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Leiters Health Issues Voluntary Nationwide Recall of Vancomycin IV Bags, Phenylephrine IV Bags, and Fentanyl IV Bags due to Potential for Superpotent Drug

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FOR IMMEDIATE RELEASE – January 5, 2024 – Englewood, Colorado, Leiters Health is voluntarily recalling 33 lots of products listed below to the user level. The recalled batches of vancomycin IV bags, phenylephrine IV bags, and fentanyl IV bags are being recalled due to the potential for superpotency because they may contain twice the labeled amount of drug. The semi-automated IV bag filling equipment used to fill the recalled batches may not eject the IV bags properly when compressed air tanks become low or a leak was detected, causing the recalled IV bags to be dosed twice.

Item #	Product Description	Lot #	Expiration
F3355	FentaNYL 1000 mcg (10 mcg/mL) (as FentaNYL Citrate) PF (from API) added to 0.9% Sodium Chloride 100 mL IV bag	2331062	2/8/2024
		2331224	3/18/2024
		2331270	3/28/2024
F3342	FentaNYL 2500 mcg (10 mcg/mL) (as FentaNYL Citrate) PF (from API) added to 0.9% Sodium Chloride 250 mL IV bag	2330988	1/31/2024
		2331058	2/18/2024
		2331150	3/10/2024
		2331231	3/24/2024
		2331289	3/30/2024
F3360	Phenylephrine HCl 20 mg (80 mcg/mL) (from FDP) added to 0.9% Sodium Chloride 250 mL IV Bag	2330993	2/15/2024
		2331010	2/10/2024
		2331055	1/18/2024
		2331113	2/26/2024
		2331181	3/4/2024
		2331187	3/23/2024
		2331266	3/31/2024
		2331343	4/1/2024
		2331349	4/23/2024

		2331433	5/5/2024
F3352	Phenylephrine HCl 40 mg (160 mcg/mL) (from FDP) added to 0.9% Sodium Chloride 250 mL IV Bag	2330939	1/30/2024
		2331032	2/3/2024
		2331112	3/19/2024
		2331190	3/26/2024
		2331429	4/28/2024
F3206	Vancomycin HCl 1.25 g PF added to 0.9% Sodium Chloride 250 mL IV Bag	2331184	2/13/2024
		2331185	2/10/2024
		2331189	2/20/2024
		2331191	2/24/2024
		2331258	3/3/2024
		2331317	3/15/2024
F3208	Vancomycin HCl 1.5 g PF added to 0.9% Sodium Chloride 250 mL IV Bag	2331140	2/8/2024
		2331188	2/15/2024
		2331261	3/5/2024
		2331287	3/14/2024

Risk Statement: There is a reasonable probability that the use of the defective vancomycin and fentanyl IV bags will be associated with life-threatening adverse events. Administration of vancomycin at twice the infusion rate has been associated with low blood pressure, including shock and cardiac arrest, as well as wheezing, shortness of breath, hives, itchy skin and skin redness. Also, overdosing of vancomycin may be associated with acute kidney injury and ototoxicity. Administration of higher doses of fentanyl than intended can result in profound respiratory depression, which may not automatically be mitigated and treated, resulting in potential for delay in care and serious adverse outcomes from hypoxia, including permanent neurologic sequelae and death. In addition to respiratory depression, fentanyl can cause serious cardiac adverse events, such as hypotension, bradycardia, and vasodilation resulting in decrease in cardiac output and cardiac arrest. In addition, administration of a higher dose of phenylephrine than intended may cause higher-than-intended blood pressures in some patients.

To date, Leiters Health has not received any reports of adverse events related to this recall.

Fentanyl is an analgesic packaged in an IV bag under codes F3355 and F3342.

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Phenylephrine is used for perioperative hypotension, hypotension during anesthesia, and shock and is packaged in an IV bag under codes F3360 and F3352.

Vancomycin is used for endocarditis and staphylococcal infections and is packaged in an IV bag under codes F3206 and F3208.

The products were distributed nationwide to hospitals for administration in the hospital. Leiters Health has notified its customers by a letter sent via mail, requiring signature upon receipt, and an email to all affected customers. Leiters Health is arranging for a credit for all recalled products. Customers that have product which is being recalled should cease using it and return it to Leiters Health.

Consumers with questions regarding this recall can contact Leiters Health by phone at 1-800-292-6772 or e-mail at recall@leiters.com Monday through Friday between 8:00 AM MST and 5:30 PM MST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products. Customers will receive return shipping labels for phenylephrine and vancomycin returns via email from Leiters Health to return their products to Leiters Health at 13796 Compark Blvd., Englewood, CO 80112. Customers will receive return shipping labels, along with a DEA Form 222, for fentanyl returns via mail from Leiters Health to return their products to Leiters Health at 13796 Compark Blvd., Englewood, CO 80112.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm[1]
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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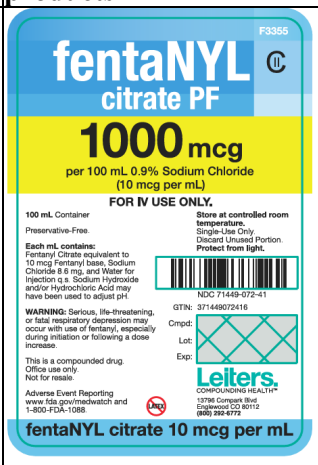
Item Number	Primary label of the products	Secondary/Tertiary label of the products
F3355		**fentaNYL citrate PF 1000 mcg** II per 100 mL 0.9% Sodium Chloride (10 mcg per mL) Item F3355 FOR IV USE ONLY. 100 mL Container **Each mL contains:** Fentanyl Citrate equivalent to 10 mcg Fentanyl base, Sodium Chloride 8.6 mg, and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH. **Preservative-Free.** **WARNING:** Serious, life-threatening, or fatal respiratory depression may occur with use of fentanyl, especially during initiation or following a dose increase. **Protect From Light** **Store at 20° to 25°C (68° to 77°F)** Single-Use Only. Discard Unused Portion. GTIN: **371449072416** Date Cmpd: **01/12/2021** Lot Number: **YY3XXXX** Expiration: **01/13/2021** Leiters. 13796 Compark Blvd Englewood CO 80112 **800-292-6772** NDC: 71449-072-41 Adverse Event Reporting www.fda.gov/medwatch and 1-800-FDA-1088
F3342		**fentaNYL citrate PF** II 2500 mcg per 250 mL (10 mcg per mL) Item F3342 FOR IV USE ONLY. 250 mL Container **Each mL contains:** Fentanyl Citrate equivalent to 10 mcg Fentanyl base, Sodium Chloride 8.8 mg, and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH. **Preservative-Free.** **WARNING:** Serious, life-threatening, or fatal respiratory depression may occur with use of fentanyl, especially during initiation or following a dose increase. **Protect From Light** **Store at 20° to 25°C (68° to 77°F)** Single-Use Only. Discard Unused Portion. GTIN: **371449072829** Date Cmpd: **01/12/2021** Lot Number: **YY3XXXX** Expiration: **01/13/2021** Leiters. 13796 Compark Blvd Englewood CO 80112 **800-292-6772** NDC: 71449-072-82 Adverse Event Reporting www.fda.gov/medwatch and 1-800-FDA-1088
F3360		**PHENYLephrine HCl 20 mg** per 250 mL 0.9% Sodium Chloride (80 mcg per mL) Item F3360 FOR IV USE ONLY. 250 mL Container **Each mL contains:** Phenylephrine Hydrochloride 80 mcg, Sodium Chloride 8.9 mg, Sodium Citrate Dihydrate 32 mcg, Citric Acid Monohydrate 8 mcg, Sodium Metabisulfite 16 mcg, and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH. **Contains Sulfites.** **Protect From Light** **Store at 20° to 25°C (68° to 77°F)** Single-Use Only. Discard Unused Portion. GTIN: **371449148944** Date Cmpd: **01/12/2021** Lot Number: **YY3XXXX** Expiration: **01/13/2021** Leiters. 13796 Compark Blvd Englewood CO 80112 **800-292-6772** NDC: 71449-148-94 Adverse Event Reporting www.fda.gov/medwatch and 1-800-FDA-1088

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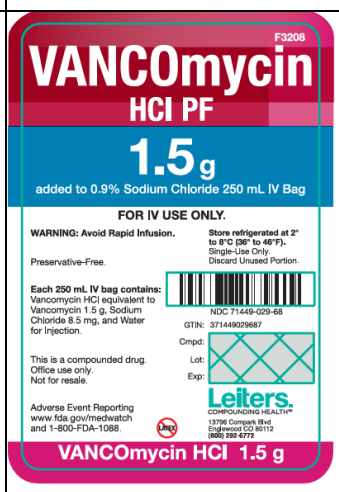
F3352		**PHENYLephrine HCl 40 mg** per 250 mL 0.9% Sodium Chloride (160 mcg per mL) Item F3352 FOR IV USE ONLY. 250 mL Container **Each mL contains:** Phenylephrine Hydrochloride 160 mcg, Sodium Chloride 8.8 mg, Sodium Citrate Dihydrate 64 mcg, Citric Acid Monohydrate 16 mcg, Sodium Metabisulfite 32 mcg, and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH. **Contains Sulfites.** **Protect From Light** **Store at 20° to 25°C (68° to 77°F)** Single-Use Only. Discard Unused Portion. GTIN: **371449150824** Date Cmpd: **01/12/2021** Lot Number: **YY3XXXX** Expiration: **01/13/2021** Leiters. 13796 Compark Blvd Englewood CO 80112 800-292-6772 NDC: 71449-150-82 Adverse Event Reporting www.fda.gov/medwatch and 1-800-FDA-1088
F3206		**VANCOmycin HCl PF 1.25 g** added to 0.9% Sodium Chloride 250 mL IV Bag Item F3206 FOR IV USE ONLY. **Each 0.9% Sodium Chloride 250 mL IV bag contains:** Vancomycin HCl equivalent to Vancomycin 1.25 g and Water for Injection. Preservative-Free. WARNING: Avoid Rapid Infusion. **Store refrigerated at 2° to 8°C (36° to 46°F)** Single-Use Only. Discard Unused Portion GTIN: **371449028680** Date Cmpd: **01/12/2021** Lot Number: **YY3XXXX** Expiration: **01/12/2021** Leiters Health 13796 Compark Blvd Englewood CO 80112 800-292-6772 NDC: 71449-028-68 Adverse Event Reporting www.fda.gov/medwatch and 1-800-FDA-1088
F3208		**VANCOmycin HCl PF 1.5 g** added to 0.9% Sodium Chloride 250 mL IV Bag Item F3208 FOR IV USE ONLY. **Each 0.9% Sodium Chloride 250 mL IV bag contains:** Vancomycin HCl equivalent to Vancomycin 1.5 g and Water for Injection. Preservative-Free. WARNING: Avoid Rapid Infusion. **Store refrigerated at 2° to 8°C (36° to 46°F)** Single-Use Only. Discard Unused Portion GTIN: **371449029687** Date Cmpd: **01/12/2021** Lot Number: **YY3XXXX** Expiration: **01/12/2021** Leiters Health 13796 Compark Blvd Englewood CO 80112 800-292-6772 NDC: 71449-029-68 Adverse Event Reporting www.fda.gov/medwatch and 1-800-FDA-1088