Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: September 28, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Lucy's Weight Loss System - RECALL [Dietary Supplement]

AFFECTED PRODUCT: **Pink Bikini and Shorts on the Beach Blue and Gold Edition**

SUMMARY: **Unclassified Recall; The Pink Bikini and Shorts on the Beach have been found positive for Sibutramine and Phenolphthalein after FDA sampling and testing.**

The recalled prducts are all lots distributed May 25 - June 23 2015 of Pink Bikini and Shorts on the Beach Blue and Gold Edition, 30 blue capsules (750MG per) capsules and 30 gold capsule (800MG per) capsules to the consumer level. The product is used as a weight loss dietary supplement and is packaged in clear bottle in blue and gold. The affected Pink Bikini and Shorts on the Beach lots include the following expiration date 7/30/2017.

Product was distributed nationwide to consumers via Internet.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Lucy's Weight Loss System by phone (682)-308-0199 or pbfitme@gmail.com on Monday thru Friday 10:00am to 5:30pm CST.**

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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.

Lucy's Weight Loss System Issues Voluntary Nationwide Recall of Pink Bikini and Shorts on The Beach Due to Undeclared Sibutramine and Phenolphthalein

Contact:
Consumer:
682-308-0199
pbfitme@gmail.com

FOR IMMEDIATE RELEASE – 09/23/2015 – Arlington, TX – Lucy's Weight Loss System is voluntarily recalling all lots distributed May 25 - June 23 2015 of Pink Bikini and Shorts on the Beach Blue and Gold Edition, 30 blue

capsules (750MG per) capsules and 30 gold capsule (800MG per) capsules to the consumer level. The Pink Bikini and Shorts on the Beach have been found positive for Sibutramine and Phenolphthalein after FDA sampling and testing.

Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010. 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. Phenolphthalein is an ingredient previously used in over-the-counter laxatives, but because of concerns of carcinogenicity, it is not currently approved for marketing in the United States. Health risks associated with phenolphthalein could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use. These undeclared ingredients make these products unapproved new drugs for which safety and efficacy have not been established. These products may also interact in life-threatening ways with other medications a consumer may be taking.

Lucy's Weight Loss System has received not received any complaints to date. Lucy's Weight Loss System has not received any reports of adverse events related to this recall.

The product is used as a weight loss dietary supplement and is packaged in clear bottle in blue and gold. The affected Pink Bikini and Shorts on the Beach lots include the following expiration date 7/30/2017. Product was distributed nationwide to consumers via Internet.

Lucys Weight Loss System is notifying its customers by Email and is arranging for return. Consumers that have recalled Pink Bikini and Shorts on the Beach should stop using and discard.

Consumers with questions regarding this recall can contact Lucy's Weight Loss System by phone (682)-308-0199 or pbfitme@gmail.com on Monday thru Friday 10:00am to 5:30pm CST. 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.

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