Company Announcement

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Cantrell Drug Company Issues Voluntary Recall of Select Sterile Drug Products Due to Lack of Sterility Assurance

For Immediate Release

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Announcement

Little Rock, AK - Cantrell Drug Company is voluntarily recalling certain unexpired sterile drug products due to lack of sterility assurance.

The recalled products, distributed nationwide to health care facilities from May 25 to October 31, 2016, are the following:

Drug Product Name	NDC	Lot Number	Manufacture Date	Beyond Use Date
CALCIUM CHLORIDE 1 G ADDED TO 5% DEXTROSE 50 ML BAG	52533-175-37	169170	10/15/2016	1/5/2017
CALCIUM CHLORIDE 10 G IN 0.9% SODIUM CHLORIDE 500 ML BAG	52533-102-09	168032	9/12/2016	12/11/2016

Drug Product Name	NDC	Lot Number	Manufacture Date	Beyond Use Date
CALCIUM CHLORIDE 10% INJECTION SOLUTION 10 ML VIAL	n/a	169924	10/26/2016	4/15/2017
FENTANYL CITRATE 10 MCG/ML IN 0.9% SODIUM CHLORIDE 150 ML BAG	52533-024-35	9002	9/6/2016	3/5/2017
FENTANYL CITRATE 10 MCG/ML IN 0.9% SODIUM CHLORIDE 250 ML BAG	52533-024-61	8990	8/31/2016	2/27/2017
FENTANYL CITRATE 2 MCG/ML & BUPIVACAINE HCL 0.125% IN 0.9% SODIUM CHLORIDE 100 ML BAG	52533-080-75	8942	8/23/2016	2/19/2017
FENTANYL CITRATE 2 MCG/ML & BUPIVACAINE HCL 0.125% IN 0.9% SODIUM CHLORIDE 250 ML BAG	52533-080-61	9029	9/12/2016	3/11/2017
FENTANYL CITRATE 2 MCG/ML & BUPIVACAINE HCL 0.125% IN 0.9% SODIUM CHLORIDE 100 ML BAG	52533-080-75	9207	10/19/2016	04/17/2017
GLYCOPYRROLATE 0.2 MG/ML INJECTION SOLUTION 5 ML SYRINGE	52533-028-15	9006	9/7/2016	1/20/2017
GLYCOPYRROLATE 0.2 MG/ML INJECTION SOLUTION 5 ML SYRINGE	52533-028-15	8757	7/18/2016	11/30/2016
GLYCOPYRROLATE 0.2 MG/ML INJECTION SOLUTION 5 ML SYRINGE	52533-028-15	8954	8/24/2016	1/6/2017
GLYCOPYRROLATE 0.2 MG/ML INJECTION SOLUTION 5 ML SYRINGE	52533-028-15	9174	10/11/2016	2/20/2017
HEPARIN SODIUM 0.5 USP UNITS/ML IN 0.45% SODIUM CHLORIDE 2 ML SYRINGE	52533-148-16	9220	10/20/2016	4/18/2017
HEPARIN SODIUM 5,000 USP UNITS ADDED TO 0.9% SODIUM CHLORIDE 1,000 ML BAG	52533-097-24	167081	8/18/2016	2/14/2017
HYDROMORPHONE HCL 0.2 MG/ML IN 0.9% SODIUM CHLORIDE 30 ML SYRINGE	52533-002-03	8742	7/13/2016	1/9/2017
HYDROMORPHONE HCL 1 MG/ML IN 0.9% SODIUM CHLORIDE 30 ML PCA VIAL	52533-006-10	163941	6/21/2016	11/30/2016
HYDROMORPHONE HCL 1 MG/ML IN 0.9% SODIUM CHLORIDE 50 ML SYRINGE	52533-006-04	9016	9/9/2016	3/7/2017
LIDOCAINE HCL 1% INJECTION SOLUTION 10 ML SYRINGE	n/a	165538	7/19/2016	1/8/2017
MIDAZOLAM HCL 1 MG/ML IN 0.9% SODIUM CHLORIDE 50 ML SYRINGE	52533-001-04	169619	10/20/2016	2/7/2017

Drug Product Name	NDC	Lot Number	Manufacture Date	Beyond Use Date
MORPHINE SULFATE 1 MG/ML IN 0.9% SODIUM CHLORIDE 100 ML BAG	52533-160-75	8625	6/18/2016	12/15/2016
NEOSTIGMINE METHYLSULFATE 1 MG/ML INJECTION SOLUTION 5 ML SYRINGE	52533-046-15	8997	9/2/2016	12/1/2016
NEOSTIGMINE METHYLSULFATE 1 MG/ML INJECTION SOLUTION 5 ML SYRINGE	52533-046-15	9246	10/26/2016	1/23/2017
OXYTOCIN 30 USP UNITS ADDED TO 0.9% SODIUM CHLORIDE 500 ML BAG	52533-056-30	9210	10/19/2016	1/17/2017
PHENYLEPHRINE HCL 100 MCG/ML IN 0.9% SODIUM CHLORIDE 10 ML SYRINGE	52533-171-12	8502	5/25/2016	11/21/2016
PHENYLEPHRINE HCL 100 MCG/ML IN 0.9% SODIUM CHLORIDE 10 ML SYRINGE	52533-171-12	8962	8/25/2016	2/21/2017
ROCURONIUM BROMIDE 10 MG/ML INJECTION SOLUTION 5 ML SYRINGE	52533-064-15	8995	9/1/2016	2/28/2017
ROPIVACAINE HCL 0.25% IN 0.9% SODIUM CHLORIDE 100 ML BAG	52533-185-75	169064	10/20/2016	1/2/2017
SUCCINYLCHOLINE CHLORIDE 20 MG/ML INJECTION SOLUTION 10 ML SYRINGE	52533-067-12	169262	10/11/2016	1/8/2017
SUCCINYLCHOLINE CHLORIDE 20 MG/ML INJECTION SOLUTION 10 ML SYRINGE	52533-067-12	169812	10/24/2016	1/19/2017

Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. The company has not received any reports of adverse events, but is issuing this recall out of an abundance of caution following a recent inspection of the company's facility.

Cantrell Drug Company will begin notifying its customers by email and phone and is arranging for the return of all recalled products. Consumers who have product subject to the recall should stop using it and contact the company.

"Because patient safety is our top priority, we immediately began addressing the issues raised and are working closely with health officials," said Dell McCarley, Chairman & CEO of Cantrell Drug Company. "We have received no reports of injury or illness, and it's important to note that all of our sterile products are tested for sterility before they are shipped. We deeply regret the impact this voluntary recall has on providers and patients, but our culture is one of safety first and we take absolutely no chances."

To return medication or request assistance related to this recall, contact Cantrell Drug Company at 877-666-5222, Monday through Friday between 9 a.m. and 5 p.m. CST.

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.

- Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://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.

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