



**Indiana State
Department of Health**
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 31, 2014

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

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

SUBJECT: Nova Products, Inc. - [Drug]

AFFECTED

PRODUCT: African Black Ant, Black Ant, XZen Gold, ZXen Platinum, XZen 1200, XZone Gold and XZone 1200.

SUMMARY: Unclassified Recall; This recall has been initiated because analysis on these products has determined that they contain undeclared amounts of sildenafil and tadalafil, active ingredients of FDA-approved drugs used to treat erectile dysfunction.

These products are marketed as dietary supplements for sexual enhancement and packaged in blister packs, envelopes, bottles, and/or boxes and the lot numbers are identified on the back or side of each product. The products and lot numbers are as follows:

African Black Ant (Lot# 2006-000926), Black Ant (Lot# 2006-3627878), XZen Gold (Lot# 130310GL), ZXen Platinum (Lot# 130520PL), XZen 1200 (Lot# 13051012), XZone Gold (Lot# 131110GL), and XZone 1200 (Lot# 13071012).

The recalled lots were distributed to consumers nationwide at retail stores.

SUGGESTED

ACTION: For consumer inquiry only. Consumers with questions regarding this recall can contact Nova Products, Inc. by telephone at 610-459-7709 between 9:00 a.m. and 5:00 p.m. EST.

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.

Nova Products, Inc. Issues Voluntary Nationwide Recall of Dietary Supplements with Undeclared Active Pharmaceutical Ingredients

Contact

Consumer:
610-459-7709

Media:
Michael Ruggieri
610-459-7709

FOR IMMEDIATE RELEASE - March 27, 2014 - Nova Products, Inc. of Aston, Pennsylvania is voluntarily recalling the following products: African Black Ant (Lot# 2006-000926), Black Ant (Lot# 2006-3627878), XZen Gold (Lot# 130310GL), ZXen Platinum (Lot# 130520PL), XZen 1200 (Lot# 13051012), XZone Gold (Lot# 131110GL), and XZone 1200 (Lot# 13071012) at the retail level. Lot numbers are identified on the back or side of each product. FDA laboratory analysis on these products has determined that they contain undeclared amounts of sildenafil and tadalafil, active ingredients of FDA-approved drugs used to treat erectile dysfunction.

These undeclared active ingredients pose a threat to consumers because they can interact with nitrates found in some prescription drugs (such as nitroglycerin), resulting in decreased blood pressure. Prescription drugs containing nitrates are frequently prescribed for individuals with diabetes, high blood pressure, high cholesterol, or heart disease. Additionally, these products may cause side effects such as headaches and flushing.

These products are marketed as dietary supplements for sexual enhancement and packaged in blister packs, envelopes, bottles, and/or boxes distributed to consumers nationwide at retail stores. Nova Products, Inc. has discontinued distribution and sales of these products.

Nova Products, Inc. is notifying its distributors by mail of this voluntary recall. Consumers that possess these products should stop using them immediately and can return the products to Nova Products, Inc., 5 Mount Pleasant Road, Aston, Pennsylvania.

Consumers with questions regarding this recall can contact Nova Products, Inc. by telephone at 610-459-7709 between 9:00 a.m. and 5:00 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these products. Consumers can report adverse reactions or quality control problems to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax as follows:

- Complete and submit reporting form online at <http://www.fda.gov/MedWatch/report.htm>; or
- Mail or fax reporting form. Download form at <http://www.fda.gov/MedWatch/getforms.htm> or call 1-800-332-1088 to request a reporting form. Complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-1078.

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

###