

Central Admixture Pharmacy Services, Inc.
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September 16, 2005

URGENT DRUG RECALL

Dear CAPS Customer:

This is to inform you of a product recall involving **all injectable products** manufactured by **Central Admixture Pharmacy Services, Inc. of Lanham, Maryland ("CAPS")**. CAPS of Lanham, Maryland, distributed the affected injectable products to hospitals in **Maryland, Delaware, Washington, D.C., and Virginia**.

This recall has been initiated due to concerns regarding the sterility of certain of our products. Specifically, Gram negative rods have been identified in two lots of cardioplegia solution manufactured by CAPS, Lanham, Maryland. Non-sterility of injectable products could represent a serious hazard to health that could lead to life-threatening injuries and death.

Immediately examine your inventory and quarantine product subject to this recall. In addition, if you may have further distributed this product, please identify your consignees and notify them at once of this product recall.

The following products distributed up to September 16, 2005, are affected by this action:

- Cardioplegia solutions including: Cardioplegia, Cold Cardioplegia, Warm Cardioplegia, Blood Cardioplegia 1, Blood Cardioplegia 2, Cardioplegia Base 1, Cardioplegia Base 2, Cardioplegia Base, Cardioplegia Reperfusion, Cardioplegia High Potassium, Cardioplegia Low Potassium, Cardioplegia #1, Cardioplegia #2, Cardioplegia #3; Maintenance Cardioplegia, Enriched Cardioplegia, Cardioplegia Hot Shot, Cardioplegia Base Enriched
- Oxytocin injectable products including: Oxytocin Infusion, Oxytocin 20 units, Oxytocin 30 units, Oxytocin D5 ½ NS, Oxytocin in Lactated Ringers
- Promethazine
- Magnesium-containing injectable products including: Magnesium 1 GM, Magnesium 2 GM, Magnesium Sulfate 2 GM, Magnesium 4 GM, Hydration-Magnesium in D5W, Magnesium Infusion, Magnesium in Lactated Ringers
- Heparin Replacement

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- Antibiotic Irrigation Bag and Bottle
- Bupivacaine 0.25 % and 0.5%, Pain Bags (Bupivacaine 0.25 %)
- Dialysate solutions including: Citrate Dialysate, Heparin Dialysate, Pediatric Dialysate, Hydration Dialysate #1, Hydration Dialysate #2, CRRT Dialysate, CVVHD (Dialysate) 300, CVVHD (Dialysate) 342, CVVHD Pediatric Formula (Normocarb), CVVHD Formalin #1, CVVHD Formalin #2, CVVHD Formalin #3, CVVHD Non-Standard, CVVHD D5W, CVVHD ½ NS, CVVHD NS
- Total Parenteral Nutrition (TPN) products including: TPN-Day, TPN-Day 1 Neonatal Stock Solution
- Diltiazem (Cardizem)
- Norepinephrine (Levophed)
- Cefazolin

You will be instructed later as to what you should do with the quarantined product. Your assistance is appreciated and necessary to prevent patient harm.

CAPS, Lanham, Maryland, has voluntarily suspended distribution of all injectable products pending its investigation into this contamination. In the interim, manufactured product will be serviced from other CAPS locations. Customers with questions may contact the company at 301-459-9301 or 877-416-5376.

You should also notify FDA of any complaints or problems associated with these products. These reports may be made to MedWatch, the FDA's voluntary reporting program, by phone at 1-800-FDA-1088 or on line at www.fda.gov/medwatch/report.htm.

This notification is being made with the knowledge of the Food and Drug Administration.



Michael A. Koch, R.Ph., MBA
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