Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 February 2015

FDA Advisory No. 2015-015

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCH OF PACLITAXEL 30mg/1.5mL SOLUTION FOR NANOPARTICLE INJECTION (NANOXEL) AND ACCOMPANYING CONCENTRATE OF EXCIPIENTS

This is to inform the public that the recall order issued on batch 873TF00103 of Paclitaxel 30mg/1.5mL Solution for Nanoparticle Injection (Nanoxel) accompanied with batch 873RX001 Concentrate of Excipients (DR-XY42006) is hereby terminated by the Food and Drug Administration (FDA). This product is manufactured by Fresenius Kabi Oncology Ltd. - India and imported by Fresenius Kabi Philippines, Inc.

As stated in the FDA Advisory No. 2014-025 dated 25 March 2014, FDA ordered a recall of the product batch due to Out of Specification result on the physical appearance of the accompanying Concentrate of Excipients wherein it was observed as a yellow liquid which is different from the registered specification (clear colorless). The color of the solution has changed before the completion of the approved shelf-life.

After careful evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the Marketing Authorization Holder (MAH), Fresenius Kabi Philippines, Inc., to recall and properly destroy the impacted product batch 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 any findings of any violation of existing laws, rules and regulations.

All field Food and Drug Regulation Officers are ordered to monitor and seize the cited product batches if found available in the market.

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.

ATTY. NICOLAS B. LUTERO III, CESO III
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