Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 19, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Fit Firm and Fabulous – RECALL [Drug]

AFFECTED PRODUCT: **Ultimate Herbal Slimcap capsules**

SUMMARY: **Unclassified Recall; FDA analysis has found the product to contain undeclared sibutramine. Sibutramine was a previously approved controlled substance that was removed from the U.S. market in October 2010 for safety reasons. This ingredient makes Ultimate Herbal Slimcap an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.**

The product is a dietary supplement marketed for weight loss and is packaged in 30-count bottles, labeled Part 1 of 3, UPC 5 42423 25422 1. The affected Ultimate Herbal Slimcap lots include the following lots 05/02/2015 to 05/01/2017.

Ultimate Herbal Slimcaps was distributed Nationwide via the website.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Fit Firm and Fabulous by e-mail at customerservice@fitfirmandfabulous.com on Monday through Friday from 9 am EST and 5 pm EST.**

****

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.

Fit Firm and Fabulous Issues Voluntary Nationwide Recall of Ultimate Herbal Slimcaps Due to the Presence of Undeclared Sibutramine

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.

For Immediate Release

November 19, 2015

Contact

Consumers

Mark Harris
Email - customerservice@fitfirmandfabulous.com
267-721-5585

Firm Press Release

Fit Firm and Fabulous is voluntarily recalling lots 05/02/2015 to 05/01/2017 of Ultimate Herbal Slimcap capsules, to the consumer level. FDA analysis has found the product to contain undeclared sibutramine. Sibutramine was a previously approved controlled substance that was removed from the U.S. market in October 2010 for safety reasons. This ingredient makes Ultimate Herbal Slimcap an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Products containing sibutramine pose 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. These products may also interact in life threatening ways with other medications a consumer may be taking. To date, Fit Firm and Fabulous has not received any reports of adverse events related to this recall.

The product is a dietary supplement marketed for weight loss and is packaged in 30-count bottles, labeled Part 1 of 3, UPC 5 42423 25422 1. The affected Ultimate Herbal Slimcap lots include the following lots 05/02/2015 to 05/01/2017. The product can be identified by. Ultimate Herbal Slimcaps was distributed Nationwide via the website.

Fit Firm and Fabulous has notified its distributors and customers by telephone and has arranged for return or destroy of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using and discard.

Consumers with questions regarding this recall can contact Fit Firm and Fabulous by e-mail at customerservice@fitfirmandfabulous.com on Monday through Friday from 9 am EST and 5 pm EST Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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.

###