

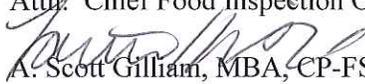


Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 28, 2013

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

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

SUBJECT: Hardmenstore.Com Recall [Drug]

AFFECTED PRODUCT(S) 72HP, Evil Root, and Pro Power Max Due to Undeclared Sildenafil

SUGGESTED ACTION: Unclassified Recall; Upon request of the FDA, Hardmenstore.com is voluntarily recalling 1000 lots of 72HP, Evil Root and Pro Power Max at the consumer level. According to representatives of the FDA, 72HP, Evil Root and Pro Power Max have reportedly been found to contain amounts of the PDE-5 Inhibitor, sildenafil, which is the active ingredient in an FDA-approved drug for erectile dysfunction (ED). Sildenafil is not listed on the product labels; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. Products were distributed nationwide through distributors and online. 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.



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To promote and provide
essential public health services.

Hardmenstore.com Issues Voluntary Nationwide Recall of 72HP, Evil Root and Pro Power Max Due to Undeclared Sildenafil

Contact:

Consumer
Howard Andrew
954-636-3468

FOR IMMEDIATE RELEASE - August 27, 2013 - Fort Lauderdale, Florida – Upon request of the FDA, Hardmenstore.com is voluntarily recalling 1000 lots of 72HP, Evil Root and Pro Power Max at the consumer level. According to representatives of the FDA, 72HP, Evil Root and Pro Power Max have reportedly been found to contain amounts of the PDE-5 Inhibitor, sildenafil, which is the active ingredient in an FDA-approved drug for erectile dysfunction (ED).

Sildenafil is not listed on the product labels. Sildenafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

These products are intended to be used as a dietary supplement and sexual supplement. 72HP is packaged in a single blister pack containing 1 dose. Evil Root is packaged in box containing a bottle of 6 pills. Pro Power Max is packaged in a single blister pack containing 1 dose.

All lots of 72HP, Evil Root and Pro Power Max are included in this recall. 72HP can be identified by the yellow packaging with a black horse insignia. Evil Root can be identified by its orange box with blue Chinese characters. Pro Power Max can be identified by the black and red packaging with flames on the bottom of the packaging. These sealed and packaged products were delivered to Hardmenstore.com as having contained only legitimate and lawful ingredients.

Aided with the information provided by the FDA, Hardmenstore.com is now notifying its distributors and customers by an email and online notice on the homepage of our site. It is arranging for a return of all recalled products. Consumers and retailers that have the 72HP, Evil Root or Pro Power Max supplements should stop using this product immediately, and contact a doctor if any of the side effects have been felt.

Consumers with questions regarding this voluntary recall can contact Howard Andrew by email at info@hardmenstore.com from Monday to Friday, 11am to 5pm, EST.

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.

- **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 and at the request of the U.S. Food and Drug Administration.

“As hardmenstore.com receives this product from overseas in a sealed package, representing that it contains only lawful and legitimate ingredients, we are relying on the representations of the Food and Drug Administration that the public interest would best be served by voluntarily complying with their request to get the product off the shelves. Our goal is to protect the safety of the consumer,” stated Howard Andrew, on behalf of Hardmenstore.com.

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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