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: May 29, 2012

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

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

SUBJECT: The Menz Club, LLC Recall

SUGGESTED ACTION: **Unclassified Recall; An FDA lab analysis of V Maxx Rx Lot # 101109 distributed by The Menz Club, LLC was found to contain undeclared sulfoaidenafil. Sulfoaidenafil is an analog of sildenafil, an FDA approved prescription drug used to treat Erectile Dysfunction (ED); 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. The affected products may have been ordered online at www.vmaxxrx.com[1] or www.themenzclub.net[2] and were distributed to customers and distributors nationwide. Detail information is not available at this time. In addition, if any recalled products are 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.

The Menz Club, LLC Issues a Voluntary Nationwide Recall of V Maxx Rx due to Undeclared Sulfoaildenafil

Contact:
Consumer:
James H. Jones, Jr.
(601) 866-6746

FOR IMMEDIATE RELEASE - May 25, 2012 - The Menz Club, LLC is conducting a voluntary recall of V Maxx RX to the consumer level of the following lot numbers:

Single Count, UPC Code 2802803561, Lot Nos. 101108, 101009, 101010, 101011 , Five Count, UPC Code 0972859402, Lot Nos.: 101108, 101109, 101110, Ten Count, UPC code 0913251017, Lot Nos.: 301000, 301001

An FDA lab analysis of V Maxx Rx Lot # 101109 distributed by The Menz Club, LLC was found to contain undeclared sulfoaidenafil. Sulfoaidenafil is an analog of sildenafil, an FDA approved prescription drug used to treat Erectile Dysfunction (ED), making V Maxx Rx, an unapproved new drug. The Menz Club is recalling the above listed lots of this product which can pose a serious risk to health. Since the product has the same formulation, additional lots are being recalled.

FDA advises that this poses a threat to consumers because sildenafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Men with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. The firm has not received any reports of adverse events related to this recall.

The affected products may have been ordered online at www.vmaxxrx.com[1] or www.themenzclub.net[2] and were distributed to customers and distributors nationwide. This product is marketed as a dietary supplement intended for use as a male enhancement product and is packaged in one (1) and five (5) count blister packs and ten (10) count bottles.

The Menz Club, LLC is notifying its customers and distributors by email and/or phone to return or destroy all recalled products. Any consumer having V Maxx Rx should immediately stop using it and destroy the unused product or return it to **ATTN: Product Returns, The Menz Club, LLC, P. O. Box 906, Madison, MS 39110.** Customers with questions may call (601) 866-6746 Monday through Friday, 9:00 AM – 4:30 PM CDT for further instructions or information with respect to the return process.

Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using these products.

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: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm[3]

Regular mail: use postage-paid, pre-addressed Form FDA 3500 available at:

http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm[4]. 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.

###

Photo: Product Labels[7]