



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 9, 2013

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

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

SUBJECT: University Compounding Pharmacy Recall [Drug]

AFFECTED PRODUCT Certain Products Being Recalled Due to Questions Surrounding an Independent Third Party's of the Sterility Testing

SUGGESTED ACTION: Unclassified Recall; University Compounding Pharmacy is voluntarily recalling certain sterile compounded consumer products (see table). FDA investigators observed that methods used by the Independent Third Party laboratory to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. A list of the recalled products is listed below. Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The prescription preparations were distributed nationwide from May 9th, 2013 to September 7th, 2013. The preparations would have been sold, directly to customers by pick up and by mail from University Compounding Pharmacy 1875 3rd Avenue San Diego CA. 92101. 619) 683-2005.

Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-3213.

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.



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

University Compounding Pharmacy Initiates a Nationwide Voluntary Recall of Certain Pharmacy Products due to Lack of Assurance of Sterility Concerns

Contact:

Consumer:
(619) 683-2005

FOR IMMEDIATE RELEASE - September 6, 2013, San Diego, CA - University Compounding Pharmacy is voluntarily recalling the following preparations (see below) for injection, to the consumer level. In a recent inspection, FDA investigators observed that methods used by the Independent Third Party laboratory to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. FDA has concerns that results obtained from the laboratory are not reliable.

If there is microbial contamination in products intended to be sterile, patients are at risk of serious infections which may be life threatening. To date there have been NO reported adverse events associated with the use of these products and there has been no confirmation of lack of sterility of these products. We are voluntarily recalling the products as a precautionary measure for the safety of our patients.

The prescription preparations were distributed nationwide from May 9th, 2013 to September 7th, 2013. The preparations would have been sold, directly to customers by pick up and by mail from;

University Compounding Pharmacy 1875 3rd Avenue San Diego CA. 92101. 619) 683-2005

Product Name	Lot Number	Expiry
Testosterone Cypionate (Sesame Oil) 200mg/mL Inj.	511017	11/30/2013
Testosterone Cypionate/Testosterone Propionate 180-20mg/mL Inj	513593	11/30/2013
PGE-1 NS 20mcg/mL Inj.	497940	9/6/2013
PGE-1 NS 100mcg/mL Inj.	497930	11/5/2013
Testosterone CYP (Sesame Oil) 200mg/mL Inj.	498616	9/25/2013

University Compounding Pharmacy 1765 4th Avenue San Diego CA. 92101. 619) 398-1800

Testosterone CYP (Sesame Oil) 200mg/mL Inj.	474323	9/13/2013
Testosterone CYP (Sesame Oil) 200mg/mL Inj.	475475	9/26/2013

University Compounding Pharmacy is notifying its customers by phone and mail and is arranging for return of all recalled product lots. Customers that have product which is being recalled should

stop using it and contact University Compounding Pharmacy to arrange for return of unused product.

Customers with questions regarding this recall can contact University Compounding Pharmacy at 1875 Third Ave, San Diego CA 92101 619-683-2005. Monday through Friday, 8 A.M. to 6 P.M, Pacific Standard time. Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these preparations.

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

- **Online:** www.fda.gov/medwatch/report.htm¹
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm². Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

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

###

[RSS Feed for FDA Recalls Information](#)³ [[what's this?](#)⁴]

Photo: [Product Labels](#)⁵

Recalled Product Photos Are Also Available on FDA's [Flickr Photostream](#).⁶