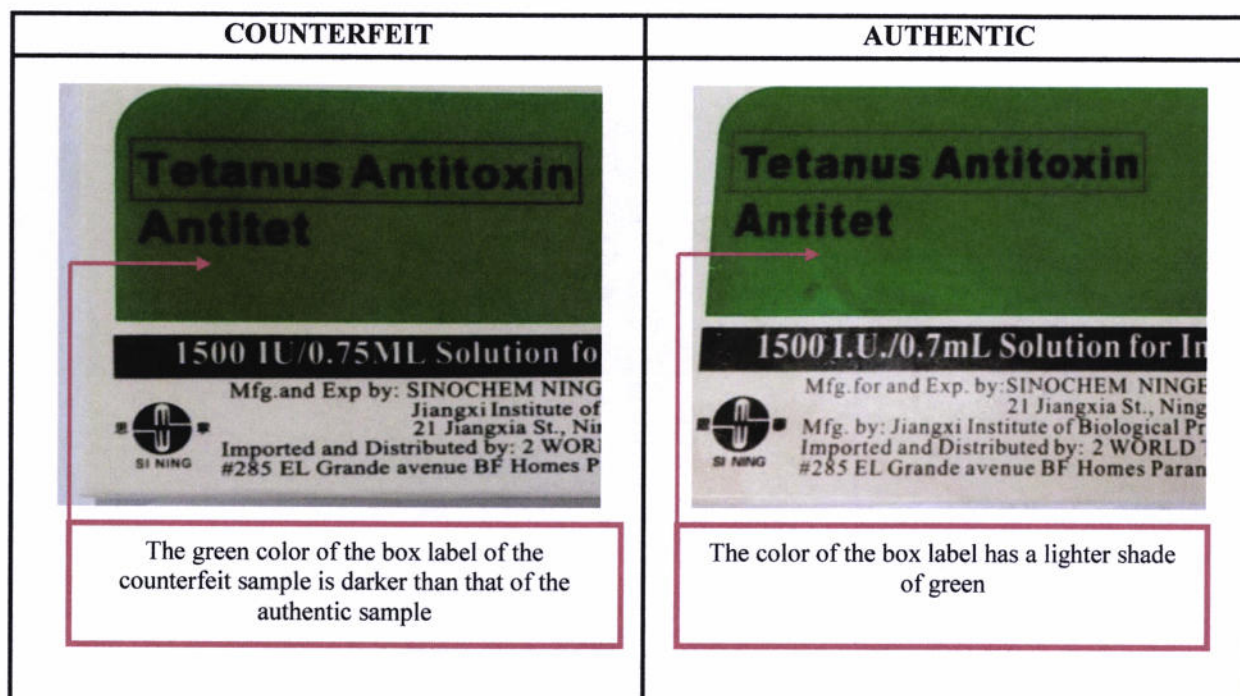


Figure 3. Comparison of the box color of the counterfeit against the authentic product Antitet 1500 IU/0.7 mL Solution for Injection (IM/IV/SC)



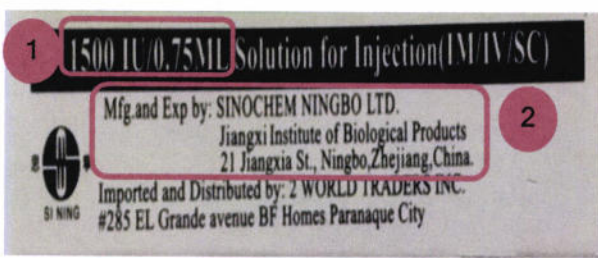
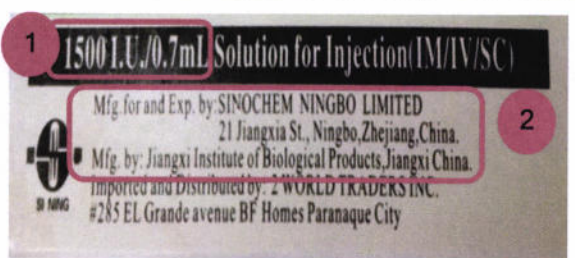
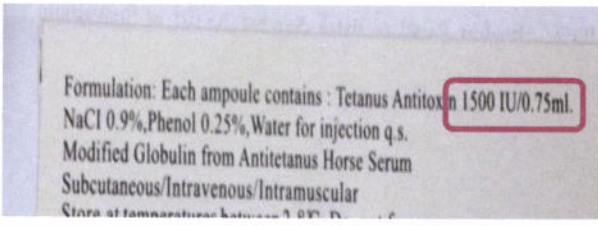
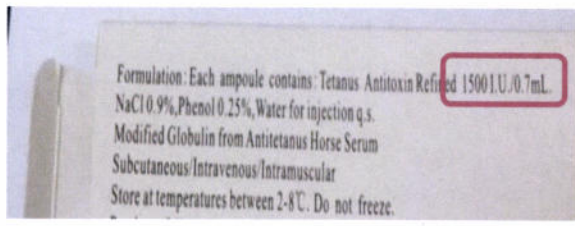
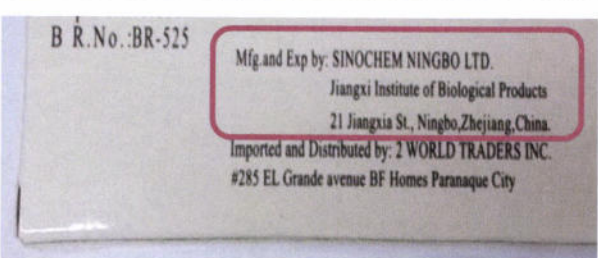
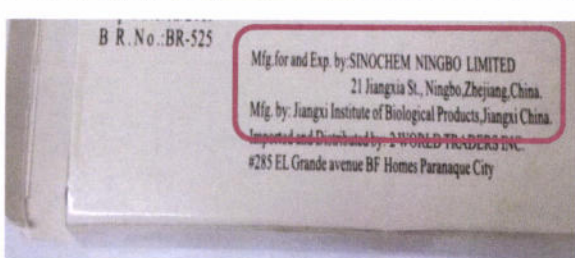

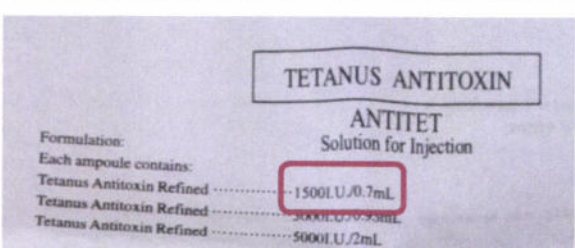
| COUNTERFEIT  | AUTHENTIC   |
|--|---|
|  <p>1 Dosage strength printed in the secondary packaging is <b>1500 IU/0.75ML</b></p> <p>2 Manufacturer printed in the Principal Display Panel is <b>Sinochem Ningbo Ltd.</b></p> <p><u>SECONDARY PACKAGING (FRONT)</u></p> |  <p>1 Dosage strength printed in the secondary packaging is <b>1500 IU/0.7mL</b></p> <p>2 Manufacturer of authentic Antitet is <b>Jiangxi Institute of Biological Products.</b> Trader is <b>Sinochem Ningbo Limited.</b></p> <p><u>SECONDARY PACKAGING (FRONT)</u></p> |
|  <p>Dosage strength printed is <b>1500 IU/0.75ml</b></p> <p><u>SECONDARY PACKAGING (BACK)</u></p>  |  <p>Dosage strength printed is <b>1500 IU/0.7 mL</b></p> <p><u>SECONDARY PACKAGING (BACK)</u></p>  |
|  <p>Reflected Manufacturer is <b>Sinochem Ningbo Ltd.</b></p> <p><u>SECONDARY PACKAGING (BACK)</u></p>  |  <p>Manufacturer of authentic Antitet is <b>Jiangxi Institute of Biological Products.</b> Trader is <b>Sinochem Ningbo Limited.</b></p> <p><u>SECONDARY PACKAGING (BACK)</u></p>  |
|  <p>Dosage strength reflected is <b>1500 IU/0.75ML</b></p> <p><u>PACKAGE INSERT</u></p>   |  <p>Dosage strength reflected is <b>1500 IU/0.7 mL</b></p> <p><u>PACKAGE INSERT</u></p>   |

Figure 4. Comparison between the secondary packaging and package insert of the counterfeit product against the authentic Tetanus Antitoxin (Antitet) 1500 IU/0.7 mL Solution for Injection (IM/IV/SC)



| COUNTERFEIT  | AUTHENTIC   |
|--|---|
|  <p>Labels are misaligned; Gap between the label is inconsistent</p>  |  <p>Label placement is accurate</p>                             |
|  <p>Counterfeit samples contain clear colorless solution but an ampoule with milky white liquid was found in a box of 10's</p> |  <p>Authentic sample contains a clear, colorless solution</p> |

Figure 5. Comparison between the ampoules of the counterfeit and authentic Tetanus Antitoxin (Antitet) 1500 IU/0.7 mL Solution for Injection (IM/IV/SC)

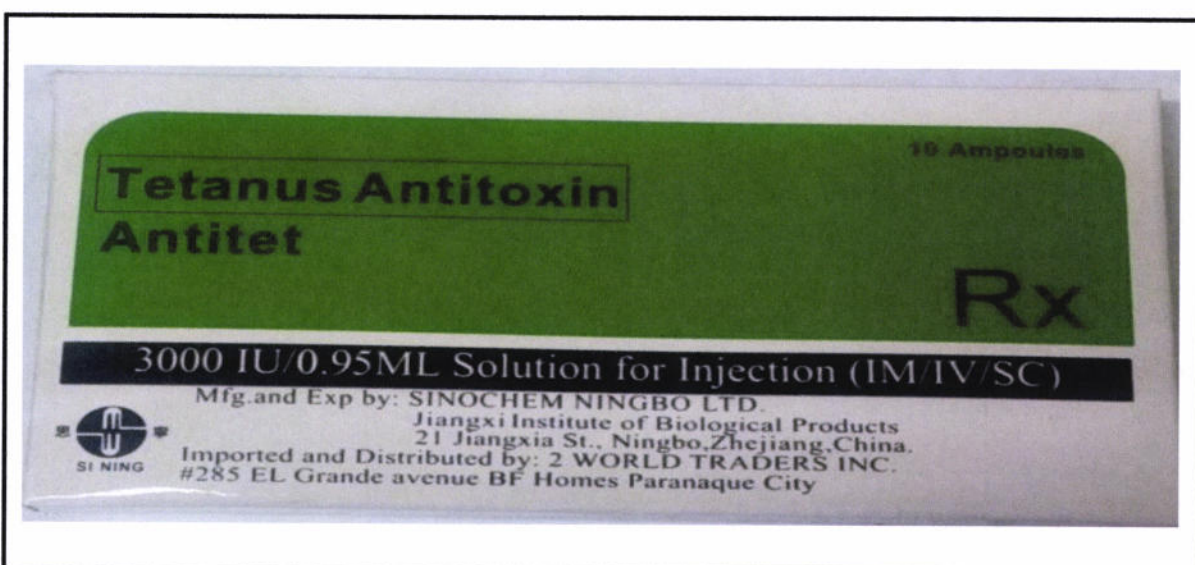


Figure 6. Secondary packaging of the counterfeit Tetanus Antitoxin (Antitet) 3000 IU/0.95 mL Solution for Injection (IM/IV/SC)

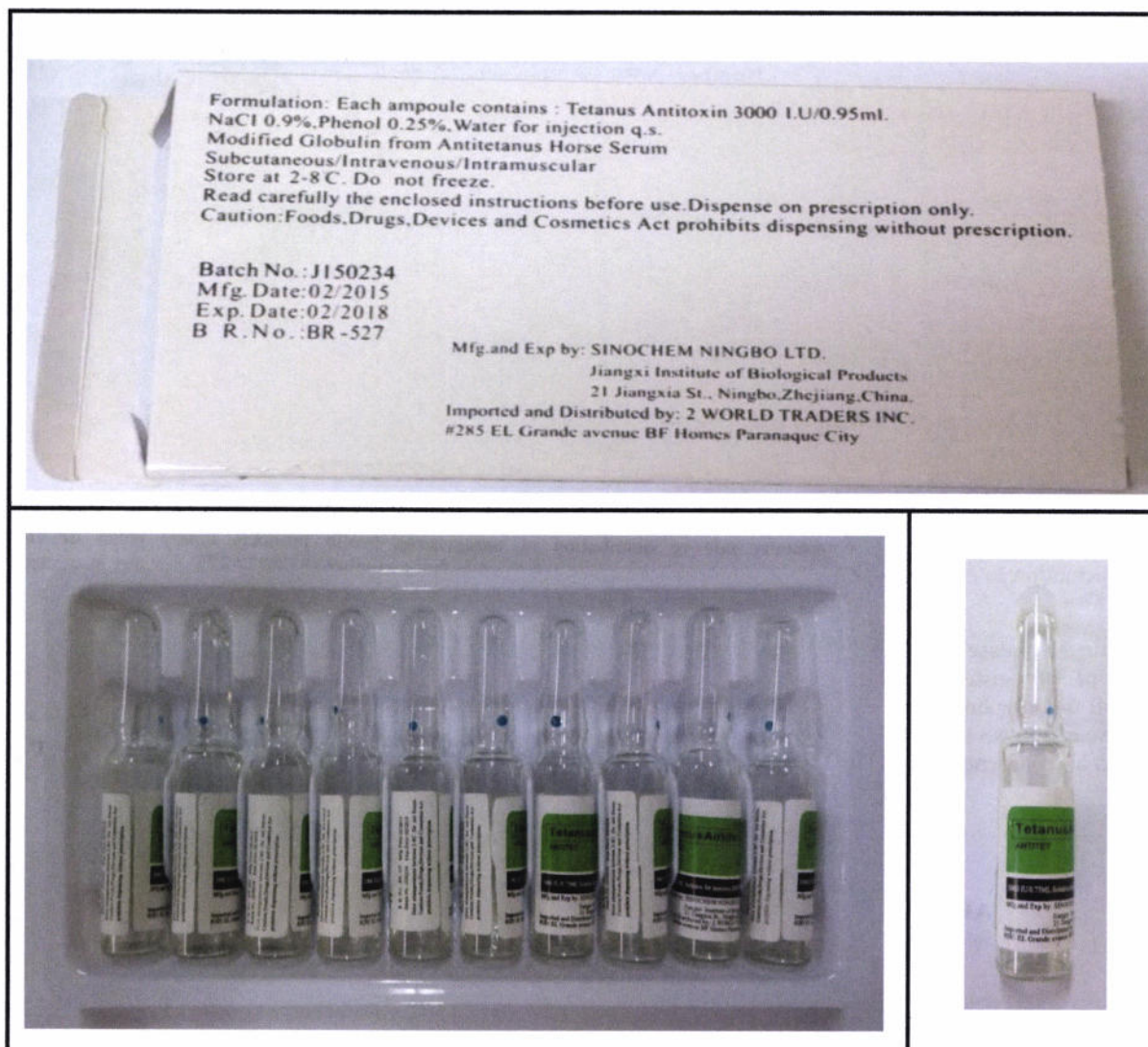


Figure 7. Secondary packaging and ampoules of the counterfeit Tetanus Antitoxin (Antitet) 3000 IU/0.95 mL Solution for Injection (IM/IV/SC)

| COUNTERFEIT  | AUTHENTIC   |
|--|---|
|  <p>Manufacturer printed is <b>Sinochem Ningbo Ltd.</b></p> |  <p>Manufacturer of authentic Antitet is <b>Jiangxi Institute of Biological Products</b>. Trader is <b>Sinochem Ningbo Limited</b>.</p> |

Figure 8. Comparison between the secondary packaging of the counterfeit product against the authentic Tetanus Antitoxin (Antitet) 3000 IU/0.95 mL Solution for Injection (IM/IV/SC)



| COUNTERFEIT   | AUTHENTIC  |
|---|--|
|  <p data-bbox="268 539 786 645">Manufacturer printed is <b>Sinochem Ningbo Ltd.</b></p>                |  <p data-bbox="874 539 1385 651">Manufacturer of authentic Antitet is <b>Jiangxi Institute of Biological Products</b>. Trader is <b>Sinochem Ningbo Limited</b>.</p> |
|  <p data-bbox="228 1160 812 1249">Labels are misaligned; Gap between labels is inconsistent</p>       |  <p data-bbox="890 1160 1401 1234">Label placement is accurate</p>  |
|  <p data-bbox="496 1491 783 1615">Dosage strength printed in the label is <b>3000 IU/0.75 ML</b></p> |  <p data-bbox="1094 1491 1382 1615">Dosage strength printed in the label is <b>3000 IU/0.95 mL</b></p>   |

Figure 9. Comparison between the secondary packaging and ampoules of the counterfeit product against the authentic Tetanus Antitoxin (Antitet) 3000 IU/0.95 mL Solution for Injection (IM/IV/SC)

The Food and Drug Administration together with the Marketing Authorization Holder, 2 World Traders Inc., and legitimate supplier, Sinochem Ningbo Limited, have confirmed that the aforementioned products are counterfeit.

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. 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.


All establishments and outlets are hereby warned against selling and/or dispensing the above identified drug products. Anyone found selling the said drug products will be penalized.

The officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act No. 9711. Likewise, all local government units and law enforcement agencies are requested to ensure that these drug products are not sold or offered for sale in their localities or areas of jurisdiction.

Consumers are advised to purchase drug products only from FDA-licensed establishments. Always look for the FDA Registration number on the product label. Be reminded that drug products registered with FDA Philippines bear in their labels information in both English and Filipino for all consumers to understand.

For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products kindly e-mail us via [report@fda.gov.ph](mailto:report@fda.gov.ph) or call telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: [www.fda.gov.ph/adr-report-new](http://www.fda.gov.ph/adr-report-new) and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
**MARIA LOURDES C. SANTIAGO, MSc, MM**  
OIC, Director General

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