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: April 23, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

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

SUBJECT: XROCK INDUSTRIES, LLC Recall

SUGGESTED ACTION: **Unclassified Recall; X-ROCK for Men was tested and preliminarily found to contain an analogue of an ingredient in an FDA-approved 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. XRock for Men was distributed in single blister cards. XRock for Men was distributed Nationwide to wholesalers and retail to the consumer via internet orders from www.XRockMe.com[1], www.XRockHim.com[2], and www.XRockFlorida.com[3], and by telephone. Detail information is not available at this time. In addition, if any recalled product is 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

XROCK INDUSTRIES, LLC Issues a Voluntary Nationwide Recall of X-ROCK, a Product Marketed as a Dietary Supplement to Support Male Sexual Performance, Due to Unlisted, Potentially Hazardous Ingredient

Contact:
Consumer
877-976-2563
info@xrockindustries.com

FOR IMMEDIATE RELEASE – Fort Lauderdale, FL – April 19, 2012 --- XROCK INDUSTRIES, an independent distributor of the *X-ROCK* products, is conducting a user level voluntary recall of certain supplement products sold by XROCK INDUSTRIES under the brand name of X-*ROCK*.

Finished product of X-ROCK for Men was tested and preliminarily found to contain an analogue of an ingredient in an FDA-approved drug. Analytical tests conducted by the Food and Drug Administration (FDA) of X-ROCK for Men 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.

All codes of X-Rock for Men, within expiration, are included in this recall.

UPC	PACKAGING TYPE	NUMBER OF CAPSULES	LOT NUMBER	EXPIRATION DATES
0030950792	One Capsule Blister Card - sold individually	1	All lot numbers	within expiration

XROCK Industries has not received any reports of adverse events related to this recall.

XRock for Men was distributed in single blister cards. See attached photograph. XRock for Men was distributed Nationwide to wholesalers and retail to the consumer via internet orders from www.XRockMe.com[1], www.XRockHim.com[2], and www.XRockFlorida.com[3], and by telephone.

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, for a refund of the full purchase price, 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. Consumers can call 877-976-2563 Monday through Saturday 9am-9pm EST to receive instructions for returning the product. Additional information is provided on the Company's website at www.XROCKME.com[4]

Any adverse events or quality problems experienced with the use of this product 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[5]**
- **Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[6]. Mail to address on the pre-addressed form.**
- **Fax: 1-800-FDA-0178**

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

The Company is taking this voluntary action because it is committed to providing accurate information on the label of its products and because it is always concerned with the health of persons who have consumed this product. The Company is reviewing the procedures and policies of all firms involved with the manufacture of the product to ensure that there will be no future issues with regard to X-ROCK's composition and labeling. The Company is working closely with the FDA in the recall process and is committed to the quality and integrity of its products. It sincerely regrets any inconvenience to consumers and its other customers and the incomplete X-ROCK labeling information.

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RSS Feed for FDA Recalls Information[7] [what's this?[8]]

Photo: Product Labels[9]