

May 15, 2023

Subject: URGENT DRUG RECALL

Drugs Manufactured by Astral SteriTech Pvt. Ltd. and Distributed by Civica, Inc., Meitheal Pharmaceuticals, Piramal Critical Care, and Xellia Pharmaceuticals

Refer to the Appendix for the complete list of affected products.

Dear Customer,

This letter is to inform you that Astral SteriTech Pvt. Ltd. (Astral) is initiating a voluntary recall of all products manufactured at its facility in Vadodara, Gujarat, India that are still within expiry as of the date of this letter. These affected products are sterile antibiotic powders for injection that were manufactured between May 2020 and April 2023. These products were distributed by and labeled in the names of the following distribution partners: **Civica, Inc., Meitheal Pharmaceuticals, Piramal Critical Care, or Xellia Pharmaceuticals**. Please refer to the **Appendix** for a complete list of affected products, including NDC numbers.

Reason for Recall

The recall is being initiated due to quality concerns Astral identified while investigating out-of-specification results in environmental monitoring at its manufacturing facility. Because of these concerns, the sterility of products manufactured at Astral's facility cannot be assured.

To date, Astral has not received reports of adverse events relating to this issue. Intravenous or intramuscular administration of a product for which sterility cannot be assured could result in serious systemic infections. Further distribution or use of these products should cease immediately.

Requested Actions

Please take the following actions to implement this recall.

1. Immediately examine your inventory, discontinue use, and quarantine all recalled products.
2. Complete **both pages** of the enclosed "Recall Response Form / Packing Slip" and email to astralsteritech8451@sedgwick.com or fax to 1-888-345-4261 as soon as possible. Please return the response form even if you do not have any inventory in your possession.
3. Using the enclosed pre-paid return label, return all products and provide a copy of **both pages** of the Recall Response Form / Packing Slip to: Sedgwick Brand Protection, Attn: Event #8451, 2670 Executive Dr., Suite A, Indianapolis, IN 46241.
4. If you have further distributed the recalled products, please send a list of any accounts or additional locations which may have received the recalled product from you to Sedgwick at astralsteritech8451@sedgwick.com. We will contact these accounts or locations directly with instructions for returning affected product.

If you received this notification without the prepaid return label or response form, need additional return labels, have large volumes of affected product (e.g., pallets) to return via freight pickup, or have questions regarding the return procedure, please contact Sedgwick at 1-888-719-5826 (Mon.-Fri. 8 am-5 pm ET). Reimbursement for products you return to Sedgwick will be handled via the distribution partner or supplier from which you purchased products, pending return verification.

This recall is being initiated with the knowledge of the U.S. Food and Drug Administration and is being carried out to the user level.

At Astral, the health and safety of the patients who use our products is our top priority. We apologize for the inconvenience this recall may cause and thank you for your cooperation. If you have any questions, please contact Sedgwick at 1-888-719-5826 (Mon.-Fri. 8 am-5 pm ET).

Yours sincerely,

Astral SteriTech Pvt. Ltd.

APPENDIX – List of Recalled Products

Product Description	Distributor Name on Label	Strength	NDC Number
Ampicillin Sodium USP (sterile)	Piramal Critical Care	250mg	66794-220-41
	Piramal Critical Care	500mg	66794-221-41
	Piramal Critical Care	1g	66794-222-41
	Piramal Critical Care	2g	66794-223-41
	Piramal Critical Care	10g	66794-224-15
	Xellia Pharmaceuticals	250mg	70594-084-02
	Xellia Pharmaceuticals	500mg	70594-085-02
	Xellia Pharmaceuticals	1g	70594-086-02
	Xellia Pharmaceuticals	2g	70594-087-02
	Xellia Pharmaceuticals	10g	70594-088-01
Ampicillin & Sulbactam For Injection USP (Sterile Mixture 2:1)	Civica, Inc.	1.5g	72572-021-10
	Civica, Inc.	3g	72572-022-10
	Meitheal Pharmaceuticals	1.5g	71288-005-20
	Meitheal Pharmaceuticals	3g	71288-006-30
	Meitheal Pharmaceuticals	15g	71288-007-75
	Piramal Critical Care	1.5g	66794-206-41
	Piramal Critical Care	1.5g	66794-241-41
	Piramal Critical Care	3g	66794-207-41
	Piramal Critical Care	3g	66794-242-41
	Piramal Critical Care	15g	66794-208-15
	Piramal Critical Care	15g	66794-243-15
	Xellia Pharmaceuticals	1.5g	70594-081-02
	Xellia Pharmaceuticals	3g	70594-082-02
	Xellia Pharmaceuticals	15g	70594-083-01
Cefepime for Injection (Mixture of Cefepime HCl and L-arginine) Sterile	Civica, Inc.	1g	72572-057-10
	Civica, Inc.	2g	72572-058-10
	Meitheal Pharmaceuticals	2g	71288-009-20
	Piramal Critical Care	1g	66794-209-41
	Piramal Critical Care	2g	66794-210-41
	Xellia Pharmaceuticals	1g	70594-089-02
	Xellia Pharmaceuticals	2g	70594-090-02
Ceftriaxone Sodium Sterile	Piramal Critical Care	250mg	66794-211-42
	Piramal Critical Care	500mg	66794-212-42
	Piramal Critical Care	1g	66794-213-42
	Piramal Critical Care	2g	66794-214-42
	Piramal Critical Care	10g	66794-215-15
	Xellia Pharmaceuticals	250mg	70594-094-02
	Xellia Pharmaceuticals	500mg	70594-095-02
	Xellia Pharmaceuticals	1g	70594-096-02
	Xellia Pharmaceuticals	2g	70594-097-02
	Xellia Pharmaceuticals	10g	70594-098-01
Piperacillin Sodium + Tazobactam Sodium (8:1) Sterile	Civica, Inc.	3.375g	72572-576-10
	Civica, Inc.	4.5g	72572-577-10
	Meitheal Pharmaceuticals	2.25g	71288-002-31
	Meitheal Pharmaceuticals	3.375g	71288-003-31
	Meitheal Pharmaceuticals	4.5g	71288-004-51
	Piramal Critical Care	2.25g	66794-216-41
	Piramal Critical Care	3.375g	66794-217-41
	Piramal Critical Care	4.5g	66794-218-41
	Xellia Pharmaceuticals	2.25g	70594-078-02
	Xellia Pharmaceuticals	3.375g	70594-079-02
	Xellia Pharmaceuticals	4.5g	70594-080-02

RECALL RESPONSE FORM / PACKING SLIP – PAGE 1 OF 2

Please review and check ALL applicable boxes and return completed response form by email to astralsteritech8451@sedgwick.com or by fax to 1-888-345-4261.

PLEASE MAKE SURE TO SUBMIT BOTH PAGES OF THIS RESPONSE FORM.

- I have read and understand the instructions provided in the Recall Notification.
- I do not have any recalled products in my possession.
- I have specified the quantity of each product I am returning in the Recalled Products Being Returned table on the following page.
- I will return all recalled products using the enclosed pre-paid return label.
- I will call Sedgwick at 1-888-719-5826 (Mon.-Fri. 8 am-5 pm ET) to schedule a freight pickup.
- I have provided a list of my accounts/customers who may have received the recalled products to Sedgwick at astralsteritech8451@sedgwick.com.

Any adverse events associated with recalled products?

- Yes No

If yes, please explain: _____

If applicable, identify the wholesaler from which you purchased the products you are returning:

Please check the appropriate box(es) to describe your business:

- | | | |
|--|--|---------------------------------|
| <input type="checkbox"/> Wholesaler/distributor | <input type="checkbox"/> Pharmacy - retail | <input type="checkbox"/> Other: |
| <input type="checkbox"/> Hospital/medical facility | <input type="checkbox"/> Hospital Pharmacy | |

Name: _____

Email: _____ Tel. number: _____

Company/Facility: _____

Address: _____

City, State Zip: _____

Date: _____

PLEASE INCLUDE A COPY OF THIS RESPONSE FORM, INCLUDING THE LIST OF RECALLED PRODUCTS BEING RETURNED, IN YOUR RETURN PACKAGE.

If you have any questions, please contact Sedgwick at astralsteritech8451@sedgwick.com or by phone at 1-888-719-5826 (Mon.-Fri. 8 am-5 pm ET).

RECALL RESPONSE FORM / PACKING SLIP – PAGE 2 OF 2

Recalled Products Being Returned					
Product Description	Distributor Name on Label	Strength	NDC Number	Product Being Returned	
				Cartons	Loose Vials
Ampicillin Sodium USP (sterile)	Piramal Critical Care	250mg	66794-220-41		
	Piramal Critical Care	500mg	66794-221-41		
	Piramal Critical Care	1g	66794-222-41		
	Piramal Critical Care	2g	66794-223-41		
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