Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 28, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: JCB Laboratories Recall [Drug]

AFFECTED PRODUCT(S)
Sodium Thiosulfate, 25% (250 mg/mL)
Sodium Citrate, 4% Solution for Injection, 30 mL Multiple Dose Vial
Sodium Citrate, 4% with Genatmicin 320 mcg/mL Solution for Injection, 30mL Multiple Dose Vial
Acetylcysteine, 20% Solution for Inhalation, 4 mL Single Dose Vials

SUGGESTED ACTION:

Unclassified Recall; JCB Laboratories[1] (JCB) is issuing a recall of six lots of sterile drug products to the user level due to concerns of sterility assurance; 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); Information is provided in case of a consumer inquiry.

From the information provided by FDA, the recalled products were distributed to outpatient dialysis clinics in multiple states from July 8, 2013, through Aug. 20, 2013.

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. In addition, if any recalled products are found, please notify this office at 317-233-3213.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

JCB Laboratories Issues Voluntary Recall of Six Drug Product Lots Due to Concerns of Sterility Assurance at Testing Vendor

Contact
Consumer:
316-773-0405

Media:
Greg Turner
617-243-9950
greg@ballcg.com

FOR IMMEDIATE RELEASE - August 26, 2013 - WICHITA, Kan. – JCB Laboratories[1] (JCB) is issuing a recall of six lots of sterile drug products to the user level due to concerns of sterility assurance following a recent inspection by the U.S. Food and Drug Administration of Front Range Laboratories of Loveland, Colo., one of the contract testing labs used by JCB.

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. If there is microbial contamination in products intended to be sterile, patients are at risk for serious, potentially life-threatening infections.

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

In the recent inspection of Front Range Labs, the FDA stated it "observed that methods used by Front Range to assess sterility and other qualities (e.g., strength and stability) may have resulted in pharmacies receiving inaccurate laboratory test results. FDA has concerns that results obtained from Front Range are not reliable. FDA recommends that pharmacies not use this firm for sterility and other quality attributes testing at this time."
(http://www.fda.gov/Drugs/DrugSafety/ucm365920.htm[2], 8/21/13)

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

"Our top priority is to protect patient safety," said Brian Williamson, PharmD, President and CEO of JCB Laboratories. "We have never had to issue a recall, but we believe this action is a reflection of our tradition of total transparency and our commitment to the highest quality standards. We regret any inconvenience this recall may cause our valued customers."

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.

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[3]
- **Mail**: use postage-paid, pre-addressed Form FDA 3500 at http://www.fda.gov/MedWatch/getforms.htm[4].
- **Fax**: 1-800-FDA-0178

This recall is being conducted with the knowledge of the FDA.

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