CLARIFICATION: A notice issued 1/26/21 by the Board of Pharmacy incompletely identified the product recalled by Meitheal Pharmaceuticals as "cisatracurium." The recalled product is properly identifed as "cisatracurium besylate injection, USP 10mg per 5mL."

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

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: Mislabeled 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 to the user level. This recall has been 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 mislabeled 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.

For additional information, read the Meitheal announcement on the FDA website: Meitheal Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Cisatracurium Besylate Injection, USP 10mg per 5mL Due to Mislabeling.