**Company Announcement**

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

# Shoreside Enterprises Issues Voluntary Nationwide Recall of 7K and Poseidon 4500 (Extreme 1000 Mg) Due to Presence of Undeclared Sildenafil and Tadalafil

## For Immediate Release

May 17, 2018

## Contact

### Consumers

Shoreside Enterprises
(727) 236-0576

## Announcement

**View Product Photos**

Shoreside Enterprises, Inc. is voluntarily recalling 7K (Lot specific: Lot #RO) and Poseidon 4500 (Extreme 1000 mg) (Lot specific: Lot #20117BL) to the consumer level. FDA analysis found the samples of these products to contain undeclared Sildenafil and/or Tadalafil. Sildenafil and Tadalafil are active ingredients in two FDA-approved prescription drugs used for the treatment of erectile dysfunction (ED). The presence of Sildenafil and Tadalafil renders them unapproved drugs for which safety and efficacy have not been established and, therefore, subject to recall.

Use of products with the undeclared active ingredients, sildenafil and tadalafil, may pose a threat to consumers because the active ingredient may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may cause a significant drop in blood pressure that may be life threatening. Among the adult male population who

are most likely to use these products, adult males who use nitrates for cardiac conditions are the most at risk from these products. These products are considered tainted. To date, Shoreside Enterprises, Inc. has not received any reports of adverse events related to this recall.

The products are marketed as dietary supplements for male sexual enhancement. The products can also be identified by their blue color, and lot numbers located on their individual packaging Poseidon 4500 Extreme 1000 Lot #20117BL, and 7k Lot #RO. These products are packaged in 1 capsule blister packs.
These products were distributed from February 2, 2017, to December 19, 2017, to retail locations in Illinois, Ohio, North Carolina, Massachusetts, and Florida by Shoreside Enterprises.

Shoreside Enterprises, Inc. is notifying its customers by email and is arranging for return and refunds 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 Shoreside Enterprises 6345 Newtown Circle A-3, Tampa, FL 33615 for a full refund.

Consumers with questions regarding this recall can contact Shoreside Enterprises by phone (727-236- 0576), Monday to Friday, 09:00am-5:00pm, Eastern 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 fax.

1. Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
2. Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm[2] (http://www.fda.gov/MedWatch/getforms.htm2)** 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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