Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20231836

02 AUG 2023

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Voluntary Product Recall of Specific Batch of Cefuroxime Axetil 125 mg/5 mL Suspension [Zinnat] 70 mL

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall by the marketing authorization holder (MAH) on the affected batch of the subject product from the market. The details of the product are as follows:

DRUG PRODUCT	**CEFUROXIME AXETIL 125 mg/5 mL SUSPENSION [ZINNAT] 70 mL**	
REGISTRATION NO.	**DRP-11854**	
BATCH NO./EXP. DATE	**PK4Y**	**December 2024**
MANUFACTURER	**GLAXO OPERATIONS UK LTD-** Harmine Road, Barnard Castle. D12 8DT, United Kingdom	
IMPORTER & DISTRIBUTOR	**SANDOZ PHILIPPINES CORPORATION**–5th and 6th floor Ayala North Exchange Tower (HQ) Ayala Avenue corner Salcedo and Amorsolo Sts., Brgy. San Lorenzo, Makati City	

Figure 1. Cefuroxime Axetil 125 mg/5 mL Suspension [Zinnat] 70 mL for Voluntary Recall

Cefuroxime axetil is used to treat a wide variety of bacterial infections. This medication is known as a cephalosporin antibiotic and it works by stopping the growth of bacteria.

The MAH pursued the voluntary recall of the drug product due to the irregularities in the necks of some glass bottles which led to bottles with leaking sealing membranes. The identified quality defect on the neck of the bottle may cause microbial contamination and affect the safety and efficacy of the product, thereby leading to health risk to patients, specifically children. Therefore, the stated batch presents quality and safety concerns.

Distributors, hospitals, retailers, pharmacies, or clinics that have the affected batch of the drug product are therefore instructed to discontinue further distribution, sale, and use. All consumers are likewise advised not to purchase or use the affected product batch and may contact Sandoz Philippines Corporation through grace.olympia@sandoz.com for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product batch is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report continuous sale or distribution of the abovementioned, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. Any suspected adverse reaction experienced from the use of the products should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

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