Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 September 2014

FDA Advisory
No. ~~2014~~ -076

SUBJECT: VOLUNTARY RECALL OF LOT SPECIFIC DOXORUBICIN HYDROCHLORIDE 2 MG/ML (20 MG/10ML) PEGYLATED LIPOSOMAL CONCENTRATE FOR I.V. INFUSION (CASPRIA)

This is to inform the public that Merck Sharp & Dohme (I.A.) Corporation, a Philippine subsidiary of Merck & Co., Inc. has notified the Food and Drug Administration (FDA) of their intent to voluntarily recall lot JKN0969B of Doxorubicin Hydrochloride 2 mg/mL (20 mg/10mL) Pegylated Liposomal Concentrate for I.V. Infusion (Caspria) due to lack of assurance of compliance with current Good Manufacturing Practice (cGMP) of the product manufacturer. The details of the product are as follows:

REGISTRATION NUMBER	**DR-XY43268**
LOT NUMBER	**JKN0969B**
MANUFACTURER NAME AND ADDRESS	**SUN PHARMACEUTICAL INDUSTRIES, LTD. – HALOL-BARODA HIGHWAY-389 350, DIST. PANCHMAHAL, GUJARAT , INDIA**
IMPORTER NAME AND ADDRESS	**MERCK SHARP & DOHME (I.A.) CORPORATION – 26th FLR. PHILAM LIFE TOWER, 8767 PASEO DE ROXAS, MAKATI CITY.**

Doxorubicin Hydrochloride 2 mg/mL (20 mg/10mL) Pegylated Liposomal Concentrate for I.V. Infusion (Caspria) is used in association with other antineoplastic agents in the treatment of acute leukemia, lymphoma, sarcoma and other range of tumors. This product is packed in ten (10) mL USP Type I colorless tubular glass vial (Box of 1 vial).

The affected product presents safety risk and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies, or clinics that have the affected lot of Doxorubicin Hydrochloride 2 mg/mL (20 mg/10mL) Pegylated Liposomal Concentrate for I.V. Infusion (Caspria) are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected products.

All the field Food and Drug Regulation Officers are ordered to monitor the availability of the product batches in the market.

Consumers may contact Merck Sharp & Dohme (I.A.) Corporation at telephone number +632 784-9500 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

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Acting Director General