Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 March 2014

FDA Advisory
No. 2014-025

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

This is to inform the public that Fresenius Kabi Philippines, Inc. is initiating a voluntary recall of Paclitaxel 30mg/1.5mL Solution for Nanoparticle Injection (Nanoxel) due to Out of Specification result on the physical appearance of the accompanying Concentrate of Excipients. The Concentrate of Excipients was observed as yellow liquid which is different from the registered specification (clear colorless) before the completion of the approved shelf-life. The details of the affected batch are as follows:

Details	Nanoxel Injection	Accompanying Concentrate of Excipients
Batch Number	873TF00103	873RX001
Manufacturing Date	Jan 2013	Jan 2013
Expiry Date	Dec 2014	Dec 2014

Paclitaxel 30mg/1.5mL Solution for Nanoparticle Injection (Nanoxel) is used in the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. It is packaged in a box containing 1 vial of Paclitaxel Solution and 1 vial of Concentrate of Excipients.

Distributors, retailers, hospitals, pharmacies, or clinics that have the affected batch of Paclitaxel 30mg/mL Solution for Nanoparticle Injection (Nanoxel) and accompanying Concentrate of Excipients are instructed to stop the use and discontinue from further distribution.

Consumers with questions regarding the recall may contact the assigned safety officer of Fresenius Kabi Philippines, Inc., Ms. Cristina Aguilar-Cu. Below are the contact details:

(Office) +632 889 6492 loc. 111
Monday to Friday from 8:30am to 5:30pm
(Email) cristina.aguilar@fresenius-kabi.com

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any report about establishments dealing illegally with sale or offer for sale of unregistered health products should be reported immediately to FDA at report@fda.gov.ph.

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Acting Director General