Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 22, 2013

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

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

SUBJECT: Volcano Company Recall [Drug]

SUGGESTED ACTION: **Unclassified Recall; All lots of Volcano Male Enhancement Liquid and Volcano Male Enhancement Capsules to the consumer level. FDA test results revealed that Dapoxetine is an active ingredient not approved by the U.S. Food and Drug Administration (FDA); Information is provided in case of consumer inquiry.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The products were distributed through the internet. The product can be identified by the Volcano Male Enhancement logo displayed on the front side of product package. Volcano Male Enhancement was distributed Worldwide/Nationwide.

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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.

Volcano Company, Issues Voluntary Worldwide/Nationwide Recall of Volcano Male Enhancement Liquid and Volcano Male Enhancement Capsules, Marketed as a Dietary Supplement, Due to Undeclared Active Ingredients

Contact:
Consumer:
562-363-5362

FOR IMMEDIATE RELEASE - July 18, 2013 - Long Beach, CA, Volcano Company is voluntarily recalling all lots of Volcano Male Enhancement Liquid and Volcano Male Enhancement Capsules to the consumer level. FDA test results revealed the Volcano Male Enhancement Liquid has been found to contain undeclared Desmethyl Carbodenafil, Dimethylsildenafil, and Dapoxetine. FDA test results revealed Volcano Capsules have been found to contain undeclared Desmethyl Carbodenafil and Dapoxetine. Desmethyl Carbodenafil and Dimethylsilsildenafil are Phosphodiesterase (PDE) 5 inhibitors which is a class of drugs used to treat male erectile dysfunction, making these products unapproved new drugs. Dapoxetine is an active ingredient not approved by the U.S. Food and Drug Administration (FDA).

Desmthyl Carbodenafil and Dimethylsidenafil may pose a threat to consumers because these PDE 5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels that can be life threatening. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Dapoxetine has not been approved by the FDA and therefore its safety or efficacy has not been established. Chemically, dapoxetine belongs to a class of drugs known as selective serotonin reuptake inhibitors (SSRIs) used to treat depression. Studies have shown that antidepressants increased the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults when compared to placebo. Therefore, consuming these products presents a health risk which could be life threatening. Volcano Company has not received any reports of adverse events related to this recall.

Volcano Male Enhancement Liquid is marketed as a dietary supplement for male sexual enhancement to increase desire and sexual performance and is packaged in a 2 oz. Bottle, UPC 609613859960, LOT 301, distributed from January 1, 2013 to July 2013 and Volcano Male Enhancement Capsules is packaged in a black or white round plastic pop top container with 1 capsule inside, UPC 609613859977, LOT 7455, distributed from January 1, 2013 to July 2013. The products were distributed through the internet. The product can be identified by the Volcano Male Enhancement logo displayed on the front side of product package. Volcano Male Enhancement was distributed Worldwide/Nationwide.

Volcano Company is notifying its distributors and customers by telephone and email and is arranging for return/replacement etc. of all recalled products. Consumers/distributors/retailers that have Volcano Male Enhancement Liquid and/or Volcano Male Enhancement Capsules which is being recalled should stop using and return to place of purchase or directly to Volcano Company P.O. Box 90277, Long Beach CA, 90809. Consumers are asked to have order number or proof of purchase.

Consumers with questions regarding this recall can contact Volcano Company by phone (562) 363-5362, Monday thru Friday, from 10am to 3pm, Pacific Standard Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions 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:www.fda.gov/medwatch/report.htm[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. 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.

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

Photo: Product Labels[5]