



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 10, 2015
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: Lucy's Weight Loss System - RECALL [Drug]

AFFECTED PRODUCT: Pink Bikini – dietary supplement

SUMMARY: Unclassified Recall; The recall has been initiated because Pink Bikini has been found positive for diclofenac after FDA sampling and testing. This undeclared ingredient makes this product an unapproved new drug for which safety and efficacy have not been established.

The product is used as a weight loss dietary supplement and is packaged in clear bottle in white powder capsules. The affected Pink Bikini and lots include the following expiration date 7/30/2017.

Product was distributed nationwide to consumers via PinkBikini.BigCartel.com.

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 pbfirme@gmail.com on Monday thru Friday 10:00am to 5:30pm CST.

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 Dietary Supplement Due to Undeclared Diclofenac

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For Immediate Release

December 9, 2015



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To promote and provide
essential public health services.

Contact

Consumers

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Lucerito Orozco
(682)-308-0199

Firm Press Release

Arlington, TX – Lucy's Weight Loss System is voluntarily recalling all lots of Pink Bikini White powder Capsules, 30 white (750MG per capsule) to the consumer level. Pink Bikini has been found positive for diclofenac after FDA sampling and testing.

Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID). This medicine works by reducing substances in the body that cause pain and inflammation. Diclofenac can increase your risk of fatal heart attack or stroke, especially if you use it long term or take high doses, or if you have heart disease. For those that are pregnant, taking diclofenac during the last three months of pregnancy may harm the unborn baby. This undeclared ingredient makes 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. Lucy's Weight Loss System has not received any reports of adverse events related to this recall to date.

The product is used as a weight loss dietary supplement and is packaged in clear bottle in white powder capsules. The affected Pink Bikini and lots include the following expiration date 7/30/2017. Product was 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 is arranging for return. Consumers that have recalled Pink Bikini should stop using and discard.

Consumers with questions regarding this recall can contact Lucy's Weight Loss System by phone (682)-308-0199 or pbitme@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: [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.

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