

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.

This Notice of Recall is to inform you that Exela Pharma Sciences, Inc. (“Exela”) has initiated a product recall involving Sodium Bicarbonate Injection, USP 8.4% 50mL, Lots 10006417 and 10006418.

On FEB 28, 2025, Exela received complaints indicating that some vials of Sodium Bicarbonate Injection, USP 8.4% 50mL, Lot 10006418 had an insufficient crimp on the cap and stopper which resulted in the same to dislodge from the vial. The insufficient crimp on the cap and stopper may expose the drug product to the environment and could potentially impact the sterility and purity of the product. There are no known sterility failures or adverse health events as of this date. There are no known injuries to any personnel.

Exela began distributing Sodium Bicarbonate Injection, USP 8.4% 50mL, Lot 10006417 on FEB 13, 2025 and Sodium Bicarbonate Injection, USP 8.4% 50mL, Lot 10006418 on FEB 5, 2025.

<u>Date</u>	<u>Transaction ID</u>	<u>Lot</u>	<u>Cartons</u>	<u>Vials</u>
06FEB2025	80007515	10006417	70	1,750
06FEB2025	80007515	10006417	132	3,300
06FEB2025	80007515	10006417	132	3,300
06FEB2025	80007515	10006417	132	3,300
06FEB2025	80007515	10006417	132	3,300
06FEB2025	80007515	10006417	132	3,300
13FEB2025	80007557	10006417	100	2,500
13FEB2025	80007557	10006417	132	3,300
13FEB2025	80007557	10006417	132	3,300
13FEB2025	80007557	10006417	132	3,300
13FEB2025	80007557	10006417	62	1,550
Total:	1,420	35,500		

<u>Date</u>	<u>Transaction ID</u>	<u>Lot</u>	<u>Cartons</u>	<u>Vials</u>
13FEB2025	80007557	10006418	102	2,550
13FEB2025	80007557	10006418	132	3,300
Total:	134	3,350		

	<u>Cartons</u>	<u>Vials</u>
Total Lot 10006417	1,420	35,500
Total Lot 10006418	<u>134</u>	<u>3,350</u>
Total:	1,760	44,000