Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
PHILIPPINES

30 JUL 2015

FDA Advisory
No. 2015-060

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC LOT JKN0969B OF DOXORUBICIN HYDROCHLORIDE 2 mg/mL (20 mg/10 mL) PEGYLATED LIPOSOMAL CONCENTRATE FOR I.V. INFUSION (CASPRIA)

This is to inform the public that the Product Recall Order (PRO) issued on lot JKN0969B of Doxorubicin HCl (Caspria) 2 mg/mL (20 mg/10 mL) Pegylated Liposomal Concentrate for I.V. Infusion is hereby terminated by the Food and Drug Administration (FDA). This product was manufactured by Sun Pharmaceutical Industries Ltd. in India and imported by Merck Sharp & Dohme (I.A.) Corp.

As stated in the FDA Advisory No. 2014-076 dated 29 September 2014, FDA informed the public of the recall of the specific lot (JKN0969B) of the subject product due to the lack of assurance of the Marketing Authorization Holder (MAH) on the compliance with current Good Manufacturing Practice (cGMP) of the manufacturer, Sun Pharmaceutical Industries Ltd.

After due and thorough evaluation of the submitted documents by the MAH, FDA has determined that reasonable efforts had been made by Merck Sharp & Dohme (I.A.) Corp. to recall and properly destroy the impacted product lot in accordance with Bureau Circular No. 8, s. 2001, known as the Guidelines to be Observed on the Implementation of Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of existing laws, rules and regulations.

All Field Regulatory Operations Office (FROO) Officers are ordered to appropriately seal discovered stocks of the affected lot of the product, and to instruct the concerned establishment to give back the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA representative.

Consumers may contact FDA at telephone number +632 857-1900 or via e-mail at info@fda.gov.ph for any questions or additional information regarding this recalled product.

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Secretary of Health
Acting Director General[1]

DTN: 20150713110159
[1]Pursuant to DPO 2015-1845