Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 27, 2013

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

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

SUBJECT: Pallimed Solutions, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Visible particulates (filaments) were observed in vials of sterile compounded products: TRIMIX, BIMIX (Lot 02252013@3), ALPROSTADIL, DMSO 50 PERCENT – IRRIGATION (Lot 03122013@19), and BACTERIOSTATIC WATER FOR INJECTION (Lot 01072013@28); Information is provided in case of consumer inquiry. From the information provided by FDA, the recalled products were distributed in the State of Indiana. All products were distributed to patients and/or physicians' offices through Friday, March 22, 2013, from Woburn, Massachusetts.**

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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.

Pallimed Solutions, Inc. Announces Voluntary Nationwide Recall of All Sterile Compounded Products Dispensed Since January 1, 2013 Due to Possible Filament Contamination

Contact:
Consumer:
781- 937-3344
Media:
Scott Farmelant
Mills Public Relations
617-350-6200

FOR IMMEDIATE RELEASE - March 25, 2013 – Pallimed Solutions, Inc. of Woburn, MA, doing business as Pallimed Pharmacy, is voluntarily recalling all sterile compound products dispensed since January 1, 2013 to the user level.

The recall resulted from a recent inspection conducted by the U.S. Food and Drug Administration and the Massachusetts Board of Registration in Pharmacy where visible particulates (filaments) were observed in vials of sterile compounded products: **TRIMIX, BIMIX (Lot 02252013@3), ALPROSTADIL, DMSO 50 PERCENT – IRRIGATION (Lot 03122013@19), and BACTERIOSTATIC WATER FOR INJECTION (Lot 01072013@28).** The potential public health risks are unknown as the particulate matter has not yet been identified. However, particulate matter has the potential to damage or obstruct blood vessels, which could induce emboli, cause systemic allergic reaction, or cause tissue responses to the foreign material.

At this time a total of 5 affected vials were discovered. To date, no injuries or illnesses have been reported. In an abundance of caution, the pharmacy included all sterile compounded products dispensed since January 1, 2013, in the voluntary recall. The company took the precautionary recall measure to ensure patient safety.

The products are used for a wide range of therapeutic uses, including for treatment of erectile dysfunction, testosterone replacement therapy, vitamin injections, and ophthalmic preparations. All products are packaged in glass vials. All products were distributed to patients and/or physicians' offices through Friday, March 22, 2013, from Woburn, Massachusetts.

The recall applies to the following sterile compound products dispensed since January 1, 2013, including all strengths, all dose forms, and all products within expiry date:

ACETYLCYSTEINE OPHTHALMIC SOLUTION
ALPROSTADIL IN NS INJECTION
ATROPINE INJECTION
BACTERIOSTATIC WATER FOR INJECTION BIMIX INJECTION
BUPRENORPHINE HCL, VETERINARY INJECTION
CIDOFOVIR OPH SOLUTION
CYCLOSPORINE OPHTHALMIC
DIAZEPAM INJECTIBLE
DEXAMETHASONE PF
DMSO AQUEOUS IRRIGATION 50%
GENTAMICIN SULFATE IRRIGATION
HCG CHORIONIC GONADOTROPIN
HYDROXYPROGESTERONE CAPR. (G.S.)
METHYLCOBALAMIN - PF
MIC WITH B6 & B12
NANDROLONE DECANOATE INJECTIBLE
QUADMIX INJECTION
TACROLIMUS OPHTHALMIC
TESTOSTERONE CYPIONATE/TESTOSTERONE ENANTHATE INJECTION
TESTOSTERONE CYPIONATE/PROPIONATE INJECTION
TESTOSTERONE CYPIONATE INJECTION
TRIMIX INJECTION
VANCOMYCIN OPTHALMIC P.F.
VERAPAMIL INJECTION

Products were distributed directly to patients and/or physicians' offices located in some or all of the following states: California, Connecticut, Florida, Georgia, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Nevada, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Wisconsin.

Users or recipients should discontinue use and return the recalled products to Pallimed. All users who received any of the recalled products have been or will be notified by telephone, fax, electronic mail and/or regular mail of the recall.

To return product, request assistance, or report complaints related to this recall, users should contact Pallimed at www.pallimed.com [1] and by telephone at (781) 937-3344, Monday through Friday, between 10:00 a.m. and 5:00 p.m.

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: http://www.fda.gov/Safety/MedWatch/default.htm[2]
- Regular Mail: use postage-paid FDA form 3500 available at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm[3] Mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Pallimed deeply regrets the impact this recall notice imposes on our customers. We will continue to do everything possible to ensure patient safety and comply with all government standards and requirements.

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

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