



DATE: July 15, 2013
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
[Signature]
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Hardmenstore.com Recall [Drug]

**SUGGESTED
ACTION:**

Unclassified Recall; 430 lots of Silver Sword and Clalis at the consumer level. According to representatives of the FDA, Silver Sword and Clalis have reportedly been found to contain amounts of PDE-5 Inhibitor Sildenafil, which could cause adverse reactions and drug interactions normally associated with the active ingredient in Viagra; 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. Aided with the information provided by the FDA, Hardmenstore.com is now notifying its distributors and customers by an email and online notice. It is arranging for a return of all recalled products. It is recommended that consumers and retailers that have the Silver Sword or Clalis supplements should stop using this product immediately, and contact a doctor if any of the side effects have been felt.

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.

Hardmenstore.com Issues Voluntary Nationwide Recall of Silver Sword and Clalis at the Request of the FDA

Contact

Consumer:
954-636-3468

FOR IMMEDIATE RELEASE - July 5, 2013 - Upon request of the FDA, Hardmenstore.com is voluntarily recalling 430 lots of Silver Sword and Clalis at the consumer level. According to representatives of the FDA, Silver Sword and Clalis have reportedly been found to contain amounts of PDE-5 Inhibitor Sildenafil, which could cause adverse reactions and drug interactions normally associated with the active ingredient in Viagra.

Risk Statement: Hardmenstore.com has been informed by the FDA that Silver Sword could potentially result in decreased blood pressure, light-headedness, and dizziness.

These products are intended to be used as a dietary supplement and sexual supplement. Silver Sword is packaged in a tin containing 8 doses, 2 pills per dose. Clalis is packaged in box containing a bottle of 6 pills. According to the FDA report, the affected Silver Sword and Clalis lots include those produced on or before April 2, 2013. The production date is stamped on the back of the packaging. Silver Sword can be identified by the tan and red tin labeled as Silver Sword. Clalis can be identified by its distinctive blue box. The sealed and packaged product was 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. It is arranging for a return of all recalled products. It is recommended that consumers and retailers that have the Silver Sword or Clalis 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 Federal 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.

[RSS Feed for FDA Recalls Information](#)³ [[what's this?](#)⁴]

[Photo: Product Labels](#)⁵