



FDA ADVISORY

No. **2019-190**

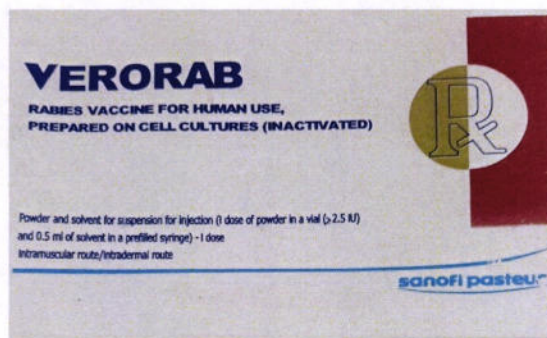
15 JUL 2019

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

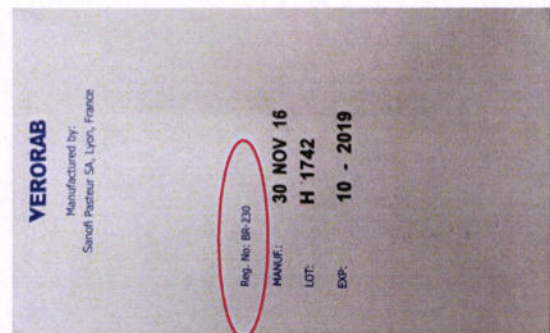
SUBJECT: Public Health Warning Against the Purchase and Use of Five Other Versions of Counterfeit VERORAB RABIES VACCINE FOR HUMAN USE, PREPARED ON CELL CULTURES (INACTIVATED)

The Food and Drug Administration (FDA) warns the public against the purchase and use of five other versions of counterfeit VERORAB RABIES VACCINE FOR HUMAN USE, PREPARED ON CELL CULTURES (INACTIVATED).

Counterfeit Version 1 (1 vial + solvent per box)



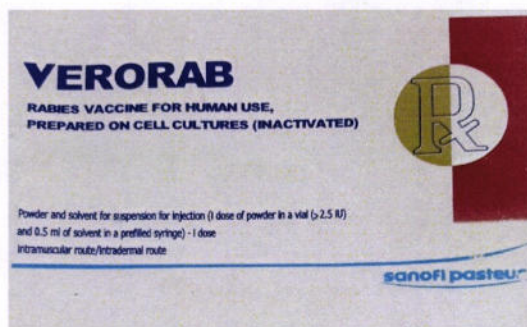
Box label (front)



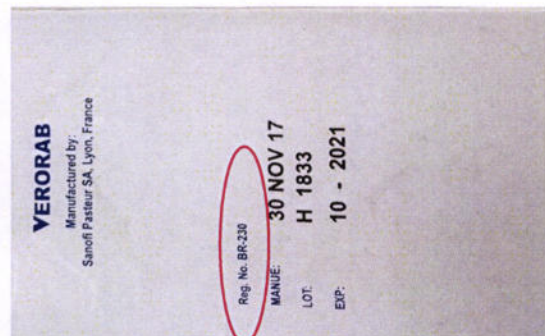
Box label (back)

Figure 1. Box labels of Counterfeit version 1 Lot no. H1742

Counterfeit Version 2 (1 vial + solvent per box)



Box label (front)

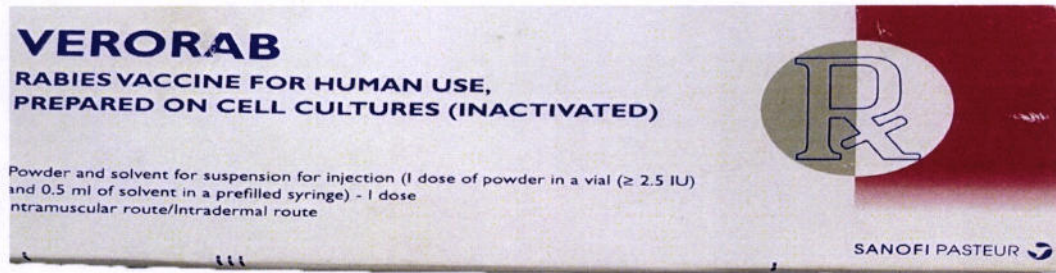


Box label (back)

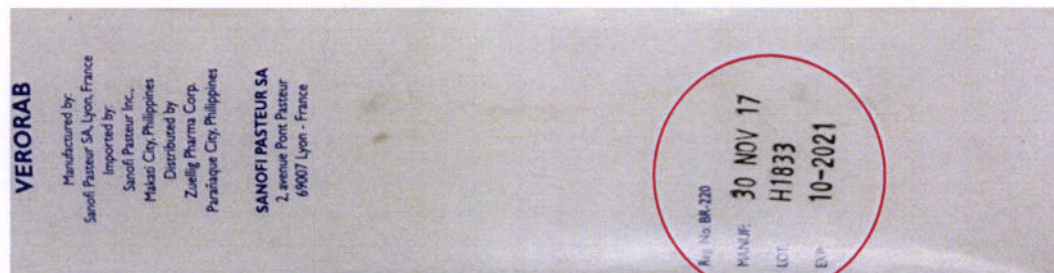
Figure 2. Box labels of Counterfeit version 2 Lot no. H1833



Counterfeit Version 3 (1 vial + solvent per box)



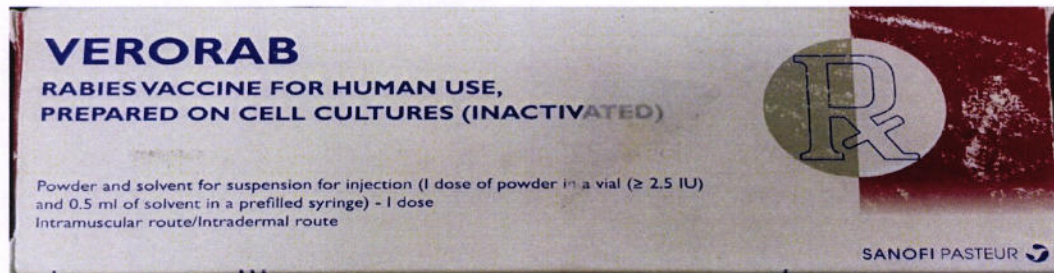
Box label (front)



Box label (back)

Figure 3. Box labels of Counterfeit version 3 Lot no. H1833

Counterfeit Version 4 (1 vial + solvent per box)



Box label (front)



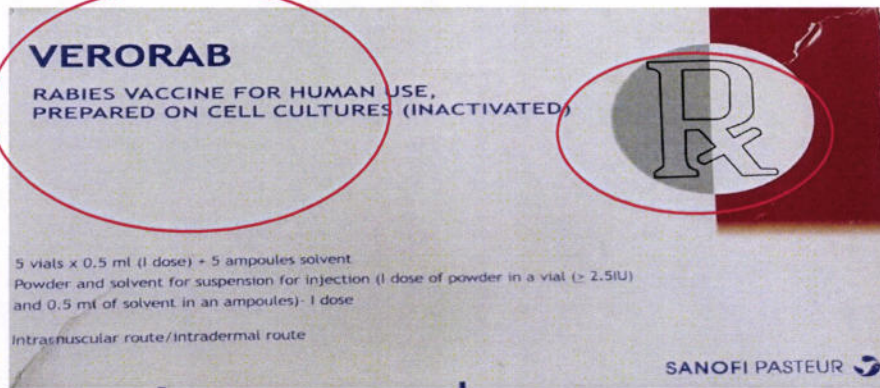
Box label (back)

Figure 4. Box labels of Counterfeit version 4 Lot no. N1E353M

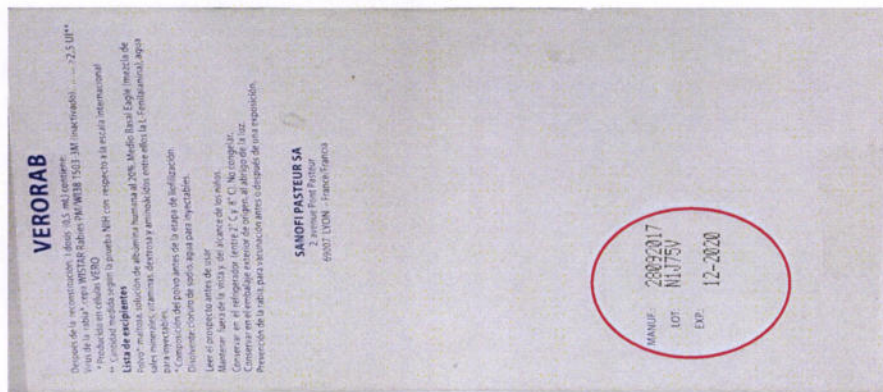
Comparison of box labels of counterfeit versions 1, 2, 3 & 4 with that of the authentic product (1 vial + solvent per box)

- Counterfeit version 1 (Lot. H1742) and counterfeit version 2 (Lot. H1833) both have registration number “BR-230” printed on their box labels while the authentic product bears the correct registration number “BR-220” on its box label.
- Counterfeit version 3 (Lot. H1833) and Counterfeit version 4 (N1E353M) both have the correct registration number “BR-220” but have larger font size and different font style used on the details of Manufacturing date, Lot number & Expiry date compared to the print details in the box label of the authentic product.

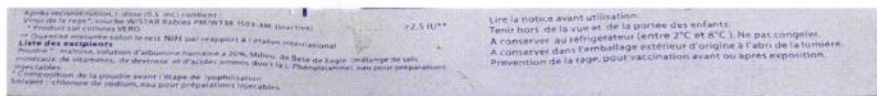
Counterfeit Version 5 (5 vials + solvent per box)



Box label (front)



Box label (back)



Box label (side)

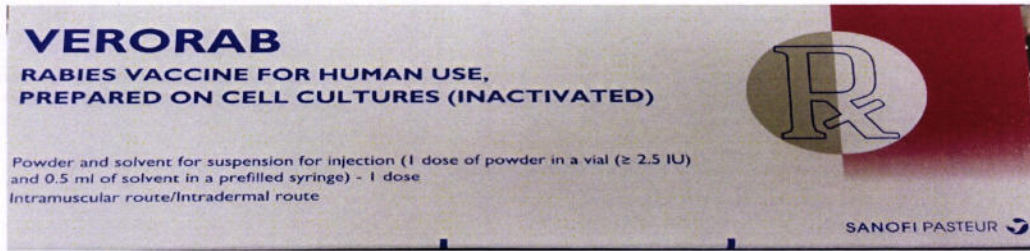
Figure 5. Box labels of Counterfeit version 5 Lot no. N1J75V

Comparison of the box label of counterfeit version 5 (Lot. N1J75V) with that of the authentic product (5 vials + solvent per box)

- The box label of **Counterfeit version 5 (Lot. N1J75V)** bears details in English only while that of the authentic product bears details in English and two other languages.
- The box label of the **Counterfeit version 5 (Lot. N1J75V)** has **no** stick-on label, the Rx symbol is printed directly on the box, and has **no** registration number. The authentic product has a stick-on label containing the Name and Address of the Manufacturer and Importer, the Rx symbol and Caution. The Registration number “BR-514” is in the stick-on label on the side panel of the box label of the authentic product.
- The print details of Manufacturing date, Lot number and Expiry date on the box label of **Counterfeit version 5 (Lot. N1J75V)** have different font style and lighter than the print details on the box label of the authentic product.

Authentic Product (1 vial + solvent per box)

Previous packaging

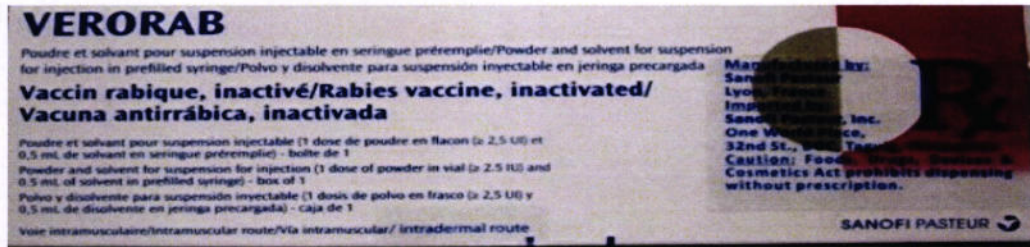


Box label (front)

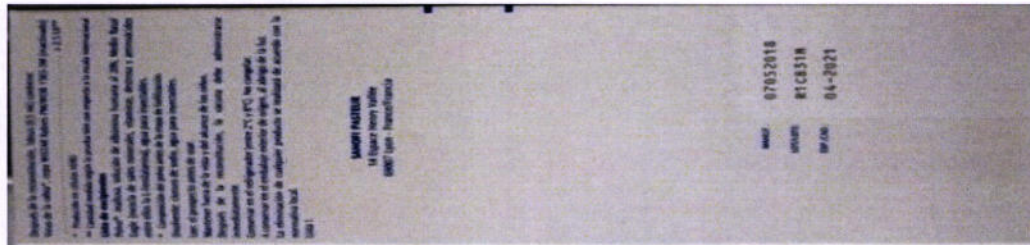


Box label (back)

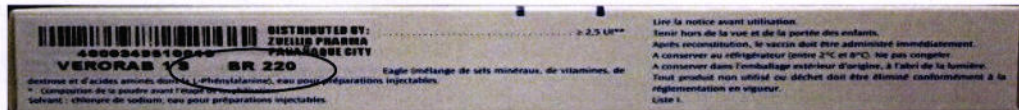
Current packaging



Box label (front)



Box label (back)

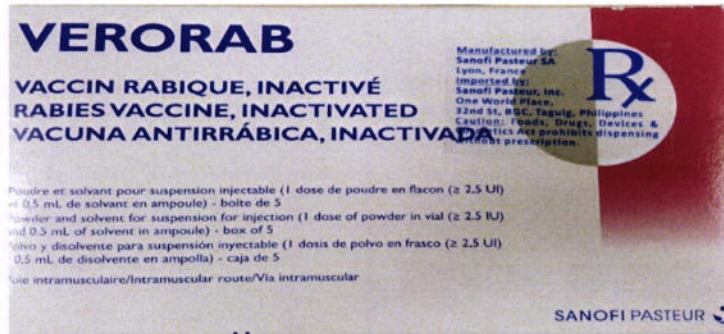


Box label (side)

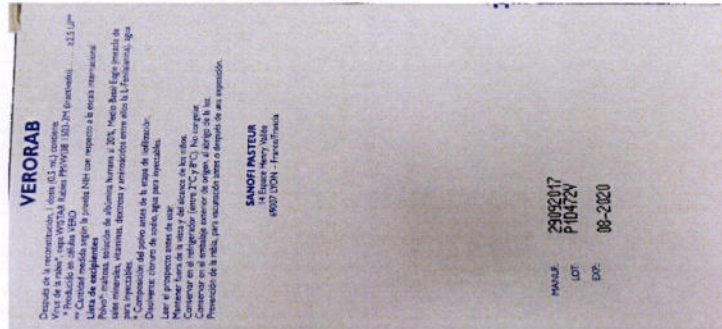
Figure 6. Box labels of **Authentic** Verorab Rabies Vaccine for Human Use, Prepared on Cell Cultures (Inactivated)

Authentic Product (5 vials + solvent per box)

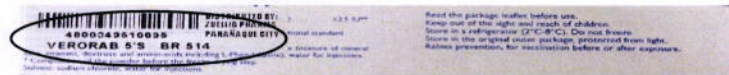
Previous packaging



Box label (front)

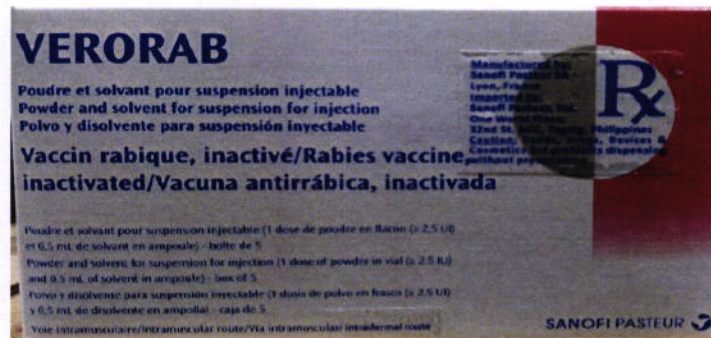


Box label (back)

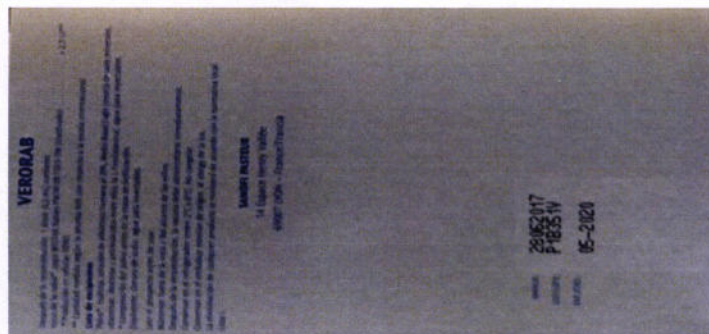


Box label (side)

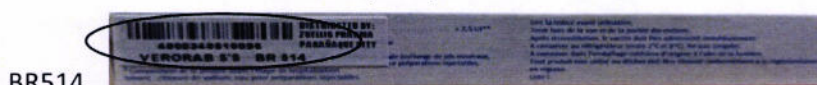
Current packaging



Box label (front)



Box label (back)



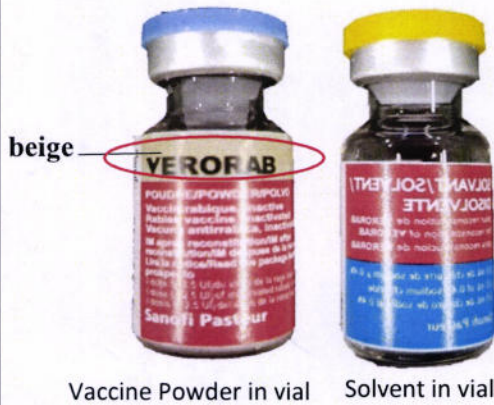
BR514

Box label (side)

Figure 7. Box labels of **Authentic** Verorab Rabies Vaccine for Human Use, Prepared on Cell Cultures (Inactivated)

Verorab Rabies Vaccine for Human Use, Prepared on Cell Cultures (Inactivated)

Counterfeit Version 1



Vaccine Powder in vial Solvent in vial

Counterfeit Version 2



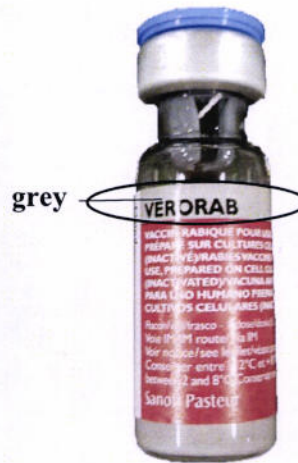
Vaccine Powder in vial Solvent in vial

Counterfeit Version 3



Vaccine Powder in vial Solvent in vial

Authentic product



Vaccine Powder in vial



Solvent in pre-filled syringe

Figure 9. Vial label and packaging of accompanying solvent of the authentic product (1 vial + solvent per box)

Comparison of vial label and packaging of accompanying solvents of counterfeit versions 1, 2 & 3 with those of the authentic product:

- The accompanying solvents of counterfeit versions 1, 2 & 3 are contained in colorless vial with yellow flip off cap while that of the authentic product is in pre-filled syringe.
- The top part of vial label of powder in counterfeit versions 1,2 & 3 are of beige color while that of the authentic product is of grey color.
- The lower part of vial label of powder in counterfeit versions 1, 2 & 3 contains the dosage strength after reconstitution written in English plus two other languages while in the authentic product this information is not shown. Instead, the dose per vial, the route of administration (IM) and storage condition (between 2° and 8°C) are printed on the same spot on the vial label of the authentic product.

Figure 8. Vial label and packaging of accompanying solvent of counterfeit versions 1, 2 & 3

The FDA, together with the Marketing Authorization Holder (MAH), Sanofi Pasteur Inc., have verified that the aforementioned products in Figures 1, 2, 3, 4, 5 & 8 are counterfeit.

The Lot numbers that were confirmed by the Marketing Authorization Holder (MAH), Sanofi Pasteur Inc. as counterfeit versions are the following. Moreover, no Lot Release Certificates were issued by FDA on these product lots:

- Lot no. H1742 (Counterfeit version 1)
- Lot no. H1833 (Counterfeit version 2 & 3)
- Lot no. N1E353M (Counterfeit version 4)
- Lot no. N1J75V (Counterfeit version 5)

All healthcare professionals, local health centers, health institutions and the general public are hereby warned of these counterfeit drug products 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.

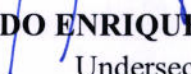
Likewise, all establishments and outlets are hereby warned against selling and/or dispensing verified counterfeit drug products with the foregoing features. The importation, selling or offering for sale, brokering, donating or possession without proof of legitimate purchase of such is in direct violation 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, therefore a penalty shall be imposed.

The Bureau of Customs is urged to restrict the entry of these counterfeit product versions of Verorab.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these 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 unregistered 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 or email cdrr@fda.gov.ph. 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 this advisory to all concerned is requested


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Undersecretary of Health
Officer-in-Charge, Director General



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