Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-187

26 FEB 2020

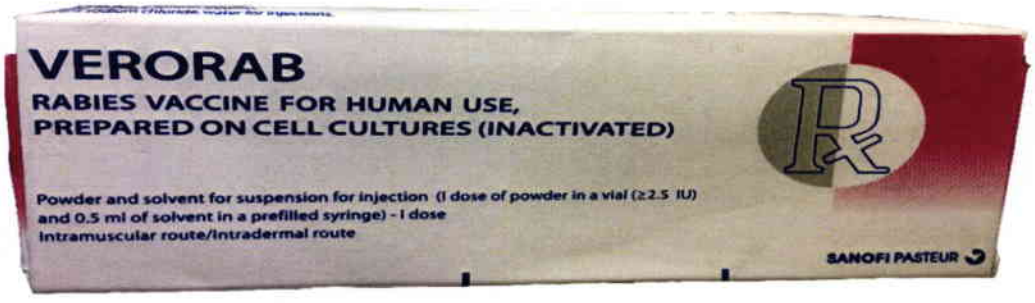
TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Counterfeit Versions of Verorab Rabies Vaccine For Human Use, Prepared On Cell Cultures (Inactivated)**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit versions of Verorab Rabies Vaccine For Human Use, Prepared On Cell Cultures (Inactivated):

Counterfeit Drug Product

Counterfeit Version 1



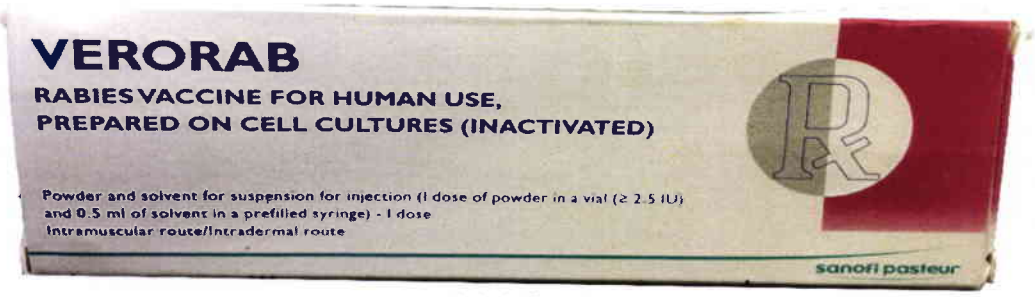
Box label (front)

Box label (back)

Box label (side)

Figure 1. Box labels of **Counterfeit version 1 (Lot no. R1A342V)**

Counterfeit Version 2



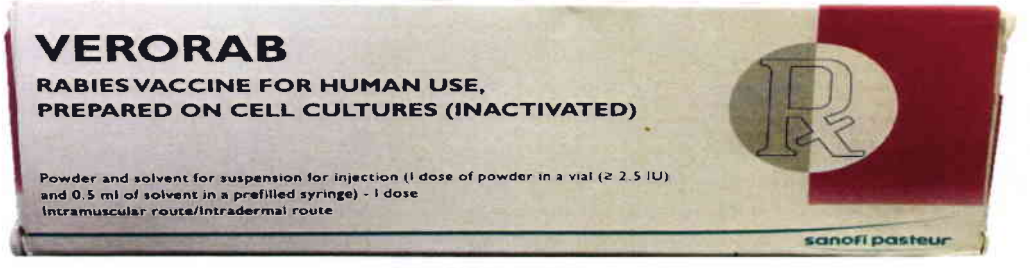
Box label (front)

Box label (back)

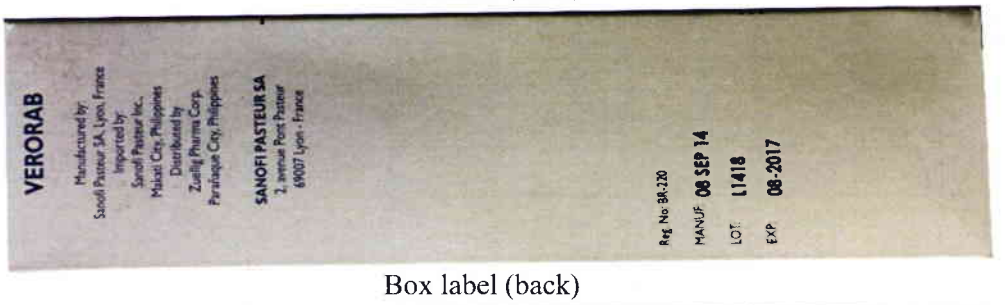
Box label (side)

Figure 2. Box labels of **Counterfeit version 2 (Lot no. L1418)**

Counterfeit Version 3



Box label (front)



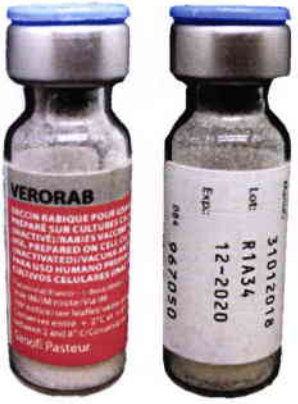
Box label (back)

Box label (side)

Figure 3. Box labels of **Counterfeit version 3 (Lot no. L1418)**

Counterfeit Drug Product

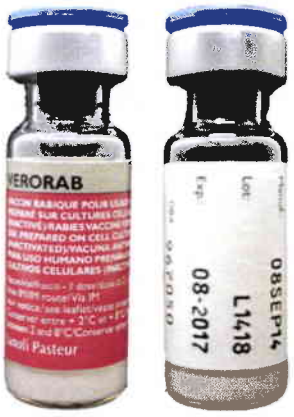
Counterfeit Version 1



Vaccine Powder in vial

Solvent in pre-filled syringe

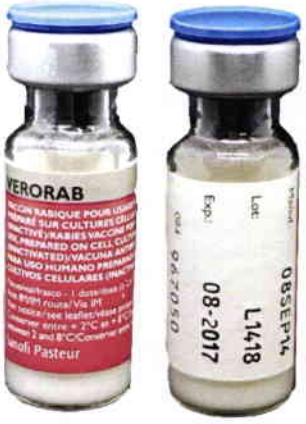
Counterfeit Version 2



Vaccine Powder in vial

Solvent in pre-filled syringe

Counterfeit Version 3



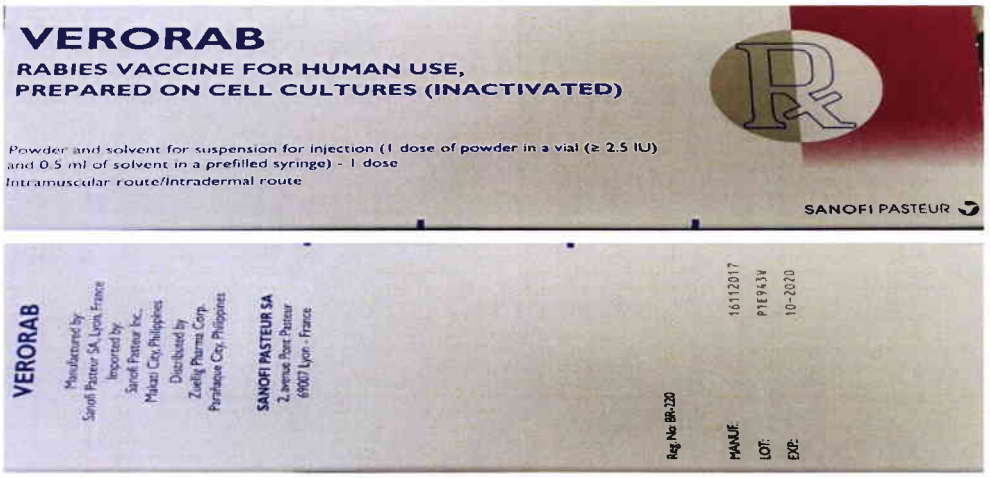
Vaccine Powder in vial

Solvent in pre-filled syringe

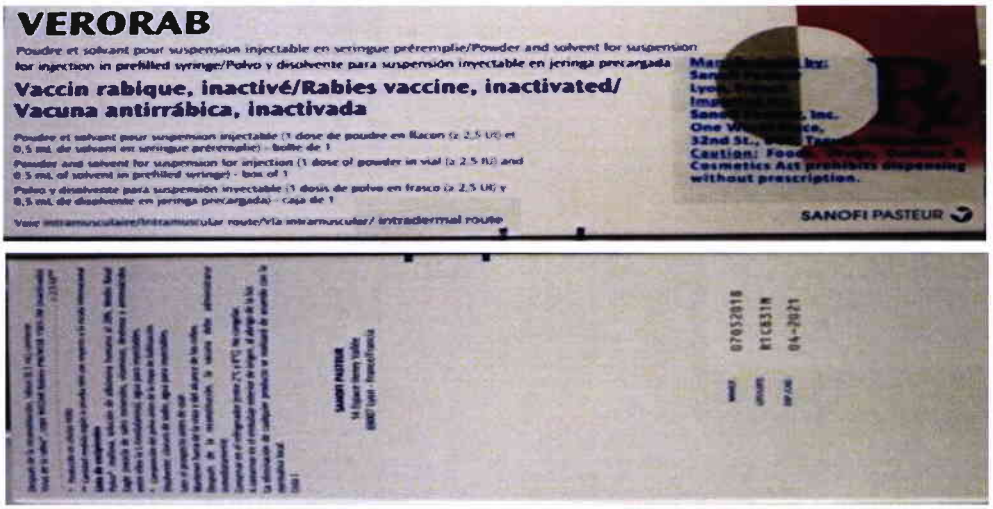
Figure 4. Vial label and packaging of accompanying solvent of **Counterfeit versions 1, 2 & 3**

Authentic Drug Product

Authentic Previous Packaging



Authentic New Packaging



Authentic Vial and Solvent

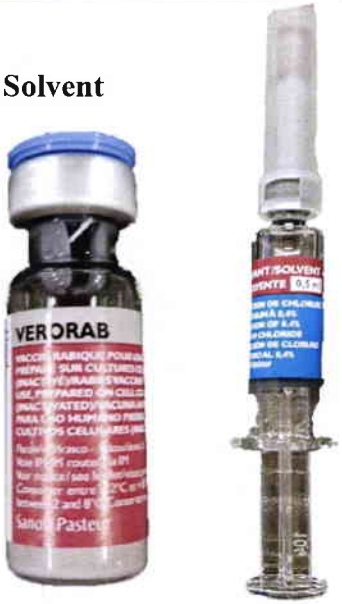


Figure 5. Box labels, vial and solvent of the **Authentic Verorab Vaccine**

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

Counterfeit	Authentic
• Box is of poor quality with no varnish or coating on the paper	• Box is varnished and appears glossy
• Vial color label is bright red	• Vial color label is dull red
• Pre-filled syringe label orientation is inverted and its color is bright red.	• Pre-filled syringe label orientation is upright and its color is dull red.

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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Undersecretary of Health
Officer-in-Charge, Director General

DTN: 20191218115318