

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



30 July 2014

FDA Advisory No. <u>2014</u> \_060

SUBJECT:

Public Health Warning Against the Use of Unregistered Product "Cefuroxime 125 mg per 5 mL Granules for Oral Suspension (CEFX)"



The Food and Drug Administration advises the public against the use of an unregistered product named CEFX 125 mg per 5 mL Granules for Oral Suspension. The product which was labeled to be antibacterial has the generic name "Cefuroxime" and is claimed to be used in the treatment of susceptible infections.

CEFX 125 mg per 5 mL Granules for Oral Suspension was found to be distributed without FDA registration. The importer and distributor of

the product, Sham Chem Pharmacals Inc., is not licensed by this Office.

The FDA warns the public that the use of this unregistered antibacterial product presents safety risks and adverse health consequences. The safety, efficacy and quality of this product cannot be guaranteed.

Retailers and distributors of FDA-regulated products are advised to source their supplies from authorized dealers so as to avoid processing fake and/or unregistered products.

The field Food and Drug Regulation Officers are ordered to confiscate all unregistered drug product, particularly CEFX found in the market or in possession of individuals.

All local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase and use only FDA-registered health products from FDA-licensed establishment. To verify if the product is registered with FDA, the general public may search the FDA website, <a href="www.fda.gov.ph">www.fda.gov.ph</a> by typing the product's name in the search tab.



For more information and inquiries, please email us at <a href="info@fda.gov.ph">info@fda.gov.ph</a>. To report continuous sales or distribution of unregistered health products kindly email us via <a href="report@fda.gov.ph">report@fda.gov.ph</a> or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report at the FDA website: <a href="www.fda.gov.ph">www.fda.gov.ph</a> through the ADR Report tab.

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