Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA ADVISORY No. 2016-042**

18 MAY 2016

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

**SUBJECT:** **Public Health Warning Against the Use of the Unregistered Drug Product with Registered Counterpart Brand "Verorab"**

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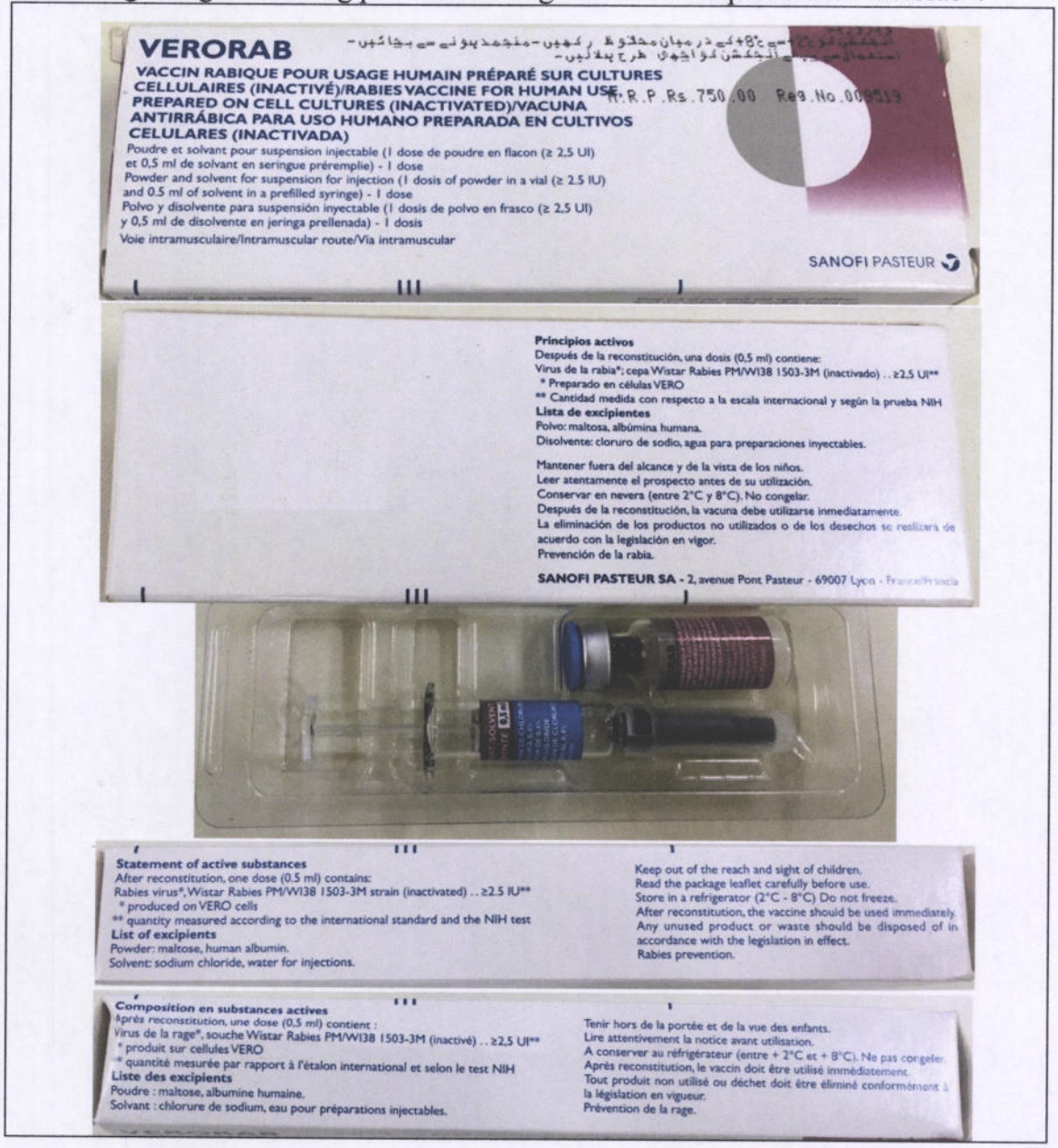
The Food and Drug Administration (FDA) advises the public against the use of the following unregistered drug product with registered counterpart brand "Verorab":

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INACTIVATED PURIFIED VEROCELL RABIES VACCINE I.P.

**VERORAB**

Powder and solvent for suspension for injection
(1 dose of powder in a vial (≥2.5IU) and 0.5 ml of solvent in an ampoule) – 1dose

Intramuscular or Intradermal route

SANOFI PASTEUR

Import Lic No SV-5-42

Manufactured by:
**SANOFI PASTEUR SA**
Parc Industriel d'Incarville
BP 101 - 27100 Val de Reuil - France

Imported and Re-assembled in India by:
**Sanofi Pasteur India Private Limited**
EI-223, T.T.C. Industrial Area, Mahape, Navi Mumbai,
Dist. Thane 400710

Marketed in India by:
**Zuventus Healthcare Limited**
A Joint Venture of Emcure
5119, Oberoi Garden Estates, D-Wing
Chandivali, Andheri (East)
Mumbai 400072

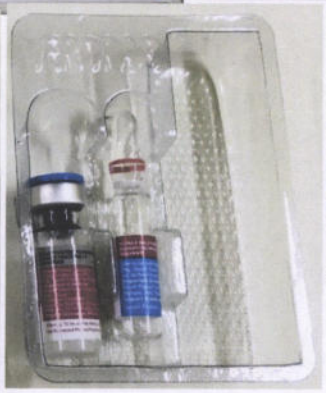
Mfg. Lic. No.: KD/8

Maximum Retail Price Rs. 337.00
Inclusive of all Taxes

**Warning:**
To be sold by retail on the prescription of the Registered Medical Practitioner

For Solvent
Batch No:
Mfg. Date:
Exp. Date:
For Vaccine
Batch No:
Mfg. Date:
Exp. Date:

Syringe &
Batch No.
Mfg. Date
Exp. Date

PURIFIED INACTIVATED
RABIES VACCINE,
PREPARED ON VERO CELLS

**VERORAB**

Rabies Vaccination Card

Zuventus Healthcare Ltd.

SANOFI PASTEUR

**Statement of active substances**
After reconstitution, one dose (0.5 ml) contains:
Rabies virus*, Wistar Rabies PM/WI38 1503-3M strain (inactivated) ..... ≥2.5 IU**

* produced on VERO cells
** quantity measured according to the international standard and the NIH test

**List of excipients**
Powder: maltose and human albumin.
Solvent: **Sterile solution of 0.4% Sodium Chloride (IP)**

Keep out of the reach and sight of children.
Read the package leaflet carefully before use.
Store in the refrigerator (2°C - 8°C). Do not freeze.
After reconstitution, the vaccine should be used immediately.
Any unused product or waste should be disposed of in accordance with the legislation in effect.
Rabies prevention.

INACTIVATED PURIFIED
VEROCELL RABIES VACCINE I.P.

**VERORAB**

5 vials x 0.5 ml (1dose) + 5 ampoules solvent
Powder and solvent for suspension for injection (1 dose of powder in a vial (≥2.5IU) and 0.5 ml of solvent in an ampoule) – 1dose

Intramuscular or Intradermal route

SANOFI PASTEUR

**VERORAB**

Manufactured by:
**SANOFI PASTEUR SA**
Parc Industriel d'Incarville
BP 101 - 27100 Val de Reuil - France

**Imported in India by:**
Sanofi Pasteur India Private Limited
EI-223, T.T.C. Industrial Area, Mahape, Navi Mumbai,
Dist. Thane 400710

MRP: Rs. 1587.50 (Inclusive of all taxes)
**Import license no: SV-5-42**

**Warning:**
To be sold by retail on the prescription of the Registered Medical Practitioner

VACCINE AND SOLVENT MFG. DATE
BATCH No.
SOLVENT BATCH No.
VACCINE AND SOLVENT EXP. DATE

Figure 1. Unregistered drug product with registered counterpart brand "Verorab"

These Verorab anti-rabies vaccines were found to be distributed in the Philippine market without approval of the FDA. Likewise, these were confirmed by the Marketing Authorization Holder (MAH), Sanofi Pasteur, Inc. to be illegally imported. The potency of these vaccines are questionable since these were obtained from unknown sources. Thus, proper handling during shipment is not assured, compromising the safety, efficacy, and quality that can result to treatment failure or even death.

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned unregistered drug product with registered counterpart brand. This poses potential danger or injury to the consuming public and 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.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified drug product. Anyone found selling the said drug product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this drug product is not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

The FDA-registered rabies vaccine, Inactivated Rabies Vaccine (Wistar Strain Rabies) [Verorab] 2.5 IU/ 0.5 mL Powder for Suspension I.D./ I.M. Injection, is manufactured by Sanofi Pasteur SA – 2 avenue Pont Pasteur 6900 Lyon, France, imported by Sanofi Pasteur, Inc. – 4F Feliza Bldg., 108 Rufino St., Legaspi Village, Makati City and distributed by Zuellig Pharma Corporation – Km 14 West Service Road SH cor. Edison Ave., Sun Valley, Parañaque City.

The principal display panel of the label of Inactivated Rabies Vaccine (Wistar Strain Rabies) [Verorab] 2.5 IU/ 0.5 mL Powder for Suspension I.D./ I.M. Injection are in English language only and bears the following:

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

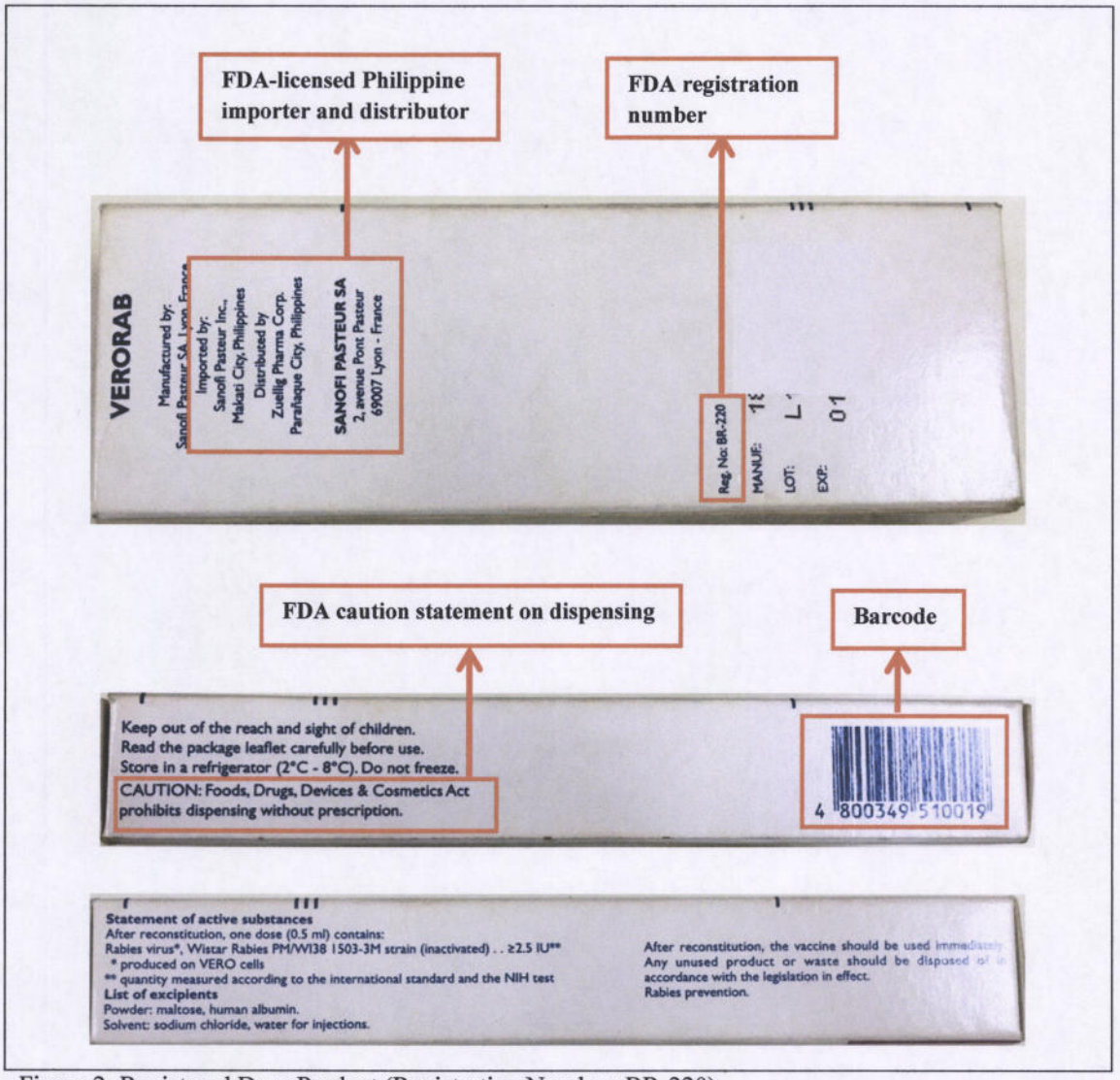
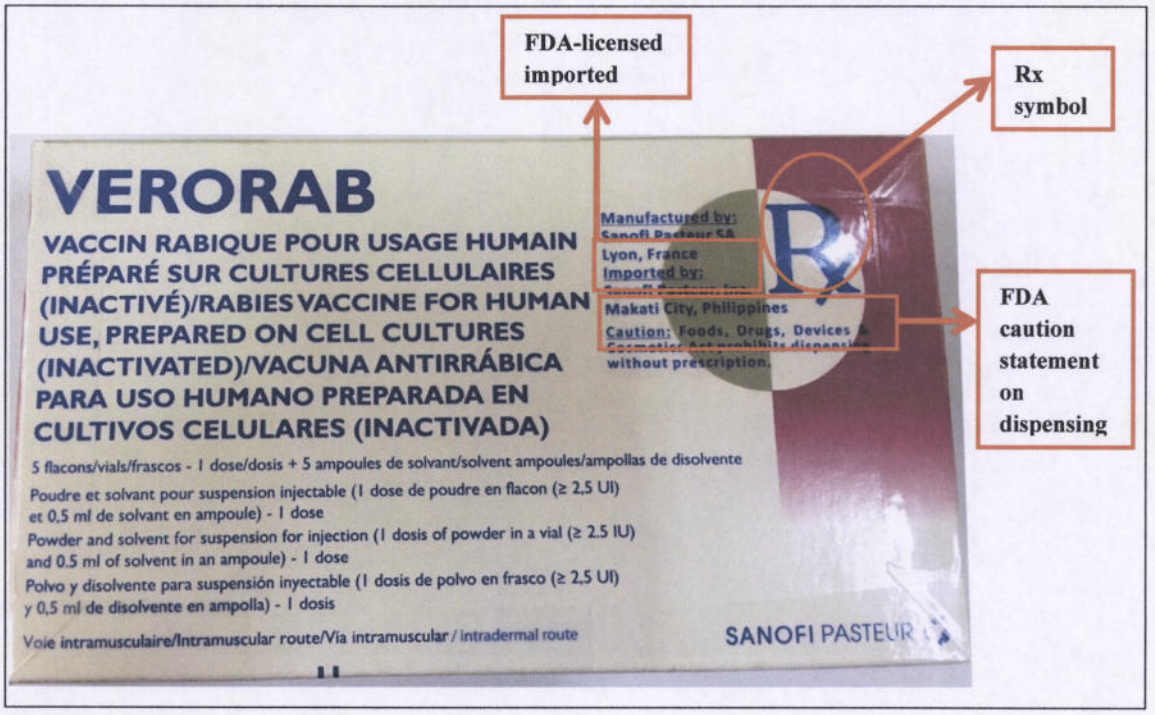



Figure 2: Registered Drug Product (Registration Number: BR-220)



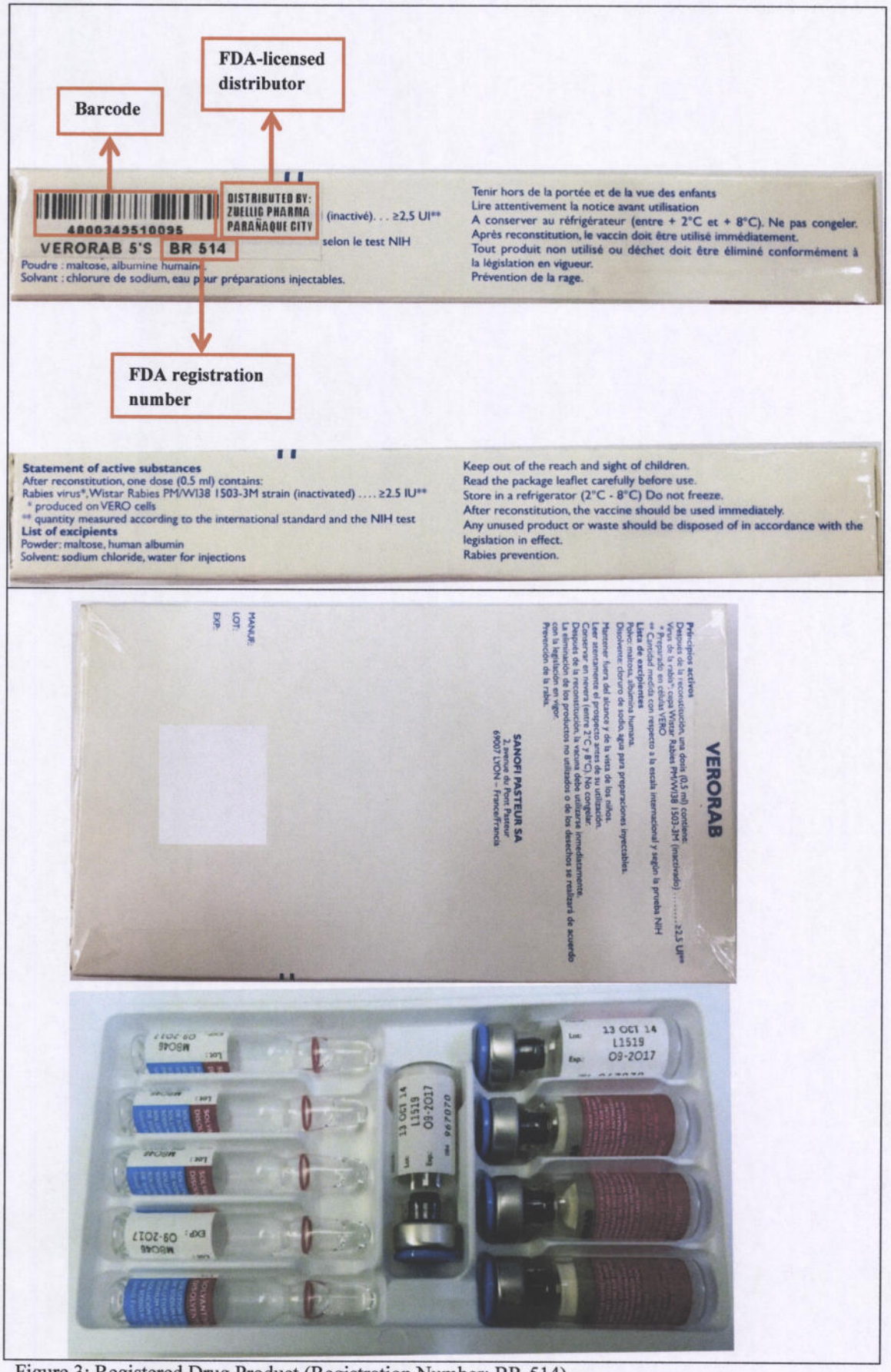



Figure 3: Registered Drug Product (Registration Number: BR-514)

Inactivated Rabies Vaccine (Wistar Strain Rabies) [Verorab] 2.5 IU/ 0.5 mL Powder for Suspension I.D./ I.M. Injection is indicated for rabies prevention in subjects exposed to risk of contamination and for infants particularly exposed to the risk of rabies. The said product is available in two packaging presentations: (1) Box of 1 vial + 1 syringe diluent (Registration Number: BR-220), and (2) Box of 5 vials + 5 ampoules diluent (Registration Number: BR-514).

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 you may call the telephone number (02)807-8275. 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.

**MARIA LOURDES C. SANTIAGO, MSc, MM**
OIC, Director General

DTN: 20160128114731