



Nebraska Department of Health and Human Services

HEALTH ALERT NETWORK

Advisory



TO: Primary Care Providers, Urgent Care, ERs, Hospitals, Pharmacies and Public Health

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RE: **FDA RECALL OF POTENTIALLY CONTAMINATED 2% CALCIUM GLUCONATE FROM AUSTIN, TEXAS COMPOUNDING PHARMACY**

DATE: August 10, 2013

***Rhodococcus equi* Bloodstream Infections Potentially Associated with Contaminated Product**

The Texas Department of Health, U.S. Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) are investigating a cluster of *Rhodococcus equi* bloodstream infections potentially associated with contaminated calcium gluconate infusions produced by Specialty Compounding. The company indicates that they distribute nationally. We are notifying Nebraska health care providers that all sterile injectable products from this company are under recall and should not be used.

The FDA is alerting health care professionals not to use any sterile products supplied by Specialty Compounding, Cedar Park, TX, because bacterial infections have been potentially associated with contaminated calcium gluconate infusions produced by the company. Calcium gluconate infusions are used to treat conditions associated with low calcium levels in certain circumstances. FDA has received reports of 15 adverse events experienced by patients in two hospitals. The 15 patients received an infusion of calcium gluconate 2 grams in Sodium Chloride 0.9% for Injection supplied by Specialty Compounding. These patients subsequently developed bloodstream infections caused by *Rhodococcus equi* which are believed to be related to the infusions. Cultures from an intact sample of calcium gluconate compounded by Specialty Compounding shows growth of bacteria that are consistent with *Rhodococcus* species.

Health care professionals should report any adverse reactions to FDA's MedWatch program either by:

- completing and submitting the report online at www.fda.gov/medwatch/report.html; or
- downloading and completing the form, then submitting it via fax at 1-800-FDA-0178.

Information related to this recall on the company website can be found here:

<http://www.austincompounding.com/recall-information/>

Laboratories, physicians, and hospitals should immediately report any positive blood cultures for *Rhodococcus equi* to their local or state health department.