Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

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

DATE: July 18, 2011

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

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

SUBJECT: Global Wellness, LLC. Expanded Recall

SUGGESTED ACTION: **Unclassified Recall; VIA XTREME ULTIMATE SEXUAL ENHANCER DIETARY SUPPLEMENT FOR MEN to the consumer level to include lot A032111; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The product was distributed throughout the U.S. Puerto Rico, Barbados, and Canada to internet and retail consumers. The product is distributed as a bottle containing six (6) blue colored capsules per package. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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.

Expanded Recall: Via Xtreme Ultimate Sexual Enhancer Dietary Supplement For Men Recall

Contact:

Consumer:
(954) 922-1133

FOR IMMEDIATE RELEASE - July 13 , 2011 - Global Wellness, LLC. Hollywood, FL is expanding its voluntary nationwide recall of **VIA XTREME ULTIMATE SEXUAL ENHANCER DIETARY SUPPLEMENT FOR MEN to the consumer level** to include lot A032111. The product was distributed throughout the U.S. Puerto Rico, Barbados, 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.

Lot numbers #809013, 806030, and A032111 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 lot #809013, 806030, and A032111 found that the product contains sulfoaildenafil 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 expanding its voluntary recall to include lot numbers #809013, 806030, and A032111. **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.htm[1]], 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.htm[2]] 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.
Global Wellness, LLC apologizes for any inconvenience and expresses its concerns for the health of consumers by conducting a voluntary recall action.

Global Wellness, LLC, remains committed to product quality and integrity of all its products and the company is working closely with the FDA in the recall process. We deeply value the trust you have placed in Global Wellness, LLC and regret any inconvenience this product recall may have caused.

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