Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-348

MAR 11 2020

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Counterfeit Versions of Purified Rabies Vaccine (Vero Cell) Speeda 2.5 I.U. and 0.5 mL of Solvent Freeze-Dried Powder for Injection**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit versions of Purified Rabies Vaccine (Vero Cell) Speeda 2.5 I.U. and 0.5 mL of Solvent Freeze-Dried Powder for Injection:

Counterfeit Drug Product

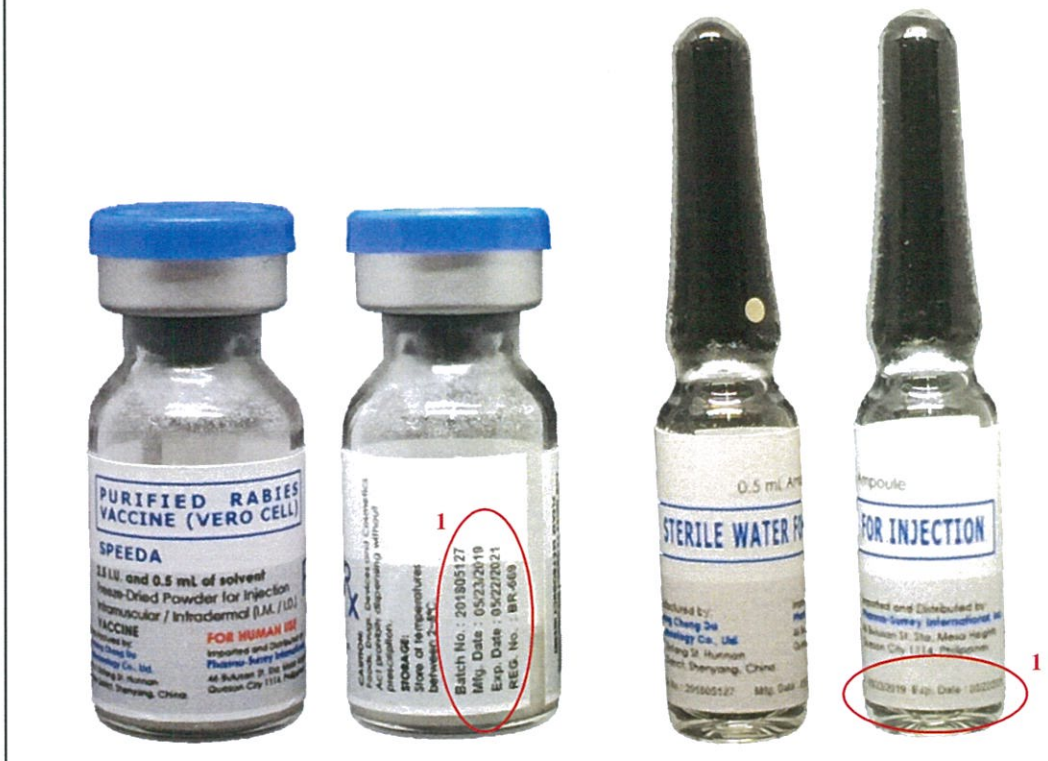

Figure 1. Vial and Ampoule labels of **Counterfeit version 1 (Vial and Ampoule: Batch no. 201805127)**

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

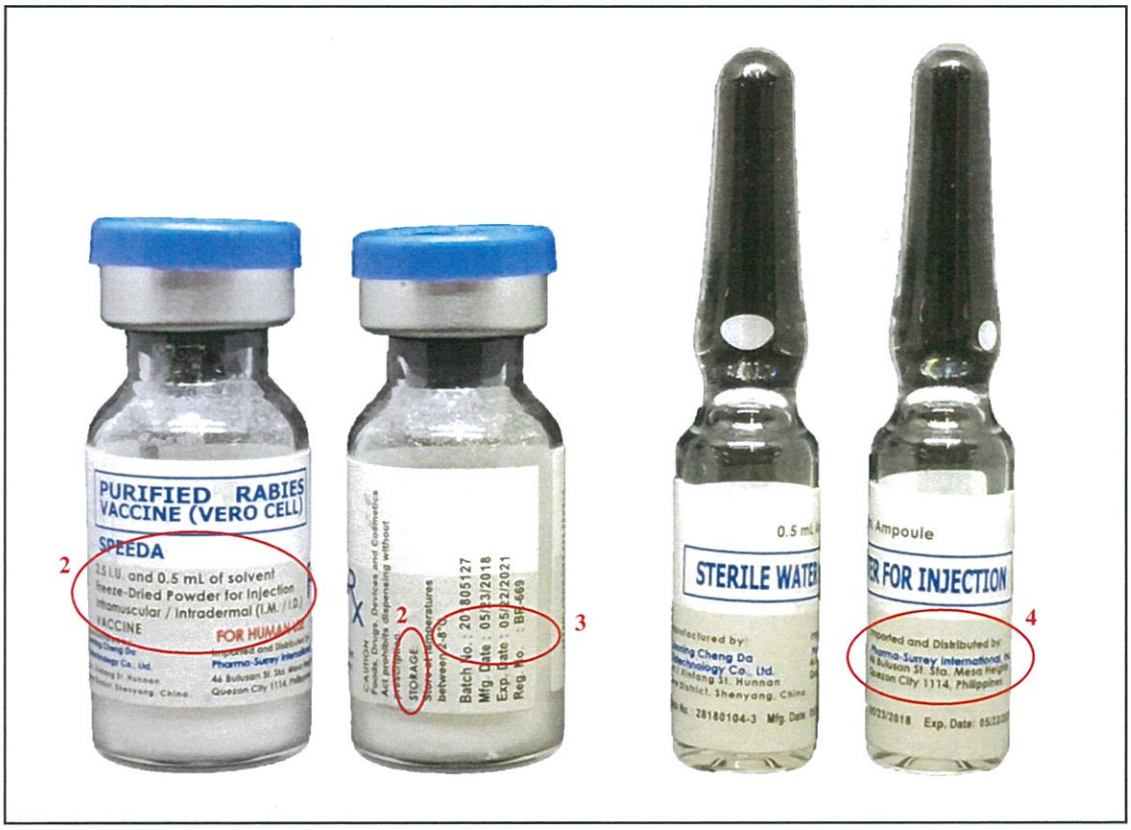

Figure 2. Vial and Ampoule labels of **Counterfeit version 2**
(Vial: Batch no. 201805127) (Ampoule: Batch no. 28180104-3)

Authentic Drug Product

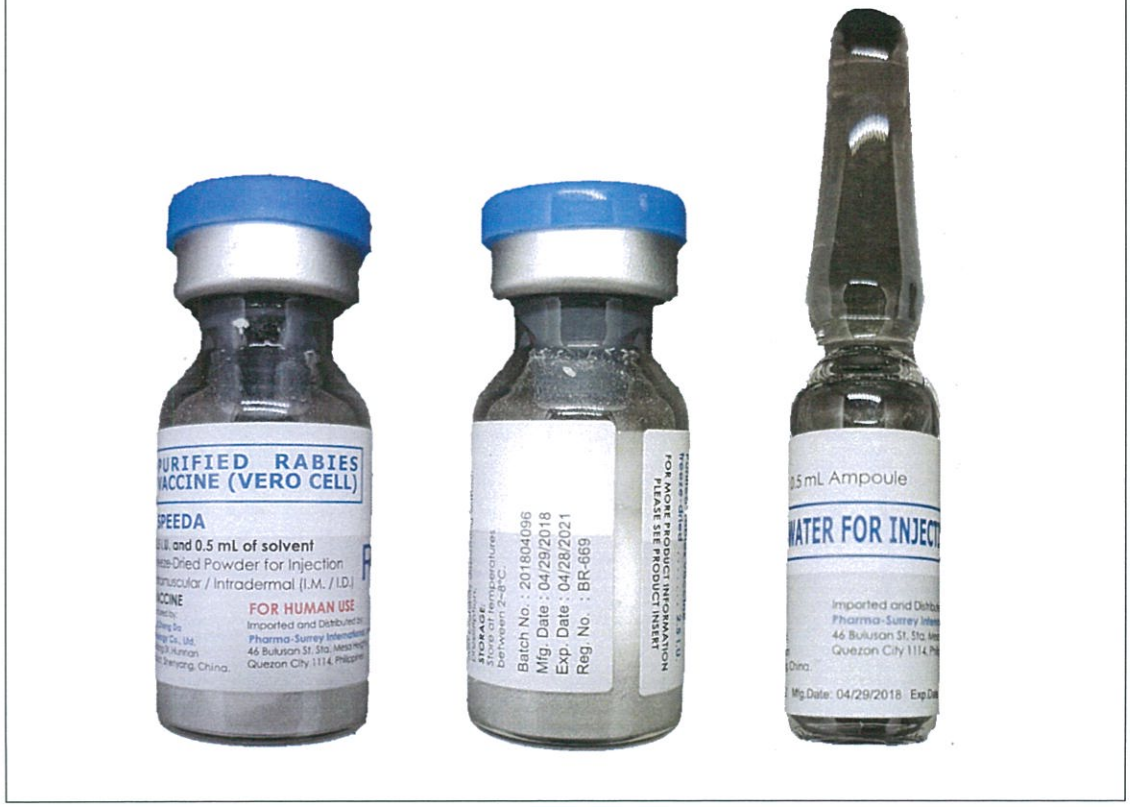

Figure 3. Vial and Ampoule labels of the **Authentic Speeda Rabies Vaccine**

The FDA together with the Marketing Authorization Holder (MAH), Pharma-Surrey International, Inc., have verified that the above-mentioned sample drug products are counterfeit. The comparison of the collected counterfeit drug products and the distinguishing feature of the authentic are as follows:

Counterfeit	Authentic
1. The shelf-life is 24 months only. 2. "2.5 IU and 0.5 ml solvent" "VACCINE" "CAUTION" and "STORAGE" are not bold. 3. Colon (:) written on Batch No., Mfg. Date, Exp. Date and Reg. No. are not aligned. 4. Spaces between "Imported and Distributed by, name of manufacturer, address of the manufacturer" are different from the authentic product.	1. The shelf-life is 36 months. 2. "2.5 IU and 0.5 ml solvent" "VACCINE" "CAUTION" and "STORAGE" are bold. 3. Colon (:) written on Batch No., Mfg. Date, Exp. Date and Reg. No. are aligned. 4. Spaces between "Imported and Distributed by, name of manufacturer, address of the manufacturer" are equal.

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 drug product with the abovementioned features of a counterfeit drug product. 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.

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Officer-in-Charge, Director General

DTN: 20200205175252