FDA Alert: 7K and Poseidon 4500 by Shoreside Enterprises: Voluntary Recall

May 18, 2018

[Posted 05/18/2018]

AUDIENCE: Consumer

ISSUE: 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).

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.

BACKGROUND: 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.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

[05/17/2018 – Recall Announcement – FDA]