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 above-mentioned batches of Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to out-of-specification (OOS) endotoxin results of certain reserve samples for batch 6133194 that were tested as part of an investigation for non-serious adverse event reports. Based upon current investigation, batches 6133156 and 6133388 are also included in this recall as a precautionary measure.

The Health Hazard Evaluation concluded moderate risk to patients. Non-serious adverse event reports potentially associated with the OOS have been received for batch 6133194. No adverse event reports have been received for batches 6133156 and 6133388 to date. Elevated endotoxin levels can precipitate severe systemic reactions such as sepsis and septic shock. Severe responses may include inflammatory and life-threatening immune responses and death.

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial	63323-739-11	63323-739-12	730912	6133156	08/2026	01/02/2025	02/11/2025
				6133194	08/2026	02/04/2025	04/11/2025
				6133388	10/2026	04/15/2025	05/23/2025