Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

**DATE:** January 13, 2014

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

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

**SUBJECT:** Midwest Wholesale [Drug]

**AFFECTED PRODUCT:** **Dietary Supplements; Boost Ultra, Sexy Monkey, Triple MiracleZen Platinum, Magic for Men, "New" Extenze, and New XZen Platinum various lots.**

**SUMMARY:** **Unclassified Recall; These products contain undeclared Sildenafil and/or Tadalafil. These products were distributed to 20 selected retail locations in several states.**

**SUGGESTED ACTION:** **For consumer inquiry only. Consumers with questions regarding this recall can contact Midwest Wholesale by phone (888-514-7110), Monday to Friday, 09:00am-5:00pm, Central Time.**

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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.

## Midwest Wholesale Issues Voluntary Recall of Boost Ultra, XZone Gold, Sexy Monkey, Triple MiracleZen Platinum, Magic for Men, "New" Extenze, and New XZen Platinum Marketed as a Dietary Supplements Due to the Presence of Undeclared Drug Ingredients

**Contact:**
Consumer:
Midwest Wholesale
(888) 514-7110

**FOR IMMEDIATE RELEASE** - January 9, 2014 - Nixa, MO, Midwest Wholesale is voluntarily recalling the following products and Lot numbers.

List of Products included in this Recall:

**Boost Ultra**
12 pill bottle, Lot#B70130, Exp 03/15
3 pill bottle, Lot#B70130, Exp 3/2015
1 pill pack, Lot#06012011, Exp 6/2014

**Boost Ultra** 1 pill pack, Lot#130710GL, Exp 7/31/18

**Sexy Monkey**
1 pill pack, Exp 12/31/14

**Triple MiracleZen Platinum**
1 pill pack, Lot# OAWF1027, Exp 1/31/15 and Lot# OAWF1003, Exp 1/31/15

**Magic for Men**
12 pill bottle, Lot# GP808, Exp 10/16
1 pill pack, Lot#BN030613, Exp 2/6/15

**"New" Extenze**
30 pill box, Lot# 0512058, Exp 05/16

**New XZen Platinum**
1 pill pack, Lot#130520PL, Exp 5/31/17

This recall is being conducted to the consumer level. FDA analysis found these products to contain undeclared Sildenafil and/or Tadalafil, the active ingredients in FDA-approved prescription drugs used to treat erectile dysfunction (ED). These undeclared ingredients may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels. Men with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

Consumers should stop using this product immediately and throw it away. Consumers who have experienced any negative side effects should consult a health care professional as soon as possible.

These products are labeled and intended to be used as dietary supplements for sexual enhancement. The products are packaged in 1 capsule blister packs, 3 pill bottles, 6 pill bottles, 12 pill bottles and 30 tablet boxes. These products were distributed to 20 selected retail locations in several states by Midwest Wholesale from August 1, 2013 to October 22, 2013.

Midwest Wholesale is notifying its retailers and customers by telephone and recall letter and is arranging for return of all recalled products. Consumers and retailers that have these products which are being recalled should stop consumption or further distribution and return to place of purchase or directly to Midwest Wholesale, 617 N Althea Ave, Nixa, MO 65714.

Consumers are requested to have their order number or proof of purchase.

Consumers with questions regarding this recall can contact Midwest Wholesale by phone (888-514-7110), Monday to Friday, 09:00am-5:00pm, Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems 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.

Complete and submit the report online: www.fda.gov/medwatch/report.htm

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm, or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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

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