Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 12, 2013

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

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

SUBJECT: Specialty Compounding, LLC Recall [Drug]

SUGGESTED ACTION: **Unclassified Recall; All lots of sterile medications within expiry, after reports of bacterial infection affecting 15 patients at two Texas hospitals; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. Recalled products were distributed directly to hospitals and physician offices in Texas. Recalled products were also sent directly to patients located nationwide with the exception of North Carolina. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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.

Specialty Compounding, LLC Issues Nationwide Voluntary Recall of All Lots of Unexpired Sterile Products Due to Reports of Adverse Events

Contact
Consumer
512-219-0724
info@austincompounding.com

Media Contact:
David Ball
617-243-9950 (Office), 617-548-7809 (Mobile)
david@ballcg.com

FOR IMMEDIATE RELEASE - August 9, 2013 - Cedar Park, Texas – Specialty Compounding, LLC, a subsidiary of Peoples Pharmacy Inc., is voluntarily recalling all lots of sterile medications within expiry.

The recall was initiated after reports of bacterial infection affecting 15 patients at two Texas hospitals, Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area, whose treatment included IV infusions of calcium gluconate from Specialty Compounding. There is a potential association between the infections and the medication at this time.

If there is microbial contamination in products intended to be sterile, patients are at risk of serious infections which may be life threatening.

"Because of the potential association between the hospital-based infections and sterile compounded medications produced by Specialty Compounding, we are voluntarily recalling all sterile products out of an abundance of caution," said Ray Solano, R.Ph., pharmacist in charge at Specialty Compounding. "We deeply regret the impact this recall has on our patients and the hospitals that we serve, but patient safety must always be our first concern."

The recall applies to all unexpired sterile compounded products dispensed since May 9, 2013, including all strengths and dosage forms.

Recalled products were distributed directly to hospitals and physician offices in Texas. Recalled products were also sent directly to patients located nationwide with the exception of North Carolina.

Specialty Compounding is notifying its customers by telephone, fax, electronic mail and/or regular mail of this recall. Users or recipients of these products should immediately discontinue use and return the recalled unexpired products to Specialty Compounding.

To return product or request assistance related to this recall, users should contact Specialty Compounding at 512-219-0724, Monday through Friday, between 10:00 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 these drug products.

Adverse reactions 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[1]
Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
Fax: 1-800-FDA-0178

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

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