

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 provides important information concerning the recall of a limited number of lots of Leiters Health's 5 mL syringe products identified below. Leiters Health has identified a container defect (specifically, cracks in these syringes) in a small number of units of these lots. We have not received any reports of adverse events associated with these lots; however, out of an abundance of caution, Leiters Health is recalling these lots.

The root cause of this defect is due to a design issue with a transfer rail on a new piece of semi automated labeling equipment. This issue has caused damage to a small number of the syringes in these lots during the labeling process, causing cracks in the syringes.

Item Number	NDC Number	Established Drug Name	Lot Number	Expiration Date
F3106	71449-104-11	Glycopyrrolate 0.2 mg/mL, 5 mL in 5 mL Syringe	2431015B	4/10/2025
F3151	71449-131-11	Dexmedetomidine HCl 4 mcg/mL PF (from API) in 0.9% Sodium Chloride, 5 mL in 5 mL Syringe	2431276A	4/20/2025
F3001	71449-068-11	Phenylephrine HCl 100 mcg/mL in 0.9% Sodium Chloride, 5mL in 5 mL Syringe	2431349A	6/16/2025
F3080	71449-068-11	Ketamine HCl 10 mg/mL (from API), 5 mL in a 5 mL Syringe	2530019	7/10/2025
F3012	71449004-11	Rocuronium Bromide 10 mg/mL, 5 mL in 5 mL Syringe	2530023	7/12/2025

F3080

71449-068-
11

Ketamine HCl 10 mg/mL (from API),
5 mL in a 5mL Syringe

2530053

7/19/2025