

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION Fund and Drug Administration PHILIPPINES



FDA ADVISORY

No. 2018-334

2 7 DEC 2018

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 Drug Product Verorab Rabies Vaccine

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Verorab rabies vaccine.

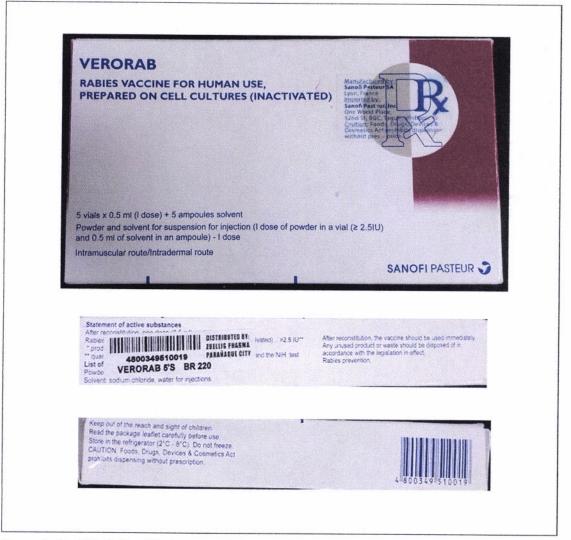


Figure 1. Box label of verified counterfeit Verorab Rabies Vaccine





Figure 2. Verified counterfeit sample vials and ampoules of Verorab Rabies vaccine.

The FDA, together with the Marketing Authorization Holder (MAH), Sanofi Pausteur Inc., have verified that the above mentioned in Figure 1 and 2 sample drug product is counterfeit.

Figures 3 and 4 show the registered drug product Verorab Rabies Vaccine.

The principal display panel of the label of Verorab Rabies Vaccine for Human Use Prepared on Cell Culture (Inactivated) 2.5 IU/ 0.5 mL Powder for Suspension I.D./ I.M. Injection bears the following:

- 1. FDA-licensed Philippine importer and distributor
- 2. FDA registration number (BR-514)
- 3. Rx symbol
- 4. FDA caution statement on dispensing
- 5. Barcode

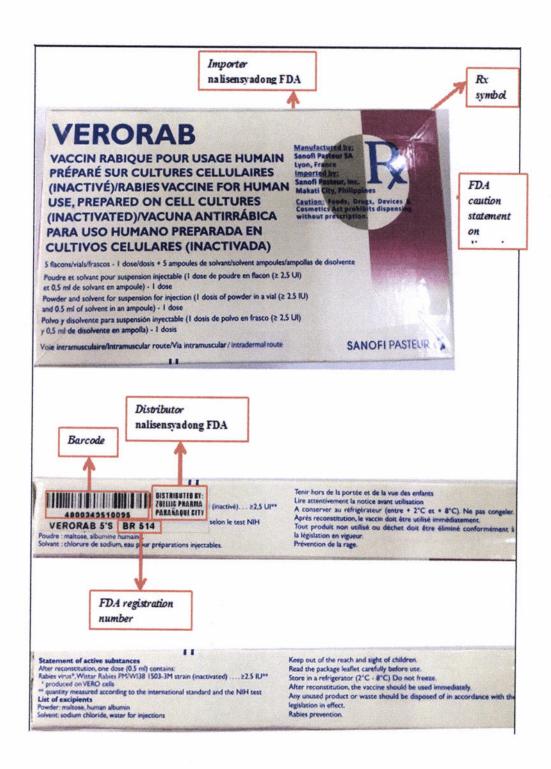


Figure 3. Box Label of Authentic Verorab Rabies Vaccine bearing the correct registration number (BR-514)



Figure 4. Registered Drug Product vials and ampoules of Verorab Rabies Vaccine

All healthcare professionals, local health centers, health institutions and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose 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 this verified counterfeit drug product with the foregoing features. 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, therefore a penalty shall be imposed.

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 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. 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.

ELA CHARADE G. PUNO, RPh

Director General

20181221143520