



Governor
John R. Kasich

Lieutenant Governor
Mary Taylor

ODA Director
James Zehringer

ODH Director
Theodore E. Wymyslo, M.D.

Date: June 8, 2011

TO: Health Commissioners, Directors of Environmental Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2011-070

Global Wellness, LLC Conducts a Nationwide Voluntary Recall of VIA XTREME ULTIMATE SEXUAL ENHANCER DIETARY SUPPLEMENT FOR MEN Due to Presence of Undeclared Drug

June 6, 2011 - Global Wellness, LLC. Hollywood, FL is conducting a voluntary nationwide recall of VIA XTREME ULTIMATE SEXUAL ENHANCER DIETARY SUPPLEMENT FOR MEN to the consumer level. The product was distributed throughout the U.S. Puerto Rico, and Canada to internet and retail consumers. The product is distributed as a bottle containing six (6) blue colored capsules per package. The label on the packaging lists the company name Global Wellness, LLC, Hollywood Florida. Only Lots 809013 and 806030 are covered in this recall.

The company has been informed by representatives of the Food and Drug Administration (FDA) that laboratory analysis conducted by FDA for Lots 809013 and 806030 found that the product contains sulfoildenafil methanesulfonate, sulfosildenafil and dimethylsildenafil analogs of sildenafil. Sildenafil is an active ingredient of an FDA approved drug for erectile dysfunction (ED), making Via Xtreme Ultimate Sexual Enhancer Dietary Supplement for Men an unapproved drug. The active drug ingredient is not listed on the product label. The undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

No illnesses have been reported to Global Wellness, LLC to date in connection with these products.

With an abundance of caution, Global Wellness, LLC is voluntarily recalling only lots 809013 and 806030 of VIA XTREME ULTIMATE SEXUAL ENHANCER DIETARY SUPPLEMENT FOR MEN. This recall does not affect sales and distribution of SLIM XTREME GOLD™ and GELSLIM™.

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.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm¹], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm²] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Consumers with questions may contact the company at (954) 922-1133 Monday through Friday from 9:00am to 4:00pm EST for instructions on the return process.