Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 November 2014

FDA Advisory
No. 2014-087

SUBJECT: TERMINATION OF BATCH SPECIFIC PRODUCT RECALL ORDER ISSUED ON CEFUROXIME (AS SODIUM) 750 mg POWDER FOR INJECTION (IM/IV) WITH BRAND NAMES ZURENIX AND ZURENIX WFI

This is to inform the public that the recall order issued on batch 9600 of Cefuroxime (as sodium) 750 mg Powder for Injection (IM/IV) with brand names Zurenix and Zurenix WFI with registration numbers DRP-282 and DRP-954, respectively, is hereby terminated by the Food and Drug Administration (FDA). These products are manufactured by Flamingo Pharmaceuticals Ltd. in India and imported by Pasteur Pharmaceutical Sales.

As per FDA Advisory No. 2014-020 dated 12 March 2014, FDA ordered a recall of batch 9600 of the subject products due to out-of-specification results obtained on assay tests performed by the FDA Central Laboratory.

After careful evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the Marketing Authorization Holder (MAH), Pasteur Pharmaceutical Sales, 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 batch 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 these recalled products.

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