



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 27, 2013

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

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

SUBJECT: Park Pharmacy & Compounding Center Recall [Drug]

AFFECTED PRODUCT(S) Methylcobalamin 5mg/ml 30ml Amber Vials Lot #06132013@1 Exp: 12/10/2013
Multitrace-5 Concentrate 10ml Amber Vials Lot #05212013@20 Exp: 11/17/2013
Due to Lack of Sterility Assurance

SUGGESTED

ACTION: Unclassified Recall; Park Pharmacy & Compounding Center is voluntarily recalling two lots of products Methylcobalamin 5mg/ml 30ml Amber Vials Lot #06132013@1 Exp: 12/10/2013 and Multitrace-5 Concentrate 10ml Amber Vials Lot #05212013@20 Exp: 11/17/2013 for injection, to the consumer level due to lack of sterility assurance. Recommend notification of physicians and patients using this product to contact Park Pharmacy & Compounding Center. Park Pharmacy & Compounding Center 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 Pharmacy & Compounding Center to arrange for return of unused product. Customers with questions regarding this recall can contact Park Pharmacy & 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 products.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The prescription preparations were sold during June and July of 2013, in the following states: California, Florida, New Mexico 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).

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.



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.

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 Pharmacy & Compounding Center is Issuing a Voluntary Recall of Two Compounded Sterile Preparations. The Recall is Due to a Lack of Sterility Assurance

Contact:

Consumer
949-551-7195

FOR IMMEDIATE RELEASE - August 23, 2013, Irvine, Ca. Park Pharmacy & Compounding Center is voluntarily recalling two lots of products **Methylcobalamin 5mg/ml 30ml Amber Vials Lot #06132013@1 Exp: 12/10/2013** and **Multitrace-5 Concentrate 10ml Amber Vials Lot #05212013@20 Exp: 11/17/2013** for injection, to the consumer level. In a recent inspection, FDA investigators observed that methods used by the 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.

The prescription preparations were sold during June and July of 2013, in the following states: California, Florida, New Mexico 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. We are voluntarily recalling the products as a precautionary measure for the safety of our patients.

Park Pharmacy & Compounding Center 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 Pharmacy & 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.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 recall is being conducted with the knowledge of the U.S. Food and Drug Administration

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[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

Park Pharmacy & Compounding Center is Issuing a Voluntary Recall of Two
Compounded Sterile Preparations. The Recall is Due to a Lack of Sterility
Assurance
Photo

Each ml contains
Methylcobalamin 5mg
Sodium Chloride
8.49mg Benzyl
Alcohol 0.02% as
Preservative and
Sterile Water q.s. for
Injection

Sterile 30ml Multiple Dose vial

Methylcobalamin Injection 5mg/ml

For IM or SC Administration

Compounded for a licensed
professional or patient use by



Park Compounding Irvine, Ca
(949) 551-7195 www.parkrx.com

Store under refrigeration
2°-8°C (36° - 46°F) Do not
permitt to freeze Protect from
light Discard if solution is
cloudy or contains a
precipitate
Should only be administered
by a physician familiar with
this drug
Rx Only - Not For Retail

Lot #06132013@40
Exp: 12/10/2013

Each ml provides:
Chromium 10mcg, Copper
1mg, Manganese 0.5mg,
Selenium 60mcg and Zinc
5mg. Ea ml contains
Chromium Cl (hexahydrate),
Cupric Sulfate (pentahydrate),
Manganese Sulfate
(monohydrate), Selenium (Sod
Selenite), and Zinc Sulfate
(heptahydrate), Benzyl Alcohol
0.9% as preservative and
Sterile Water qs for Injection
Sulfuric Acid may have been
used to adjust pH.

Sterile 10ml Multiple Dose Vial

Multitrace - S Concentrate (Trace Elements - S Conc. Injection) Solution

For Slow IV Administration
After Dilution Only

Compounded for a licensed
professional or patient use by



Park Compounding Irvine, Ca
(949) 551-7195 www.parkrx.com

Store at controlled room
temperature 15° - 30°C
(59° - 86°F). Discard if
solution is cloudy or
contains a precipitate
Should only be
administered by a physician
familiar with this drug
Rx Only - Not For Retail

Lot #05212013@20
Exp: 11/17/2013