Meitheal Pharmaceuticals
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631

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Customer Notification Recall Communication Letter

Urgent: Cisatracurium Besylate Injection, USP 10mg per 5mL RECALL

January 27, 2021

Dear Valued Customer:

This letter is to inform you that Meitheal Pharmaceuticals, Inc. ("Meitheal") is voluntarily recalling the following product:

Product	Lot Number	Expiration Date	NDC Number	Distribution Dates
Cisatracurium Besylate Injection, USP 10mg per 5mL	C11507A*	October 2021*	71288-712-06 (unit of sale) 71288-712-05 (unit of use)	August 19, 2020 – January 04, 2021
*Note: Mis-labeled product will have this same Lot Number of C11507A and Expiration Date of October 2021 but will be labeled on the vial as Phenylephrine Hydrochloride Injection, USP 100mg per 10mL, NDC 71288-808-77 (unit of use).				

This recall is being made with the knowledge of the Food and Drug Administration and has been initiated after a product complaint revealed that a portion of Lot C11507A of cartons labeled as Cisatracurium Besylate Injection, USP 10mg per 5mL, containing 10-vials per carton, contained 10-vials mis-labeled as Phenylephrine Hydrochloride Injection 100mg per 10mL.

There is a reasonable probability that a patient who requires cisatracurium for muscle paralysis as part of general anesthesia is administered phenylephrine instead would not receive any skeletal muscle relaxation and could cause a hyperadrenergic state resolution in elevated blood pressure, arrhythmia and cardiac/brain ischemia. If this is not quickly diagnosed and treated, severe illness or death can occur.

There is a reasonable probability that a patient who requires phenylephrine to increase their blood pressure, such as patients with severely low blood pressure, especially resulting from septic shock who is administered cisatracurium instead could result in a fast onset of muscle paralysis and decrease in oxygen. If this is not quickly diagnosed and treated, severe illness or death can occur within minutes.

To date, Meitheal has not received reports of any adverse events or identifiable safety concerns attributed to the lot listed in the table above.

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to the recall.
2. Immediately discontinue distribution of the above listed lot. Meitheal will issue a credit memo or check covering the quantity of your returned product.

3. Return product to:
   Integrated Commercialization Solutions, Inc. (ICS)
   420 International Blvd, Suite 500
   Brooks, KY 40109

   NOTE: Return shipment is free of charge. A Return Goods Authorization (RGA), a pre-printed, pre-paid return label will be provided to you for product return. Contact Customer Service at 844-824-8426, for an RGA.
4. If you have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers should include a copy of this recall notification letter and response form.
5. Please complete and return the enclosed "Customer Recall Return Response Form" as soon as possible and email the completed form to MeithealPharmaReturns@icsconnect.com.

This recall should be carried out to the **user level.**

Your assistance is greatly appreciated. We apologize for any inconvenience this may cause you.

If you have any questions, please do not hesitate to call our Customer Service at 844-824-8426, weekdays 8:00AM to 6:00PM CST, to address any concerns that you may have.

Gail Giambi

Gail Giambi
Vice President of Quality
Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60613
ggiambi@meithealpharma.com
(o) 224-443-4526
(c) 847-271-3778

Incorrect Labeling Observed:

Photo of the Mislabel Product being recalled:

Meitheal Pharmaceuticals
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Chicago, IL 60631

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CUSTOMER RECALL RETURN RESPONSE FORM

PLEASE EMAIL TO MeithealPharmaReturns@icsconnect.com

Product	Lot Number	NDC Number
Cisatracurium Besylate Injection, USP 10mg per 5mL	C11507A	71288-712-06 (unit of sale) 71288-712-05 (unit of use)

Please check ALL appropriate boxes:

□ I have read and understand the recall instructions provided in the Customer Notification Recall Communication Letter dated January 27, 2021.

□ I have checked my stock and do not have any stock of the recall lot.

OR

□ I have checked my stock and have quarantined inventory consisting of _____ units of the recall lot. The recalled units will be returned to ICS as soon as possible.

□ I have identified and notified my customers that were shipped or may have been shipped this product and have communicated that we are conducting a sub-recall to our direct account customers. This recall should be carried out to the user level.

Have there been any Adverse Events associated with the recalled product? □ Yes □ No
If yes, pleas explain:_____

Please check the appropriate box(es) to describe your business
□ wholesaler/distributor □ retailer □ pharmacy-retail
□ hospital pharmacies □ hospital/medical facility □ medical laboratory
□ Other:_____

Please Complete Contact Information for Person Completing Response:	
Name:	
Title:	
Phone #:	
Facility:	
Address:	
City, State, Zip:	