

Mitchell E. Daniels, Jr. Governor

Gregory N. Larkin, M.D., F.A.A.F.P. State Health Commissioner

DATE:

March 24, 2011

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

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

**SUBJECT:** 

USA Far Ocean Group Inc. Recall

## **SUGGESTED**

**ACTION:** 

Unclassified Recall; "U-Prosta Natural support for prostate health" found the product contains terazosin, the active ingredient of an FDA-approved drug used to treat Benign Prostatic Hyperplasia (enlarged prostate), making U-Prosta an unapproved drug; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. The product has been distributed nationwide via retail stores, internet sales and mail order. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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.

USA Far Ocean Group, Inc. Issues Voluntary Nationwide Recall of U-Prosta, a Product Marketed As a Dietary Supplement That Contains Undeclared Terazosin Hydrochloride

## **Contact:**

Jamie Sun 626-576-1299

FOR IMMEDIATE RELEASE - March 22, 2011 - USA Far Ocean Group Inc., 1609 W. Valley Blvd., #338, Alhambra, CA 91803, announced today that it is conducting a voluntary nationwide recall of the Company's supplement product sold under the name "U-Prosta Natural support for prostate health". The Company has been informed by representatives of the U.S. Food and Drug Administration (FDA) that lab analysis by FDA of U-Prosta samples found the product contains terazosin, the active ingredient of an FDA-approved drug used to treat Benign Prostatic Hyperplasia (enlarged prostate), making U-Prosta an unapproved drug.

The most likely adverse health consequences that could occur with the use of this product would be hypotension, dizziness, or syncope. Patients who are currently being treated with prescription medications for high blood pressure or enlarged prostate would be at increased risk of these events. In these patients, the hypotensive events may be more severe. No illnesses have been reported to the company to date in connection with this product.

The product has been distributed nationwide via retail stores, internet sales and mail order. All of the following U-Prosta products, which are packaged in white plastic bottles & 1 capsule blister pack, are involved in this voluntary recall:

Product	Package Size	UPC Codes
U-Prosta Dietary Supplement	30 capsules	689076499255
U-Prosta Dietary Supplement	60 capsules	88858100030
U-Prosta Dietary Supplement	1 capsule	No UPC Code

Consumers in possession of the affected product are urged to stop using it immediately and return it to the place of purchase for a full refund. Consumers with questions may contact USA Far Ocean Group, Inc. Special Recall number at 626-576-1299, Monday through Sunday, between 9 a.m. and 5 p.m. Pacific Standard Time. Consumers should contact their physician if they have experienced any problem that may be related to taking this product. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

Online: www.fda.gov/medwatch/report.htm<sup>1</sup>

• Fax: 1-800-FDA-0178

• Regular Mail: use postage-paid FDA form 3500 available at:

www.fda.gov/MedWatch/getforms.htm<sup>2</sup>

Mail to: MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.