

Governor
John R. Kasich**Lieutenant Governor**
Mary Taylor**ODA Director**
David T. Daniels**ODH Director**
Richard Hodges

DATE: February 1, 2016

TO: Health Commissioners, Directors of Environment Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2016-13

Lucy's Weight Loss System Issues Voluntary Nationwide Recall of Pink Bikini and Shorts on The Beach Dietary Supplements Due To Possible Undeclared Active Pharmaceutical Ingredient

January 28, 2016 Lucy's Weight Loss System of Arlington, TX, is voluntarily recalling all lots of Pink Bikini and Shorts on the Beach Capsules in all colors, 30 count (750MG per capsule) to the consumer level. Pink Bikini and Shorts on the Beach may contain an undeclared active pharmaceutical ingredient.

FDA analysis of Pink Bikini (white capsules, blue capsules and gold capsules) and Shorts on the Beach (blue capsules and gold capsules) found these products to be tainted with Sibutramine, Phenolphthalein, and/or Diclofenac, and that this active ingredients are not declared on the label of the product. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010.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 U.S. Health risks associated with phenolphthalein could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use. Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID). Use of diclofenac in patients already taking NSAIDS, with allergies, with underlying illnesses or with recent cardiac bypass surgery, could lead to gastrointestinal disturbances, fatal heart attack or stroke. Out of an abundance of caution, Lucy's Weight Loss System is recommending that Pink Bikini and Shorts on the Beach, in all strengths and pill colors not be consumed, as they may contain any of these undeclared active pharmaceutical ingredients and/or an unknown active pharmaceutical ingredient. Any of these undeclared ingredients would make this product an unapproved new drug for which safety and efficacy have not been established.

Lucy's Weight Loss System has not received any complaints to date.

The product is marketed as a weight loss dietary supplement and is packaged in clear bottle in multiple color capsules. The affected Pink Bikini and Shorts on the Beach lots include the following expiration date 7/30/2017. These products were distributed nationwide to consumers via PinkBikini.BigCartel.com and Waisted With Lucy Retail store.

Lucy's Weight Loss System is notifying its customers by Press Release and email. Consumers with questions regarding this recall can contact Lucy's Weight Loss System by phone (682)-308-0199 or email PBFITME@gmail.com on Monday thru Friday 10:00am to 5:30pm CST. Consumers that have recalled Pink Bikini and Shorts on the Beach should stop using and discard.

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: FDA's MedWatch Adverse Event Reporting program

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.