

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



09 December 2013

FDA Advisory 2013-066

SUBJECT: PRODUCT RECALL OF CEFAZOLIN (AS SODIUM) 1g POWDER FOR INJECTION IM/IV (CEFAZIN)

The public is hereby warned by the Food and Drug Administration (FDA) that Cefazolin (as Sodium) 1g Powder for Injection (Cefazin) with registration number DRP-2160-01 and batch number 130602, manufactured by Ningbo Tisun Medic Biochemic Co. Ltd – China, is being recalled from the market due to the inconsistency in the brand name printed on the primary label (Cefain) and the brand name printed on the secondary label (Cefazin). The product is imported by 2 World Traders Subic, Inc. and distributed by 2 World Traders Inc.

Cefazolin (Cefazin) being offered for sale presents no safety risk and adverse health consequences. However, the misspelled brand name (Cefain) on the primary label may cause confusion to the public.

The importer and distributor are hereby ordered to immediately cease and desist from further distributing, selling, or offering for sale the above-mentioned affected product. All drug retail outlets carrying the affected batch of Cefazolin (Cefazin) 1g Powder for Injection are ordered to discontinue from selling or offer for sale to the consumers. All prescribers are warned against prescribing this product, and all consumers are advised not to purchase and use the said antibiotic product.

For more information and inquiries, please e-mail us at <u>info@fda.gov.ph</u>. 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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