Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2023-1589

30 JUN 2023

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Product Recall of the Specific Specific Batches of Cefepime (as hydrochloride) 1 g Powder for Injection (I.M./I.V.) and Cefepime (as hydrochloride) 2 g Powder for Injection (I.M./I.V.)**

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 batches of the subject product from the market. The details of the products are as follows:

DRUG PRODUCT	**CEFEPIME (AS HYDROCHLORIDE)**	
DOSAGE STRENGTH	**1 G POWDER FOR INJECTION (I.M./I.V.)**	**2 G POWDER FOR INJECTION (I.M./I.V.)**
REGISTRATION NO.	**DR-XY35933**	**DR-XY35932**
PACKAGING	**USP Type III Flint Glass Vial with Royal Blue Flip-Off Seal x 15mL (Box of 1's)**	**USP Type III Flint Glass Vial with Royal Blue Flip-Off Seal x 20mL (Box of 1's)**
BATCH NO./ EXP. DATE	**SEE ATTACHED LIST**	
MANUFACTURER	**ASTRAL STERITECH PVT. LTD.- India**	
IMPORTER & DISTRIBUTOR	**RITEMED PHILS., INC.- 56 Epifanio Delos Santos Ave., Mandaluyong, Metro Manila**	

Figure 1. Cefepime (As hydrochloride)
1 g powder for injection for recall

Figure 2. Cefepime (As hydrochloride)
2 g powder for injection for recall

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Cefepime is a semi-synthetic, broad spectrum, fourth generation cephalosporin for parenteral administration which is active against a wide range of Gram-positive, Gram-negative aerobic organisms and certain anaerobes. It exerts bactericidal effect by inhibiting the synthesis of the bacterial cell wall.

The MAH pursued the voluntary recall of the drug product due to an Out-of-Specification (OOS) data observed during a routine environmental monitoring at the manufacturer's facility located in Vadodara, Gujarat, India. Due to the Good Manufacturing Practice (GMP) issues on the manufacturer's sterile facilities, the integrity of the specific batches produced could no longer be assured and could relatively cause health risks to the patients. Thus, the stated batches present quality and safety concerns.

Distributors, hospitals, retailers, pharmacies, or clinics are therefore instructed to discontinue further distribution, sale, and use of the affected batches of the drug products. All healthcare professionals and consumers are likewise advised not to purchase or use the affected product batches and may contact RiteMED Phils., Inc. through ask@ritemed.com.ph 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 batches are 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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List of Affected Batches of Cefepime (as hydrochloride)

1 G Powder for Injection & 2 G Powder for Injection (IM/IV)

PRODUCT NAME	BATCH NUMBER	MFG DATE	EXP DATE
Cefepime (as hydrochloride) 1 g Powder for Injection (IM/IV)	AUXM-201	19 Jan 2022	31 Dec 2024
Cefepime (as hydrochloride) 2 g Powder for Injection (IM/IV)	AUXI-101	07 May 2021	30 April 2024
	AUXI-201	19 January 2022	31 December 2024