News & Events

FDA NEWS RELEASE

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FDA announces nationwide voluntary recall of all products for sterile use from Specialty Compounding

The U.S. Food and Drug Administration is alerting health care providers and patients of a voluntary nationwide recall of all products produced and distributed for sterile use by Specialty Compounding, LLC, Cedar Park, TX. There have been recent reports of bacterial bloodstream infections potentially related to the company's calcium gluconate infusions.

All sterile use products produced and distributed by Specialty Compounding are being recalled and none of these products should be used by patients or administered to patients. Facilities, health care providers and patients who have received the products since May 9, 2013 should immediately discontinue use, quarantine the products, and return the products to Specialty Compounding.

According to information provided by the firm, the recalled products were distributed directly to patients nationwide, with the exception of North Carolina. Recalled products were also distributed directly to hospitals and physicians' offices in Texas.

The FDA has received reports of 15 patients from two Texas hospitals who received an infusion of calcium gluconate 2 grams in Sodium Chloride 0.9 percent for Injection, supplied by Specialty Compounding. Then the patients developed bacterial bloodstream infections caused by *Rhodococcus equi*. These infections are thought to be related to the infusions. Cultures from an intact sample of calcium gluconate compounded by Specialty Compounding show growth of bacteria that are consistent with *Rhodococcus* species.

"The FDA believes that use of these products would create an unacceptable risk for patients," said Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "Giving a patient a contaminated injectable drug could result in a life-threatening infection."

Physicians might prescribe calcium gluconate by infusion to treat conditions associated with low calcium levels in certain circumstances.

The FDA is working closely with the Centers for Disease Control and Prevention (CDC) and Texas state officials to determine the scope of the contamination.

Adverse reactions experienced with the use of any Specialty Compounding products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: https://www.accessdata.fda.gov/scripts/medwatch/
- Download form at
  http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
  or call 1-800-332-1088 to request a reporting form, then complete and mail to address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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