

Governor  
John R. KasichLieutenant Governor  
Mary TaylorODA Director  
David T. DanielsODH Director  
Theodore E. Wymyslo, M.D.

DATE: August 20, 2013

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

RE: Recall Announcement (ODA/ODH) 2013-097

**Herbal Give Care LLC Issues Voluntary Nationwide Recall of Esbelder Man Capsules, Esbelder Fem Capsules, and Esbelder Siloutte Capsules Vitamin Supplements Due to Potential Health Risks**

August 16, 2013 - Grand Prairie, Texas, Herbal Give Care LLC is voluntarily recalling all lots of Esbelder man (30 capsules), Esbelder fem (30 capsules) and Esbelder siloutte (30 capsules) to the consumer level. The products have been found to contain undeclared Sibutramine, N-Desmethyisibutramine, and N-di-Desmethyisibutramine. The presence of these undeclared ingredients makes these products unapproved drugs.

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 Esbelder fem (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 7502011000251.

The Esbelder man (30 capsules) is packaged in a white plastic bottle with a screw cap containing 30 capsules per bottle. The product was distributed Nationwide to retail customers and via the internet. UPC code for this product is 7502011000275.

The Esbelder Siloutte (30 capsules) is packaged in a white plastic bottle with a screw cap containing 30 capsules per bottle. The product was distributed Nationwide to retail customers and via internet. UPC code for this product is 7502011000268.

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](mailto:hgc-usa@hotmail.com) Monday- Friday from 9:00 am to 6:00 pm Central Daylight 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><sup>1</sup>
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm><sup>2</sup>.  
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.