



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 19, 2013

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

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

SUBJECT: Medprep Consulting Inc. Recall

SUGGESTED

ACTION: Unclassified Recall; All lots of all products compounded at its facility. The level of recall is to the user, that is, regional hospital pharmacies and related departments, and physician's office practices. The recall resulted from the pharmacy being notified by a Connecticut hospital, that it observed visible particulate contaminants in 50 ml bags of MAGNESIUM SULFATE 2GM IN DEXTROSE 5% IN WATER, 50ML FOR INJECTION intravenous solution confirmed to be mold; Information provided in case of consumer inquiry.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The products are used for a wide range of therapeutic uses for hospitalized inpatients and outpatients, and, patients directly treated by a health care professional at a physician's office practice facility or clinic

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.

Medprep Consulting Inc. Announces Voluntary Nationwide Recall Of All Lots Of All Compounded Products Due To Potential Mold Contamination

Contact

Consumer:
732-493-3390

Media:
Angelo J. Cifaldi, Esq., R.Ph.
Satish V. Poondi, Esq., R.Ph.
Counsel for Med Prep Consulting Inc.
(732)855-6096

FOR IMMEDIATE RELEASE – March 17, 2013 – Tinton Falls, NJ., Med Prep Consulting, Inc. is voluntarily recalling all lots of all products compounded at its facility. The level of recall is to the user, that is, regional hospital pharmacies and related departments, and physician's office practices. The recall resulted from the pharmacy being notified by a Connecticut hospital, that it observed visible particulate contaminants in 50 ml bags of **MAGNESIUM SULFATE 2GM IN DEXTROSE 5% IN WATER, 50ML FOR INJECTION** intravenous solution confirmed to be mold. These were unique and distinct lots compounded and dispensed by the pharmacy to the Connecticut hospital. At this time a total of five (5) contaminated bags were discovered. In an abundance of caution, the pharmacy included all compounded products in the voluntary recall due to lack of sterility assurance.

Administration of an intravenous product found to be contaminated with mold, could result in a fatal infection in a broad array of patients. To date, no injuries or illnesses have been reported.

The products are used for a wide range of therapeutic uses for hospitalized inpatients and outpatients, and, patients directly treated by a health care professional at a physician's office practice facility or clinic. None of these products are dispensed directly to patients from retail pharmacies or to home care patients for either self-administration or nursing administration. All products are packaged in plastic infusion bags, plastic infusion devices, plastic syringes and glass vials. Products packaged in plastic infusion bags, plastic infusion devices, plastic syringes and glass vials were distributed directly to regional hospital pharmacies located in New Jersey, Pennsylvania, Connecticut, and Delaware. Products packaged in plastic syringes only, were distributed nationwide to physician's office practice facilities and clinics. All of these products were distributed to the described users through March 13, 2013, from Tinton Falls, New Jersey to both regional and nationwide locations.

All facilities that received any product compounded by Med Prep Consulting, Inc. have been notified by telephone fax, electronic mail and regular mail of the recall and have been instructed to remove and return the product to the pharmacy. Facilities with questions may contact the company at 732-493-3390, Monday through Friday, between 10:00 a.m. and 5:00 p.m. EST.

Product complaints related to this recall should be reported to 732-493-3390, Monday through Friday, between 10:00 a.m. and 5:00 p.m. EST.

Adverse events that may be related to the use of these products may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm¹ ²

- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm³.
- Mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Med Prep Consulting Product List

- Acetylcystiene vials
- Alteplase syringe
- Atropine syringe
- Avastin syringe
- Aztreonam syringe
- Bacitracin vials
- Bupivacaine Bag
- Bupivacaine Syringe
- Bupivacaine OnQ Pump
- Calcium Gluconate Bag
- Calcium Gluconate syringe
- Cefazolin syringe
- Cefazolin Bag
- Cefepime syringe
- Cefepime Bag
- Cefotaxime syringe
- Cefotetan syringe
- Cefoxitin syringe
- Ceftazidime syringe
- Ceftazidime Bag
- Ceftriaxone syringe
- Ceftriaxone Bag
- Cefuroxime syringe
- Cefuroxime Bag
- Clindamycin syringe
- Darboepoetin (Aranesp) syringe
- Dexamethasone Bag
- Diltiazem Bag
- Dobutamine Bag
- Dobutamine syringe
- Ephedrine syringes
- Epinephrine Bag
- Epinephrine Bag
- Epinephrine syringe
- Epoetin Alfa syringe
- Esmolol syringes
- Famotidine syringe
- Fentanyl Citrate Bag
- Fentanyl Citrate with Bupivacaine HCL Bag
- Gentamicin syringe

- Gentamicin Bag
- Glycopyrrolate syringes
- Granisetron syringe
- Hectoral syringe
- Heparin syringe
- Heparin bag
- Hydromorphone syringe
- Hydromorphone Bag
- Hydromorphone PCA syringe
- LET Gel syringe
- LET Soln syringe
- Leukine syringe
- Magnesium Sulfate bag
- Meperidine Bag
- Midazolam Bag
- Midazolam syringe
- Morphine Sulfate Bag
- Morphine Sulfate syringe
- Norepinephrine bag
- Norepinephrine Syringe
- Ondansetron Bag
- Ondansetron syringe
- Oxacillin syringe
- Oxacillin Bag
- Oxytocin bag
- Palonosetron (Aloxi) syringe
- Penicillin syringe
- Penicillin Bag
- Phenylephrine Bags
- Phenylephrine syringes
- Potassium Chloride Bag
- Potassium Phosphate 1 bag
- Ranitidine syringe
- Rituxan syringe
- Ropivacaine Bag
- Ropivacaine OnQ Pump
- Sodium Citrate syringe
- Sodium Phosphate bag
- Succinylcholine syringes
- Sufentanil with Bupivacaine Bag
- Timentin syringe
- Tobramycin syringe
- Zometa syringe

###