Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 March 2014

FDA Advisory
No2014-020

SUBJECT: PRODUCT RECALL OF BATCH SPECIFIC CEFUROXIME 750mg POWDER FOR INJECTION

The public is hereby warned by the Food and Drug Administration (FDA) that the following Cefuroxime 750mg Powder for Injection products with batch number 9600, manufactured by Flamingo Pharmaceuticals Ltd. – India and imported by Pasteur Pharmaceuticals Sales is being recalled from the market:

Registration Number	Brand Name
DRP-282	**Zurenix**
DRP-282-02	**Eurimax**
DRP-282-03	**Cefunor**
DRP-954	**Zurenix WFI**
DRP-954-01	**Baktime WFI**
DRP-954-02	**Hiquacef**
DRP-954-03	**Cervin**
DRP-954-04	**Cefura**
DRP-954-05	**Rezafil WFI**

Based on the result of laboratory analysis conducted by FDA, it was found that the label claim of Cefuroxime 750mg Powder for Injection (Zurenix) batch 9600 is below the required potency.

The above specific batch of Cefuroxime 750mg Powder for Injection present a safety risk and adverse health consequences as it potentially exposes patients to suboptimal dose of Cefuroxime therapy.

Pasteur Pharmaceutical Sales is hereby ordered to discontinue the distribution of the affected batch of the product. All retail outlets are ordered to discontinue from selling or offering for sale the said batch of the products to the consumers. Health care professionals are advised not to use the particular batch of the product.

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph
Fax +63 2 807 0751
Email: info@fda.gov.ph

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any adverse reactions caused by the aforementioned product should be reported immediately to FDA at report@fda.gov.ph.

KENNETH HARTIGAN-GO, MD
Acting Director General