



Mitchell E. Daniels, Jr.
Governor

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

DATE: May 25, 2011
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Globe All Wellness, LLC Recall

SUGGESTED

ACTION: **Unclassified Recall; Dietary supplement was found to contain undeclared drug ingredient Sibutramine; Information provided in case of consumer inquiry.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The products listed above were sold and distributed nationwide via the internet and at the company's headquarters in Hollywood, Florida. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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.

Globe All Wellness, LLC Issues a Voluntary Recall of Dietary Supplement Found to Contain an Undeclared Drug Ingredient

Contact:
Consumer
(954) 922-1133:

FOR IMMEDIATE RELEASE - May 24, 2011 - Globe All Wellness, LLC has been informed by the Food and Drug Administration (FDA) that one of the company's weight loss dietary supplements that was sold by a seller that was not authorized by Globe All Wellness, LLC to sell the product contains an undeclared drug ingredient. FDA lab analyses of this dietary supplement

was found to contain undeclared Sibutramine. The FDA has not approved Sibutramine; therefore the safety and effectiveness of this product is unknown.

All lots of the following dietary supplement products are being recalled:

Slim Xtreme™ Herbal Slimming Capsule 30 Capsules/Bottle

The products listed above were sold and distributed nationwide via the internet and at the company's headquarters in Hollywood, Florida. The FDA advises that this product poses a threat to consumers because Sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

No illnesses or injuries have been reported to Globe All Wellness, LLC to date in connection with this product.

With abundance of caution, Globe All Wellness, LLC is voluntarily recalling all lots of SLIM XTREME™ from the market as a precautionary measure.

This recall does not affect the sales and distribution of Globe All Wellness, LLC's other products such as SLIM XTREME GOLD™ or GELSLIM™.

Globe All Wellness, LLC has taken this **voluntary** action because it is committed to providing accurate information about its products and because of the concern for the health and safety of consumers. Globe All Wellness, LLC is working with the FDA in the recall process. It sincerely regrets any inconvenience to customers.

Consumers are advised to return the above product to:

Globe All Wellness, LLC
2854 Stirling Rd Suite G
Hollywood, FL 33020

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.

Any adverse reactions experienced with the use of this product should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/Safety/MedWatch/default.htm

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RSS Feed for FDA Recalls Information¹ [what's this?²]

Photo: Product Labels³