

This letter is to provide you with important information concerning the recall of a limited number of lots of six IV bag products produced by Leiters Health due to a potency concern.

While we have not received any reports of adverse events or customer complaints associated with this concern, out of an abundance of caution and after consultation with FDA, we are initiating a voluntary recall on a limited number of lots of IV bags with this concern.

Affected product list:

Item Number	NDC Number	Product Description
F3355	71449-072-41	FentaNYI 1000 mcg (10 mcg/ml) (as FentaNYI Citrate) PF (from API) added to 0.9% Sodium Chloride <u>100 ml IV bag</u>
F3342	71449-072-82	FentaNYI 2500 mcg (10 mcg/ml) (as FentaNYI Citrate) PF (from API) added to 0.9% Sodium <u>Chloride 250ml IV bag</u>
F3360	71449-148-94	Phenylephrine HCl 20 mg (80 mcg/mL) (from FDP) added to 0.9% Sodium <u>Chloride 250 ml IV Bag</u>
F3352	71449-150-82	Phenylephrine HCl 40 mg (160 mcg/ml) (from FDP) added to 0.9% Sodium Chloride 250 ml IV Bag
F3206	71449-028-68	Vancomycin HCl 1.25 g PF added to 0.9% Sodium Chloride 250 ml IV Bag
F3208	71449-029-68	Vancomycin HCl 1.5 g PF added to 0.9% Sodium Chloride 250 ml IV Bag

With the following lot numbers:

Lot Number	Item Number	Expiration
2330939	F3352	1/30/2024
2330988	F3342	1/31/2024
2330993	F3360	2/15/2024
2331010	F3360	2/10/2024
2331032	F3352	2/3/2024
2331055	F3360	1/18/2024
2331058	F3342	2/18/2024
2331062	F3355	2/8/2024
2331112	F3352	3/19/2024
2331113	F3360	2/26/2024
2331140	F3208	2/8/2024
2331150	F3342	3/10/2024
2331181	F3360	3/4/2024
2331184	F3206	2/13/2024

2331185	F3206	2/10/2024
2331187	F3360	3/23/2024
2331188	F3208	2/16/2024
2331189	F3206	2/20/2024
2331190	F3352	3/26/2024
2331191	F3206	2/24/2024
2331224	F3355	3/18/2024
2331231	F3342	3/24/2024
2331258	F3206	3/2/2024
2331261	F3208	3/6/2024
2331266	F3360	3/31/2024
2331270	F3355	3/28/2024
2331287	F3208	3/14/2024
2331289	F3342	3/30/2024
2331317	F3206	3/15/2024
2331343	F3360	4/1/2024
2331349	F3360	4/23/2024
2331429	F3352	4/28/2024
2331433	F3360	5/5/2024

Corrective Action Taken:

An immediate corrective action to fully weigh every IV bag has been implemented for any batches still in Leiters Health's control prior to releasing any additional batches. This change will also be used for any new batches produced until other corrective or preventive actions can be put in place for the IV bag process.

