Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

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

DATE: July 25, 2012

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

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

SUBJECT: CRM Laboratories Recall

SUGGESTED ACTION: **Unclassified Recall; all X-ROCK 3 Day Pill For Men and Z-ROCK products sold between October, 2011 and April, 2012. Analytical tests conducted by the Food and Drug Administration (FDA) concluded that the products contained sildenafil and hydroxythiohomosildenafil; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. Sildenafil is the active pharmaceutical ingredient in a FDA approved drug that is used to treat erectile dysfunction (ED) making these products unapproved new drugs. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-351-7190.

****

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.

CRM Laboratories Issues a Voluntary Nationwide Recall of X-ROCK 3 Day Pill For Men and Z-ROCK All Natural Male Supplement Products Marketed as Dietary Supplements to Support Male Sexual Performance Due to Undeclared Active Ingredients

Contact
Consumer:
305-587-9830
info@crmlaboratories.com

FOR IMMEDIATE RELEASE – July 20, 2012 - CRM Laboratories is conducting a consumer/user level recall of all X-ROCK 3 Day Pill For Men and Z-ROCK products sold between October, 2011 and April, 2012. Finished product of *X-ROCK* 3 Day Pill for Men and Z-ROCK was tested and found to contain an analogue of an ingredient in an FDA-approved drug. Analytical tests conducted by the Food and Drug Administration (FDA) concluded that the products contained sildenafil and hydroxythiohomosildenafil. Hydroxythiohomosildenafil is an analogue of sildenafil and is close in structure to sildenafil and is expected to possess a similar pharmacological and adverse event profile. Sildenafil is the active pharmaceutical ingredient in a FDA approved drug that is used to treat erectile dysfunction (ED) making these products unapproved new drugs.

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 3 Day Pill for Men and Z-Rock All Natural Male Supplement, within expiration, are included in this recall. The products are blue capsules individually packaged on a cardboard blister card; some older packaging configurations include blister double pack (2 capsules per blister card) and white plastic bottles (6, 12, 24 count). The products were sold as wholesale in the US to distributors who further distributed it nationwide through internet sales and at retail.

X-Rock 3 Day Pill for Men back panel may read Distributed by XRock Industries PO Box 120863 Ft. Lauderdale, FL 33312 or MATE Enterprises 1020 N. Venetian Drive Miami, Florida 33139 www.XRockHim.com[1] [2] (888) XROCK-HIM).

Z-Rock All Natural Male Supplement back panel will read Distributed By XRock Industries PO Box 120863 Ft. Lauderdale, FL 33312 www.ZrockUSA.com[3] [4] 877-976-2563.

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

Customers who have these products in their possession should stop using them 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 products, for a refund of the full purchase price, to the retail location from which it was purchased or to the Company directly.

Consumers can call 305-587-9830 Monday through Friday 9am-5pm EST to receive instructions for returning the products.

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 preaddressed 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 our products 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.

###

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

Photo: Product Labels[9]