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

04 SEP 2018

**FDA ADVISORY**
**No. 2018-270**

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

**SUBJECT:** **Product Recall of All Batches/Lots of Rabies Vaccine (Verocell, Purified) 2.5 IU/0.5 mL Lyophilized Powder for Injection (IM/SC) (Rabiesvax-FD)**

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All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that all batches or lots of the subject product is being recalled from the market. The details of the product are as follows:

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| DRUG PRODUCT | **RABIES VACCINE (VEROCELL, PURIFIED) 2.5 IU/0.5 ML LYOPHILIZED POWDER FOR INJECTION (IM/SC) (RABIESVAX-FD)** |
| REGISTRATION NUMBER | **BR-873** |
| MANUFACTURER | **CHANGCHUN CHANGSHENG LIFE SCIENCES LTD. – NO. 1615, YUEDA ROAD, CHANGCHUN, JILIN PROVINCE, CHINA** |
| IMPORTER (Marketing Authorization Holder) | **JUVENTIS PHARMACEUTICALS PHILS., INC. – UNIT 6, 2/F, 8467 WEST SERVICE ROAD, SOUTH SUPERHIGHWAY, PARAÑAQUE CITY** |

The trigger came from the National Medical Products Administration of China (formerly China Food and Drug Administration) wherein the agency found Changchun Changsheng Life Sciences Ltd. in violation of relevant requirements of Good Manufacturing Practice (GMP), e.g. problems in data integrity. Appropriate recall of the batches or lots of the said product is on-going in China. FDA is also proceeding with the recall of all batches or lots exported to the Philippines to protect the public due to the GMP issues noting that rabies vaccines are widely used in our country.

Rabies Vaccine is indicated as prophylaxis and treatment of rabies. Rabies Vaccine (Verocell, Purified) 2.5 IU/0.5 mL Lyophilized Powder for Injection (IM/SC) (Rabiesvax-FD) is packed in a glass vial (Box of 5's) to be used as a single dose.

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have batches/lots of the drug product are instructed to discontinue further distribution, sale, and use. All consumers are likewise advised not to purchase or use any of the product batch/lot and may contact Juventis Pharmaceuticals Phils., Inc. at telephone number +632 556-7517 or e-mail us at cdrr_prsdd@fda.gov.ph for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that all of the product batches/lots are not sold or made available in their localities or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the product should be reported immediately to FDA through this link: ww2.fda.gov.ph/adr-report-new and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

**NELA CHARADE G. PUNO, RPh**
Director General

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