Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY

No. 2019-153

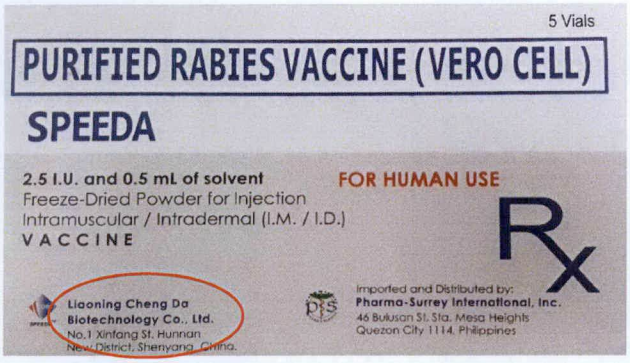
30 MAY 2019

TO: **ALL HEALTHCARE PROFESSIONALS, LOCAL HEALTH CENTERS, HEALTH INSTITUTIONS AND THE GENERAL PUBLIC**

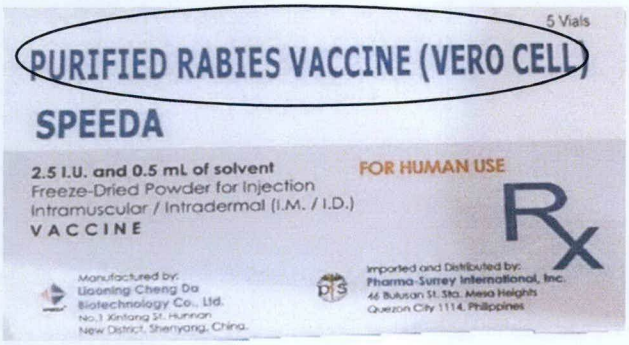
SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Versions of Drug Product Speeda Rabies Vaccine.**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit versions of drug product Speeda Rabies Vaccine.

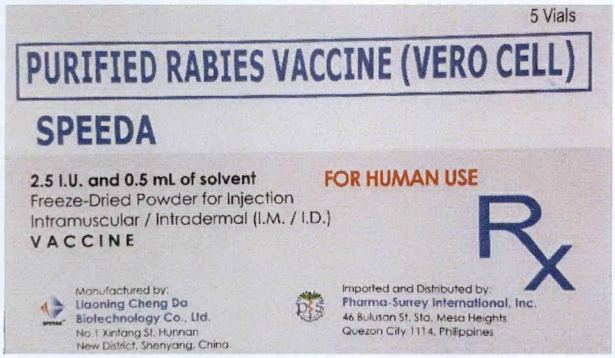
Counterfeit Version 1



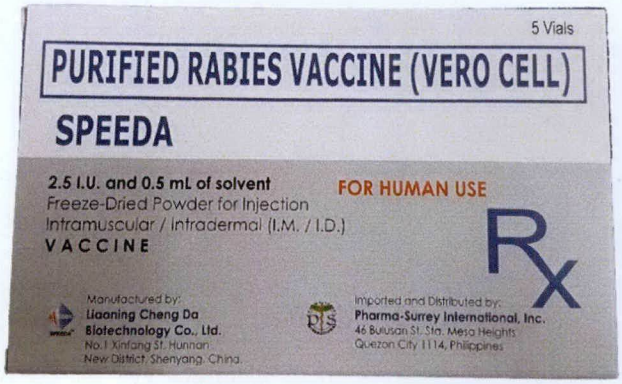
Counterfeit Version 2



Counterfeit Version 3



Authentic product



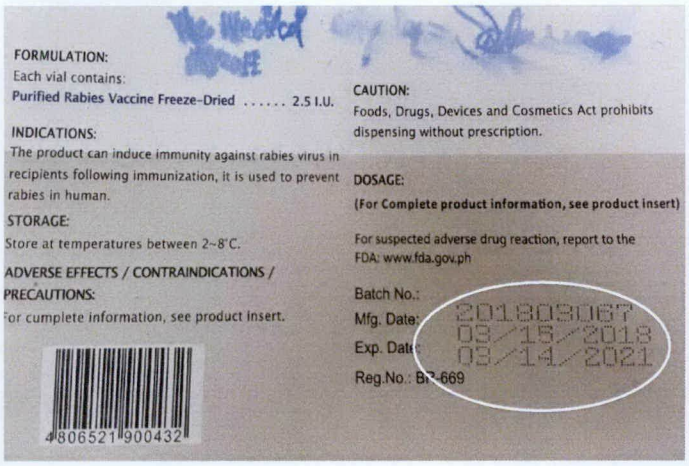
Note

- The gray panel in box label of verified **counterfeit versions 1, 2, & 3** Speeda Rabies Vaccine has a lighter shade of color than that of the authentic drug product.
- The text "Manufactured by" is included in the authentic box label but is not found in that of the box label of **counterfeit version 1**.
- The generic name of the **counterfeit version 2** is not enclosed in a generic outline box.

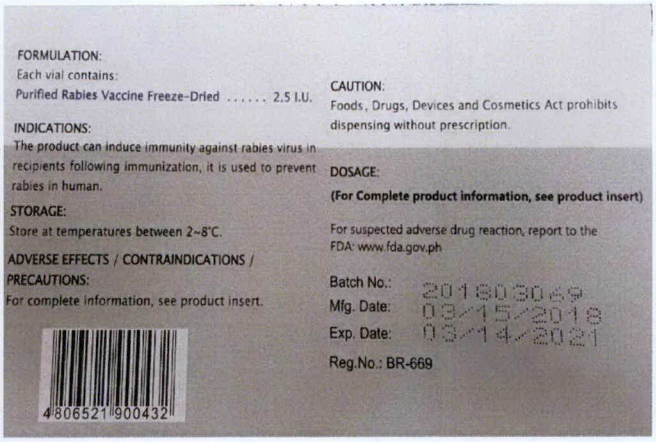
Figure 1. Comparison of box labels (front) of Verified Counterfeit Versions with the Authentic product

Civic Drive, Filinvest 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

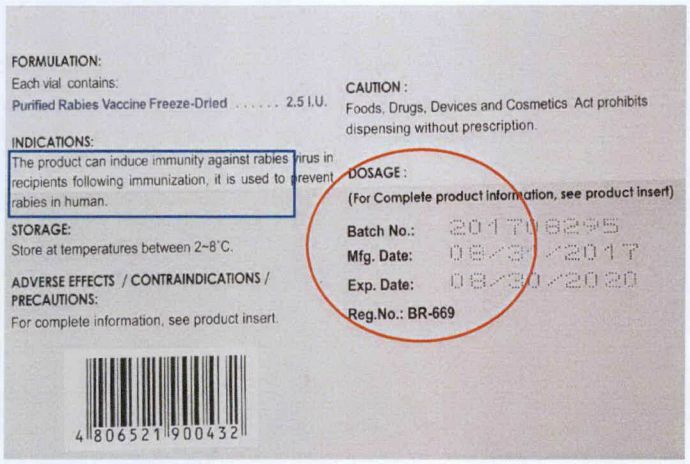
Counterfeit Version 1



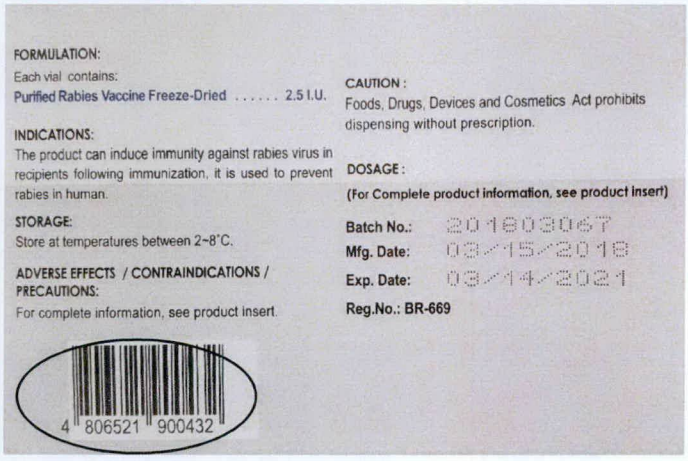
Authentic product



Counterfeit Version 2



Counterfeit Version 3

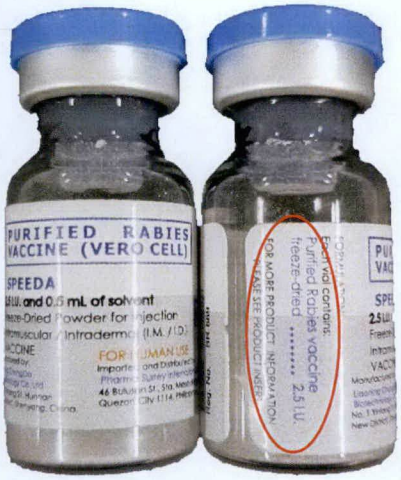


Note

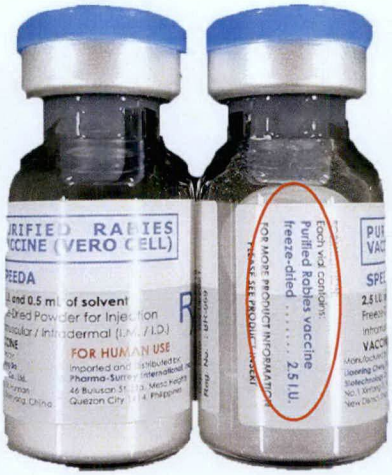
- The text details of batch number, manufacturing date and expiry date of the **counterfeit version 1** are compressed while slight gaps in between are observed in the box label of the authentic product.
- The words "Batch No", "Mfg. Date", "Exp. Date" & "Reg.No: BR-669" in the box label of **counterfeit versions 2 & 3** are in bold text format but not in the authentic product.
- The barcodes of **counterfeit versions 2 & 3** are not printed properly and the font used and spacing differ from those of the authentic drug product.
- The upper edge of gray shading in the **counterfeit versions 2 & 3** is near the text "rabies in human" while the upper shading in the authentic product is immediately below the text "INDICATIONS".
- The **counterfeit versions 2 & 3** lack the text "For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph" which is found on the authentic product.

Figure 2. Comparison of box label (back) of Verified Counterfeit versions with the Authentic product

Counterfeit Version 1



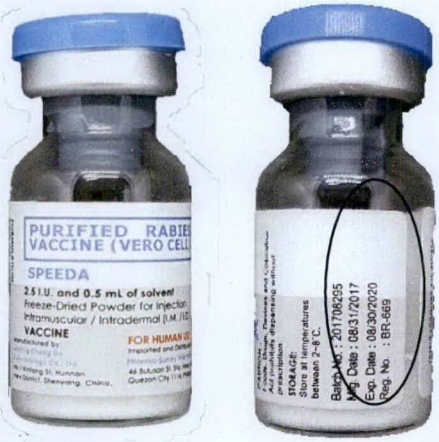
Authentic product



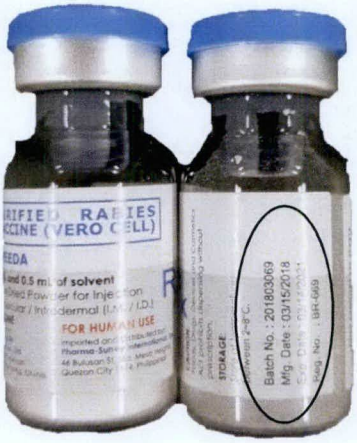
Note

- The font color of printed text on the vial labels of the **counterfeit version 1** is lighter than that of the authentic drug product.

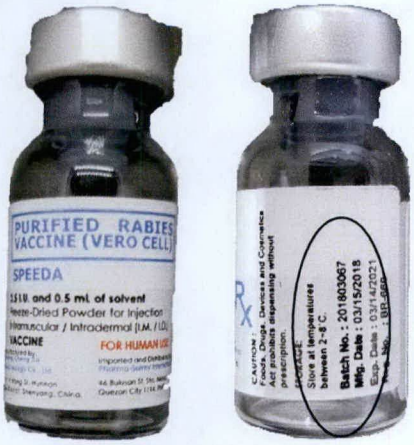
Counterfeit Version 2



Authentic product



Counterfeit Version 3



Note

- The font style of text in the vial labels of the **counterfeit versions 2 & 3** are different from that of the authentic one.

Figure 3. Comparison of vial labels of the Verified Counterfeit versions with the Authentic product

The Batch numbers that were confirmed by the Marketing Authorization Holder (MAH), Pharma Surrey International, Inc. as Counterfeit versions are the following:

- Batch 201803067 (Counterfeit version 1 & 3)
- Batch 201708295 (Counterfeit version 2)
- Batch 201710356 (Counterfeit version not in picture)
- Batch 201803069 (Counterfeit version not in picture)

All healthcare professionals, local health centers, health institutions and the general public are hereby warned of these counterfeit versions of drug product in the market which pose potential danger or injury to consumers. Consumers, distributors and retailers 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 these verified counterfeit versions of drug product with the aforementioned features. The importation, selling or offering for sale, brokering, donating or possession without proof of legitimate purchase of such are 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.

The Bureau of Customs is urged to restrain the importation or entry of these counterfeit products.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that counterfeit products are not sold, made available or used 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 suspected unregistered 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.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

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