Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 23, 2013

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

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

SUBJECT: Herbal Give Care LLC Recall [Drug]

SUGGESTED ACTION: **Unclassified Recall; All lots of Esbelin siloutte te and Esbelin siloutte Herbal Blend with L-Carnitine (30 Capsules), to the consumer level. The products have been found to contain undeclared Sibutramine, N-Desmethylsibutramine, and N-di-Desmethylsibutramine; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The recall includes all lots of the Esbelin siloutte te. Esbelin siloutte te was distributed Nationwide to retail customers and via the internet. UPC code for this product is 7562684652553. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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.

Herbal Give Care LLC Issues Voluntary Nationwide Recall of Esbelin Siloutte Te and Esbelin Siloutte Vitamin Supplement Due to Potential Health Risks

Contact
Consumer:
972-602-6850
hgc-usa@hotmail.com

Media:
Omar Martinez
972-602-6850

FOR IMMEDIATE RELEASE - July 19, 2013 - Grand Prairie, Texas, Herbal Give Care LLC is voluntarily recalling all lots of Esbelin siloutte te and Esbelin siloutte Herbal Blend with L-Carnitine (30 Capsules), to the consumer level. The products have been found to contain undeclared Sibutramine, N-Desmethylsibutramine, and N-di-Desmethylsibutramine.

These products may 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. To date, Herbal Give Care LLC has not received any reports of adverse events related to this recall.

The Esbelin siloutte Herbal Blend with L-Carnitine (30 capsules) product is used to help normalize nervous appetite, preventing fat accumulation and fluid retention in tissues. The Esbelin siloutte Herbal Blend with L-Carnitine (30 Capsules) is packaged in a white plastic bottle with a screw cap containing 30 capsules per bottle. All lots of this product are being recalled. The product was distributed Nationwide to retail customers and via the internet. UPC code for this product is 7502011000060.

Esbelin siloutte te is a product used as a fat burner, as it removes the fat stored in the body, thereby achieving elimination of the fat through the urine and preventing its accumulation. The product is also intended to promote the proper functioning of the digestive system. This product is packaged in a gold resealable foil pouch; the product does not have the unit size labeled. The recall includes all lots of the Esbelin siloutte te. Esbelin siloutte te was distributed Nationwide to retail customers and via the internet. UPC code for this product is 7562684652553.

Herbal Give Care LLC is notifying its distributors and customers by calling and mailing a letter to all of them. Herbal Give Care LLC is making arrangements for the return of all recalled products. Consumers that have the affected product(s) should immediately stop using them and return them to the place of purchase.

Consumers with questions regarding this recall can contact Herbal Give Care LLC by calling to (972)602-6850 or email to hgc-usa@hotmail.com Monday- Friday from 9:00 am to 6:00 pm Central Standard Time. 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.

- **Online**: http://www.fda.gov/MedWatch/report.htm[1]

- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2].
  Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

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

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RSS Feed for FDA Recalls Information[3] [what's this?[4]]