Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 1, 2013

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

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

SUBJECT: Haute Health LLC Recall [Drug]

AFFECTED PRODUCT: **Virilis Pro, PHUK and Prolifta Due to Undeclared Ingredients**

SUMMARY: **Unclassified Recall; Haute Health, LLC is voluntarily recalling all lots of Virilis Pro, PHUK and Prolifta at the retail and consumer level. Virilis Pro, PHUK and Prolifta have been found to contain amounts of the PDE-5 Inhibitor sildenafil, which is an active ingredient in an FDA-approved drug for erectile dysfunction (ED). Sildenafil has the potential to interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to unsafe levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, sildenafil may cause side effects, such as headaches and flushing.**

Virilis Pro is packaged in a 1 and 2 capsule blister packs and 10 capsule bottles. PHUK is packaged in 1 and 2 capsule blister packs and 4, 12, 24 capsule bottles. Prolifta is packaged in 1 and 2 capsule blister packs and 4, 12, and 24 capsule bottles. All three products are distributed nationwide to wholesale and retail customers and via the internet.

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax or e-mail. Detailed store information is not available at this time. Consumers that have Virilis Pro, PHUK or Prolifta supplements should stop using this product immediately, and contact a doctor if any of the side effects have been felt. Retailers who have Virilis Pro, PHUK or Prolifta supplements should stop selling the product. Furthermore, 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

Haute Health, LLC Conducts Voluntary Nationwide Recall of All Lots of Virilis Pro, PHUK and Prolifta Capsules Due To Undeclared Ingredients

Contact:
Consumer:
Michael Carney
(856) 404-9474
Monday to Friday, 11am to 5pm, EST
info@virilispro.com

FOR IMMEDIATE RELEASE - September 24, 2013 - Williamstown, New Jersey – Haute Health, LLC is voluntarily recalling all lots of Virilis Pro, PHUK and Prolifta at the retail and consumer level. Virilis Pro, PHUK and Prolifta have been found to contain amounts of the PDE-5 Inhibitor sildenafil, which is an active ingredient in an FDA-approved drug for erectile dysfunction (ED). This issue was brought to our attention as a result of sample-testing conducted by the FDA.

Sildenafil has the potential to interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to unsafe levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, sildenafil may cause side effects, such as headaches and flushing. To date, however, there have been no reported adverse events associated with the presence of sildenafil in Virilis Pro, PHUK or Prolifta.

Virilis Pro, PHUK and Prolifta are labeled and intended to be used as dietary supplements for sexual enhancement. Virilis Pro is packaged in a 1 and 2 capsule blister packs and 10 capsule bottles. PHUK is packaged in 1 and 2 capsule blister packs and 4, 12, 24 capsule bottles. Prolifta is packaged in 1 and 2 capsule blister packs and 4, 12, and 24 capsule bottles. All three products are distributed nationwide to wholesale and retail customers and via the internet.

Aided with the information provided by the FDA, Haute Health, LLC is notifying its distributors and customers by an email and online notice on the homepage of our website http://www.virilispro.com[1] of this voluntary recall. Although Haute Health, LLC has not yet determined whether unlisted sildenafil is contained in lots of dietary supplements not tested by the FDA, as a precaution, Haute Health, LLC is recalling all lots. Haute Health, LLC will arrange for a return of all recalled products. Consumers that have Virilis Pro, PHUK or Prolifta supplements should stop using this product immediately, and contact a doctor if any of the side effects have been felt. Retailers who have Virilis Pro, PHUK or Prolifta supplements should stop selling the product.

Consumers with questions regarding this voluntary recall can contact Michael Carney via email at info@virilispro.com or by phone at 856-404-9474 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.htm[2]
- Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[3]. 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.

Haute Health, LLC would like to ensure its customers that it takes the safety of its customers very seriously, and receives this product from the manufacturer in sealed packages and with a certificate of analysis that represents that the product contains only the lawful and legitimate listed ingredients. Haute Health, LLC is 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 recall the product. "Our goal is to protect the safety of the consumer," stated Michael Carney, on behalf of Haute Health LLC, and "we will be working with our manufacturer to discover and correct the source of any unlisted ingredient."

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