

Michael R. Pence Governor

William C. VanNess II, MD State Health Commissioner

DATE:

January 31, 2014

TO:

All Local Health Departments

Attn:/Chief Food Inspection Officer

FROM:

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

SUBJECT:

YoungYou International ("YoungYou") Drug

AFFECTED

PRODUCT:

Mega Slim Herbal Appetite Management dietary supplement.

SUMMARY:

Unclassified Recall; The recall has been issued because Mega Slim Herbal Appetite Management was found to contain <u>DMAA which is potentially dangerous to health</u> and

is an unapproved dietary ingredient.

Mega Slim Herbal Appetite Management is packaged in White Bottles with 30 white capsules. The affected lots include the following Bar Code 736211614094 and expiration date of June 2014. Mega Slim Herbal Appetite Management was made available to

consumers only through the YoungYoucorp.com website.

SUGGESTED

ACTION:

For consumer inquiry only. For additional assistance, call YoungYou by phone at (818)

344-3344 Mon-Fri, 9am-5pm PST.

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.

YoungYou International Issues Voluntary Recall of Mega Slim Herbal Appetite Management Pills Due to Presence of DMAA

Contact

Consumer: 818-344-3344



FOR IMMEDIATE RELEASE - January 30, 2014 - YoungYou International ("YoungYou") is voluntarily recalling **Mega Slim Herbal Appetite Management**, one pill a day, sold from September 15, 2013 through January 23, 2014 at the consumer level. Mega Slim Herbal Appetite Management was found to contain DMAA.

DMAA is also known as 1,3-dimethylamylamine, methylhexanamine or geranium extract. DMAA is commonly used as a stimulant, pre-workout, and weight loss ingredient in dietary supplement products. The Food and Drug Administration (FDA) has warned that DMAA is potentially dangerous to health as it might cause a rise in blood pressure or other cardiovascular problems such as shortness of breath, tightening in the chest or heart attack. The FDA has also warned that DMAA is an unapproved dietary ingredient. To learn more, please review the FDA's advisory on DMAA: http://www.fda.gov/food/dietarysupplements/qadietarysupplements/ucm346576.htm.

Mega Slim Herbal Appetite Management is packaged in White Bottles with 30 white capsules. The affected lots include the following Bar Code 736211614094 and expiration date of June 2014. The product can be identified by Mega Slim Herbal Appetite Management. Mega Slim Herbal Appetite Management was made available to consumers only through the YoungYoucorp.com website.

YoungYou is notifying its customers by email and is asking for return of all recalled product to its facility in California. Consumers in possession of the Mega Slim Herbal Appetite Management product subject to this recall are advised to **immediately stop using the product and return it to YoungYou**.

As a customer courtesy, YoungYou will issue refunds of the purchase price or credit the purchase price towards any other products sold by YoungYou. Refunds or credits will be issued only to customers who return more than 50% of unused product within 30 (thirty) calendar days from the date of publication of this advisory, or receipt of direct email notification by the customer, whihever is later, as indicated by the postmark of the customer's return package. Customers seeking a refund or credit are encouraged to ship the product in its original packaging and enclose the purchase receipt.

Although YoungYou received no customer complaints, YoungYou is conducting a voluntary Level I recall following receipt of FDA laboratory report indicating DMAA presence in Mega Slim Herbal Appetite Management.

Consumers with questions regarding this recall can contact YoungYou by phone at (818) 344-3344 Mon-Fri, 9am-5pm PST. Consumers should contact their physician or healthcare provider if they experience any problems that may be related to taking or using Mega Slim Herbal Appetite Management.

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.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm¹

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm² or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.