X-Rock: Recall - Undeclared Drug Ingredient

U.S. Food & Drug Administration

AUDIENCE: Consumer

ISSUE: X-Rock Industries LLC is conducting a recall of certain supplement products under the brand name of X-ROCK. Analytical tests of X-ROCK for Men conducted by FDA concluded that the products contained Sildenafil and Hydroxythiohomosildenafil. Hydroxythiohomosildenafil is an analogue of sildenafil. Sildenafil is the active pharmaceutical ingredient in an FDA-approved drug that is used to treat erectile dysfunction (ED). Hydroxythiohomosildenafil is close in structure to sildenafil and is expected to possess a similar pharmacological and adverse event profile.

These undeclared active ingredients pose a threat to consumers because sildenafil and hydroxythiohomosildenafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) and 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. Additionally, hydroxythiohomosildenafil, like sildenafil, may cause side effects, such as headaches and flushing.

BACKGROUND: XRock for Men was distributed Nationwide to wholesalers and retail to the consumer via internet orders. XRock for Men was distributed in single blister cards.

RECOMMENDATION: Customers who have this product in their possession should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product. The Company is advising consumers to return any unused X-Rock to the retail location from which it was purchased or to the Company directly if it was purchased from the Company as a part of its Direct Response Program.

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

[04/21/2012 - Press Release [3] - X-Rock]
[04/21/2012 - Photo Image of X-Rock [4]]

SOURCE [5]

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http://www.mdtmag.com/news/2012/04/x-rock-recall-undeclared-drug-ingredient

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[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
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