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 is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is recalling the below-mentioned lot of Morphine Sulfate Injection USP, Simplist®2 mg / 1 mL, 1 mL fill in a single dose 1 mL Simplist®prefilled syringe.

This recall is being conducted to the user level. Fresenius Kabi is taking this precautionary action following a report that a small number of correctly labeled Dilaudid® (HYDROmorphone HCl) Injection, USP Simplist® 0.5 mg/0.5 mL syringes (lot 6402813) were inadvertently mixed into a subsequent packaging lot and distributed in cartons labeled as Morphine Sulfate Injection USP, Simplist® 2 mg/1 mL (lot 6402820). The investigation revealed that this issue is limited to the product and lot indicated below.

Use of a MicroVault labeled as Morphine Sulfate Injection 2 mg/mL containing a prefilled syringe of Dilaudid (hydromorphone HCl) 0.5 mg/0.5 mL has a reasonable probability of causing serious adverse health consequences, including life-threatening respiratory depression and death. Patients at greatest risk include individuals who do not use opioids on a regular basis, those with underlying respiratory disease, pediatric patients, and those who are also taking central nervous system (CNS) depressants. To date, no adverse reports have been received for this lot number.

PRODUCT: Morphine Sulfate Injection USP, Simplist® 2 mg / 1 mL, 1 mL fill in a single dose 1 mL Simplist® prefilled syringe

NDC NUMBER: 76045-004-01

LOT NUMBER: 6402820

EXPIRATION DATE: 12/2028

DISTRIBUTION DATES: 01/29/2026 - 06/09/2026

PRODUCT CODE: 764411