
From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, January 10, 2018 4:33 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: PharMEDium Services, LLC Expands Voluntary Nationwide Recall of Additional Lots of Compounded Sterile Products Within Expiry Due to Lack of Sterility Assurance

PharMEDium Services, LLC Expands Voluntary Nationwide Recall of Additional Lots of Compounded Sterile Products Within Expiry Due to Lack of Sterility Assurance

Contact

Consumers

PharMEDium Services, LLC
Leigh Briscoe-Dwyer, Vice President Clinical Affairs
(847) 457-2801
lbriscoe@pharmedium.com

Media

Andrew Harrison, Vice President of Legal and Compliance
(847) 457-2271
sbahl@pharmedium.com

Sanjeev Bahl, Vice President Quality
(847) 457-2256
sbahl@pharmedium.com

For Immediate Release- January 10, 2018 Lake Forest, IL PharMEDium Services, LLC (PharMEDium) is voluntarily expanding the recall issued on December 27, 2017 to include [the below lots](#) of sterile drug products to the hospital/user level due to a lack of assurance of sterility. Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. To date, PharMEDium has not received any reports of adverse events related to the products but is issuing this recall out of an abundance of caution following a commitment made during a recent inspection of the company's facility.

The recall is being expanded because PharMEDium conducted an extensive review of all commercially distributed product lots compounded in the Memphis location currently within their labeled expiration date in response to an FDA request regarding microbial program controls for the ISO5 environment, personnel glove sampling results, media fill results, sterility testing results, and endotoxin results following the most recent inspection. The original recall included a total of 55 lots of different products impacting 25,327 units. The expanded recall includes all lots within expiry compounded at our Memphis, TN facility. Finished product release testing for both sterility and endotoxin were acceptable for all lots. Although there were no defects identified in these products, as a conservative measure, this recall is being expanded.

The products can be identified by referring to the sample labels provided below. These products were distributed nationwide in the USA to hospitals/clinics. A complete list of all recalled products can be found on pharmedium.com.

PharMEDium Services is notifying customers of the voluntary recall by phone and email. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy

per their hospital protocol. Customers with any of the affected medications can also reference PharMEDium Services website (pharmedium.com) for more information on the specific lot numbers affected and contact information.

Patients and healthcare providers with questions regarding this recall can contact PharMEDium Services Clinical Pharmacist at 1-800-523-7748, Monday through Friday, between 8am and 5pm Central Standard Time or via e-mail at recall17023@pharmedium.com.

Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.

Adverse reactions or quality problems experienced with the use of this product 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
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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.

Lots Affected:

Service Code	Product Description	Lot Number
2K8880	2 mcg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172790045M
2K8468	2 mcg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172790055M
2K8889	2 mcg/mL Fentanyl Citrate and 0.15% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172790091M
2P8652	1 mg/mL Morphine Sulfate in 0.9% Sodium Chloride	172790111M
2P6179	1 mg/mL Morphine Sulfate (Preservative Free) in 0.9% Sodium Chloride	172790115M
2T6165	1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride	172790156M
2K8124	2 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172820087M
3357NO-K25	20 mg/mL Succinylcholine Chloride Injection (Preserved) Kit Check Tagged	172820144M
2K8490	2 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172910035M
2K8191	0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172910106M
3217NO-K25	0.2 mg/mL Glycopyrrolate 3 mL in 3 mL BD Syringe Kit Check Tagged	172910127M
2R3303-5	50 mcg/mL Fentanyl Citrate (Preservative Free) Injection	172910135M
2K8453	5 mcg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172910154M
2P6165	1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride	172930052M

2K9115	4 mcg/mL Fentanyl Citrate (Preservative Free) in 0.9% Sodium Chloride	172930100M
2K8204	2 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	172970053M
3303NO-K25	50 mcg/mL Fentanyl Citrate (Preservative Free) Injection Kit Check Tagged	172970130M
2T6663	10 mcg/mL Fentanyl Citrate (Preservative Free) in 0.9% Sodium Chloride	172970158M
2R3303-5	50 mcg/mL Fentanyl Citrate (Preservative Free) Injection	172980111M
2K9037	1 mg/mL Midazolam HCl (Preservative Free) in 0.9% Sodium Chloride Injection USP	172980202M
2K8498	1 mg/mL Morphine Sulfate (Preservative Free) in 0.9% Sodium Chloride	173020065M
2K9100	0.5 mg/mL Midazolam HCl in 0.9% Sodium Chloride	173020131M
2T6231	3 mg/mL Adenosine Injection 30 mL in 30 mL BD Syringe	173020134M
2K8638	4 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	173020141M
2K8241	3 mcg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	173020185M
2R3306-K5	50 mcg/mL Fentanyl Citrate (Preservative Free) Injection Kit Check Tagged	173020228M
2R3333-5	50 mg/mL Ephedrine Sulfate Injection (Preservative Free)	173020233M
2T6455	2 mg/mL Morphine Sulfate in 0.9% Sodium Chloride	173030008M
2P8652	1 mg/mL Morphine Sulfate in 0.9% Sodium Chloride	173030017M
3303NO	50 mcg/mL Fentanyl Citrate (Preservative Free) Injection	173030024M
2K8869	2 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	173030050M
2K8643	3 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	173030080M
2K7710	1 mg/mL HYDROMorphone HCl in 0.9% Sodium Chloride	173030114M
2T6827	1 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 5% Dextrose	173030146M
2T6165	1 mg/mL HYDROMorphone HCl in 0.9% Sodium Chloride	173040042M
2T6165	1 mg/mL HYDROMorphone HCl in 0.9% Sodium Chloride	173040043M
2K8292	1 mg/mL Midazolam HCl in 0.9% Sodium Chloride	173040069M
2T6270	1 mg/mL Midazolam HCl in 0.9% Sodium Chloride	173040072M
2M8510	1 mg/mL HYDROMorphone HCl in 0.9% Sodium Chloride	173040078M
2K8120	0.25% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	173040265M
2T6656	5 mg/mL Morphine Sulfate (Preservative Free) in 0.9% Sodium Chloride	173040283M
2T6165	1 mg/mL HYDROMorphone HCl in 0.9% Sodium Chloride	173110038M
2K8468	2 mcg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	173110066M

2K8667	20 mcg/mL Fentanyl Citrate (Preservative Free) in 0.9% Sodium Chloride	173110079M
2T6178	1 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 0.9% Sodium Chloride	173110142M
2K5856	10 mEq Potassium Chloride in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag	173110193M
2T8474	50 mcg/mL Fentanyl Citrate (Preservative Free) Injection	173170055M
3117NO	5 mg/mL Labetalol HCl	173170127M
2K8179	1 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 0.9% Sodium Chloride	173200084M
2R3417-K5	1 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 0.9% Sodium Chloride	173200212M
2K8669	20 mcg/mL Fentanyl Citrate (Preservative Free) in 0.9% Sodium Chloride	173210054M
2K8937	0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride	173210060M
3303NO	50 mcg/mL Fentanyl Citrate (Preservative Free) Injection	173210085M
2T6401	2 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 0.9% Sodium Chloride	173210101M
2R3334-5	0.5% Ropivacaine HCl Injection (Preservative Free)	173210124M

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.