8/29/13

FDA ANNOUNCES VOLUNTARY RECALLS OF STERILE PRODUCTS BY JCB LABORATORIES (WICHITA, KS) AND WELLNESS PHARMACY (BIRMINGHAM, AL)

The FDA has announced two pharmacies permitted with the NC Board of Pharmacy are voluntarily recalling sterile compounded products. The reason for the recalls is concern that sterility testing provided to the pharmacies by an outside laboratory (Front Range Laboratories) may not have been accurate. Both recalls are voluntary and have been initiated purely as a precautionary matter.

JCB Laboratories, Wichita, Kansas

The following compounded products are subject to the recall:

- **Sodium thiosulfate, 25% (250 mg/mL)** - Lot numbers 130701@9 (Exp. 12/28/13), 130709@6 (Exp. 1/5/14) and 130717@2 (Exp. 1/13/14)
- **Sodium citrate, 4% solution for injection, 30 mL multiple dose vial** - Lot number 130710@4 (Exp. 1/6/14)
- **Sodium citrate, 4% with gentamicin 320 mcg/mL solution for injection, 30 mL multiple dose vial** - Lot number 130620@2 (Exp. 12/17/13)
- **Acetylcysteine, 20% solution for inhalation, 4 mL single dose vials** - Lot number 130627@5 (Exp. 8/26/13)

JCB has not received any reports of adverse events related to this recall to date.

The recalled products were distributed to outpatient dialysis clinics in multiple states from July 8, 2013, through Aug. 20, 2013.

Out of an abundance of caution, JCB has discontinued its relationship with Front Range Laboratories and is now testing products at a different laboratory.

JCB has begun notifying its customers by telephone, email, fax and mail. To return product or request assistance related to this recall, users should contact JCB Laboratories at 316-773-0405, Monday through Friday, between 8:00 a.m. and 5:00 p.m. CDT.

Wellness Pharmacy, Inc., Birmingham, Alabama

Wellness Pharmacy is voluntarily recalling the following medications:

Product Name	Lot#	Expiry
Dexpanthenol 250mg/ml	130605@52	12/2/2013
Magnesium sulfate 50%	130613@38	12/10/2013

Methylcobalamin 1mg/ml	130612@49	12/9/2013 10/19/2013
Sodium Phenylbutyrate 200mg/ml SDV PF	130621@28	10/19/2013
R.L. Glutathione 100mg/ml SUV PF	130710@27	1/6/2014
Ascorbic acid (cassava) 500mg/ml PF SUV	130711@13	1/7/2014

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

Recalled medications were distributed to individual patients and to physician offices nationwide. These liquid medications are in either clear or amber sterile vials ranging in size from 1ml to 50ml. The medications can be identified by the label on each vial, which will have the name of the drug, strength or concentration, lot number, use by date, and vial size.

Wellness Pharmacy is notifying its customers by telephone and regular mail of this recall. Patients and physicians should immediately discontinue use of these lots of medications, and return the recalled unexpired medications to Wellness Pharmacy.

To return medication or request assistance related to this recall, patients and physicians should contact Wellness Pharmacy at 205-879-6551 or 800-227-2627, Monday through Friday, between 9 a.m. and 4 p.m. CDT.

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Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking these medications.

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

Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product. Any problems may be reported to the FDA's MedWatch program via:

- Online: http://www.fda.gov/MedWatch/report.htm
- Mail: use postage-paid, pre-addressed Form FDA 3500 at http://www.fda.gov/MedWatch/getforms.htm.
- Fax: 1-800-FDA-0178