Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

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

DATE: March 29, 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; X-Hero and Male Enhancer lab analysis by FDA of X-Hero sample found the product contains sulfosildenafil and analysis of Male Enhancer sample found the product contains tadalafil; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. These two products have 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 X-Hero and Male Enhancer, Products Marketed as Dietary Supplements

Contact:
Consumer:
909-839-3058
Monday-Sunday; 9 a.m.-5 p.m.

Media:
Jamie Sun
909-839-3058

FOR IMMEDIATE RELEASE - March 25, 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 two supplement products sold under the names X-Hero and Male Enhancer. The Company has been informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA of X-Hero sample found the product contains sulfosildenafil, the analogue of the active ingredient of an FDA-approved drug used to treat erectile dysfunction (ED), making X-Hero an unapproved drug. In addition, FDA analysis of Male Enhancer sample found the product contains tadalafil, the active ingredient of an FDA-approved drug used to treat erectile dysfunction (ED), making Male Enhancer an unapproved drug.

FDA advised that both products pose a threat to consumers because they may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. According to the FDA, consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. FDA advises that ED is a common problem in men with these conditions, and they may seek products to enhance sexual performance. FDA advises that either sulfosidenafil or tadalafil may cause side effects, such as headaches and flushing.

These two products have been distributed nationwide via retail stores, internet sales and mail order. All of the following packages of X-Hero and Male Enhancer products are involved in this voluntary recall:

Product	Package Size	UPC Codes
X-Hero with English Label	10 capsules	689087070995
X-Hero with English Label	8 capsules	689076499255
X-Hero with Chinese/English Label	8 capsules	689076499255
X-Hero with English Label	1 capsule pack	None
Male Enhancer	60 capsule	982010061205

Consumers who have X-Hero or Male Enhancer in their possession should stop using it immediately and contact their physician if they experienced any problem that may be related to taking this product. Any adverse reactions or quality problems experienced with the use of any counterfeit products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: http://www.fda.gov/MedWatch/report.htm[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2].
- Fax: 1-800-FDA-0178

No illnesses have been reported to the Company to date in connection with this product.Consumers in possession of products should return any unused products to their immediate supplier for a direct refund. Customers with questions can call 909-839-3058 Monday through Sunday between 9 a.m. and 5 p.m. for further instructions or information with respect to the return and refund process.