



FDA ADVISORY

No. **2019-190**

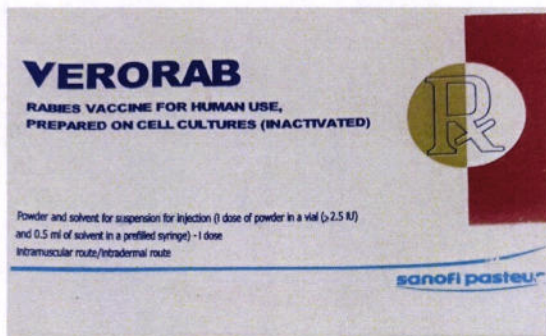
15 JUL 2019

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

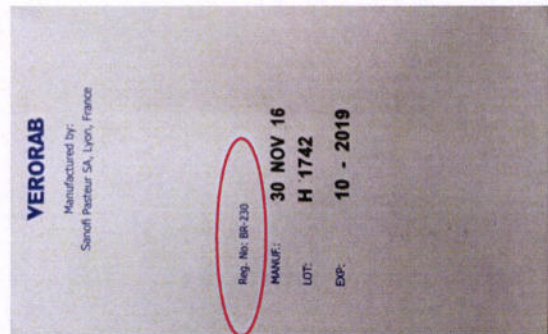
SUBJECT: Public Health Warning Against the Purchase and Use of Five Other Versions of Counterfeit VERORAB RABIES VACCINE FOR HUMAN USE, PREPARED ON CELL CULTURES (INACTIVATED)

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)



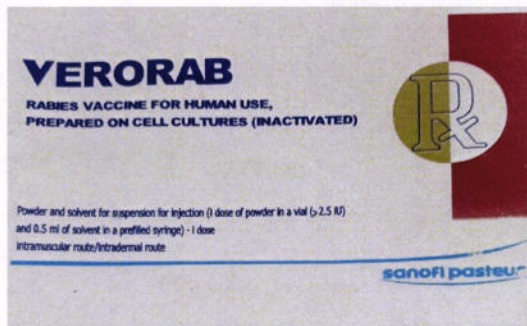
Box label (front)



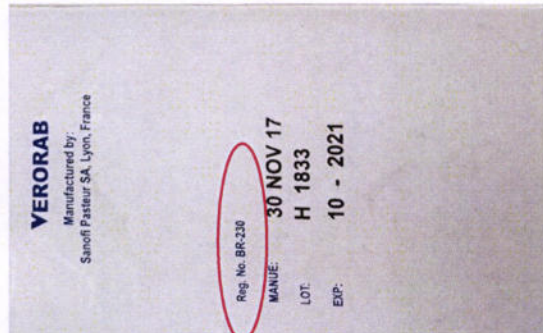
Box label (back)

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

Counterfeit Version 2 (1 vial + solvent per box)



Box label (front)

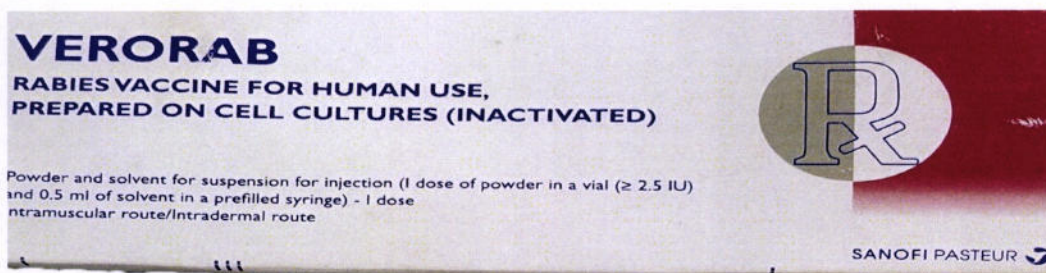


Box label (back)

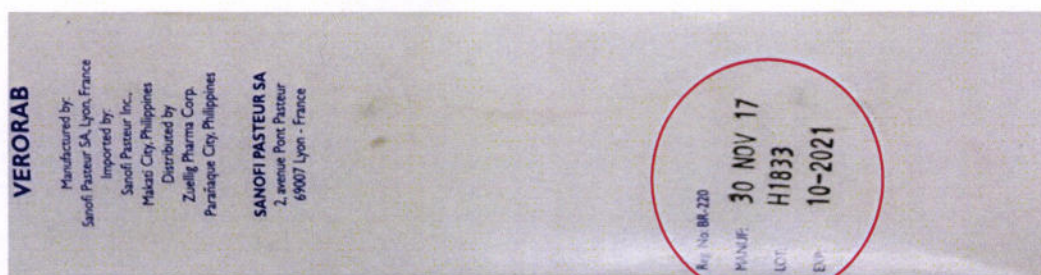
Figure 2. Box labels of Counterfeit version 2 Lot no. H1833



Counterfeit Version 3 (1 vial + solvent per box)



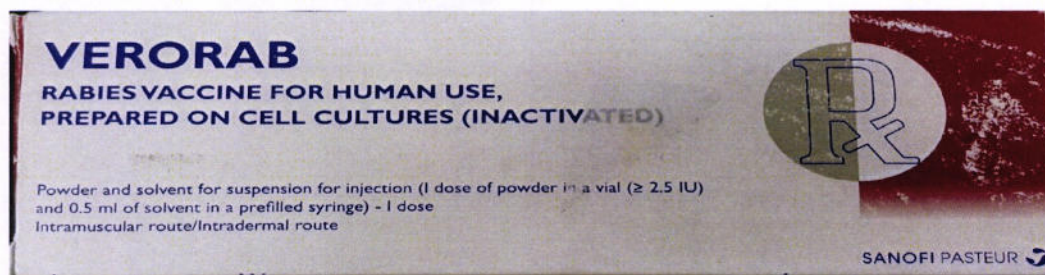
Box label (front)



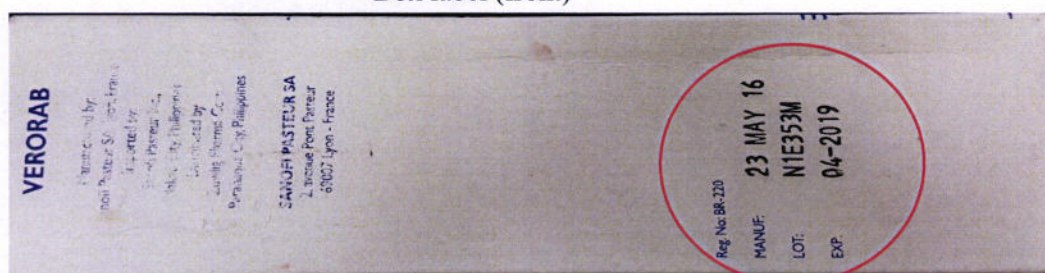
Box label (back)

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

Counterfeit Version 4 (1 vial + solvent per box)



Box label (front)



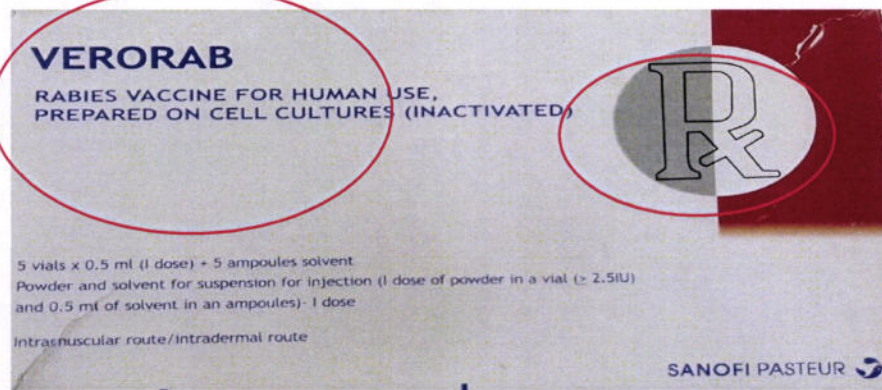
Box label (back)

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

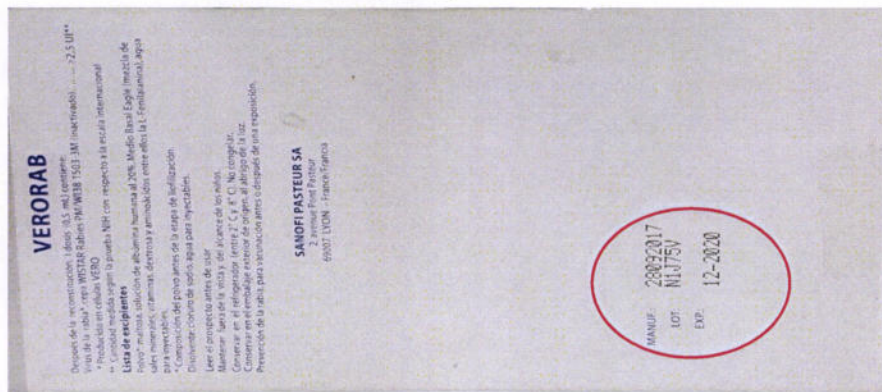
Comparison of box labels of counterfeit versions 1, 2, 3 & 4 with that of the authentic product (1 vial + solvent per box)

- **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.

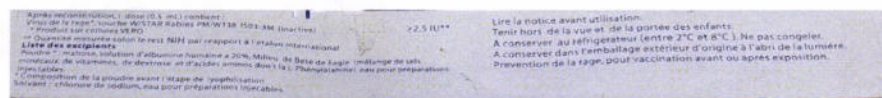
Counterfeit Version 5 (5 vials + solvent per box)



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.