X-Hero and Male Enhancer: Recall - Undeclared Drug Ingredient

U.S. Food & Drug Administration

AUDIENCE: Consumer

ISSUE: FDA lab analysis of X-Hero 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.

The 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. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and they may seek products to enhance sexual performance.

BACKGROUND: These two products have been distributed nationwide via retail stores, internet sales and mail order. See the Firm Press Release for a listing of affected products and lot numbers.

RECOMMENDATION: 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.

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.htm [1]
- Download form [2] 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

[03/25/2011 - Press Release [3] - USA Far Ocean Group Inc.]

SOURCE [4]

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