Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 10, 2013

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

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

SUBJECT: Park Compounding Recall [Drug]

AFFECTED PRODUCT: **Testoserone Cypionate (Sesame Oil) 200mg/ml Lot #05072013@1 Exp: 11/3/2013**

SUGGESTED ACTION: **Unclassified Recall; Park Compounding is voluntarily recalling one lot of sterile medication Testoserone Cypionate (Sesame Oil) 200mg/ml Lot #05072013@1 Exp: 11/3/2013 for injection in 10ml amber vials, to the consumer level. In a recent inspection, FDA investigators observed that methods used by Front Range Laboratories 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. Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, The prescription preparations were sold during May and June of 2013, in the following states: California and Indiana. The products would have been sold directly to customers (pick up and by mail) and to physician offices by prescription (pick up and by mail). Customers with questions regarding this recall can contact Park Compounding Center at 949-551-7195 or at info@parkrx.com. Monday through Friday, 9am to 5pm PST. Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these preparations.

In addition, if any recalled products are found, please notify this office at 317-233-3213.

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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.

Park Compounding: Sterile Medication Recall – Concerns of Sterility Assurance at Testing Vendor

Contact:
Consumer:
949-551-7195
info@parkrx.com

FOR IMMEDIATE RELEASE - September 10, 2013 - Park Compounding is voluntarily recalling one lot of sterile medication **Testoserone Cypionate (Sesame Oil) 200mg/ml Lot #05072013@1 Exp: 11/3/2013** for injection in 10ml amber vials, to the consumer level. In a recent inspection, FDA investigators observed that methods used by Front Range Laboratories 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.

The prescription preparations were sold during May and June of 2013, in the following states: California and Indiana. The products would have been sold directly to customers (pick up and by mail) and to physician offices by prescription (pick up and by mail).

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. If there is microbial contamination in products intended to be sterile, patients are at risk of serious infections which may be life threatening. Therefore, we decided to conduct this voluntary recall out of an abundance of caution.

Park Compounding 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 Park Compounding to arrange for return of unused product.

Customers with questions regarding this recall can contact Park Compounding Center at 949-551-7195 or at info@parkrx.com. Monday through Friday, 9am to 5pm PST. 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.htm[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

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

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