Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: April 9, 2013

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

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

SUBJECT: Consumer Concepts, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; The products contained hydroxythiohomosildenafil, which is an analogue of sildenafil, an FDA approved drug; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. All codes of ROCK-It MAN Male Enhancement Capsules are included in this recall. The products are blue capsules individually packaged on a cardboard blister card (1 capsule per blister card) and blister double pack (2 capsules per blister card). The products were sold as wholesale in the US to distributors who further distributed it nationwide through internet sales and at retail. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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.

Consumer Concepts Issues a Voluntary Nationwide Recall of ROCK-IT MAN All Natural Male Supplement Products Marketed as Dietary Supplements to Support Male Sexual Performance Due to Undeclared Active Ingredient

Contact:
Consumer:
Consumer Concepts, Inc.
(310)228-8965
sales@consumerconceptsusa.com

FOR IMMEDIATE RELEASE - April 1, 2013 - Consumer Concepts, Inc. is conducting a consumer/user level recall of all ROCK-It MAN Male Enhancement Capsules sold between October, 2012 and April, 2013. Finished product of ROCK-It MAN Male Enhancement Capsules 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 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.

This undeclared active ingredient poses a threat to consumers because 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.

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The ROCK-It MAN Male Enhancement Capsules back panel reads "Distributed by Consumer Concepts".

Consumer Concepts 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.

Customers can call 310-228-8965 Monday – Friday between the hours of 9am-4pm Central Time for directions on returning the product.

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[1]

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

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RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]