



**Ohio Department of Agriculture
and
Ohio Department of Health**



**Governor
John R. Kasich**

**Lieutenant Governor
Mary Taylor**

**ODA Director
David T. Daniels**

**ODH Director
Theodore E. Wymyslo, M.D.**

DATE: October 31, 2012

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

RE: Recall Announcement (ODA/ODH) 2012-110

Zi Xiu Tang Success, LLC Issues Voluntary Nationwide Recall Of Classic Zi Xiu Tang Bee Pollen Capsules And Ultimate Formula Capsules Due To Undeclared Sibutramine

Trexlerstown, PA, Zi Xiu Tang Success, LLC is voluntarily recalling four lots of Classic Zi Xiu Tang Bee Pollen Capsules, and three lots of Ultimate Formula Capsules to the consumer level. These products have been found to contain undeclared Sibutramine. Sibutramine was a previously approved controlled substance that was removed from the U.S. market in October 2010 for safety reasons, making these products unapproved new drugs.

Products containing Sibutramine 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. These products may also interact in life threatening ways with other medications a consumer may be taking. The company has not received any reports of adverse events related to this recall. The recall was initiated after discovering that Sibutramine was included as an ingredient by the manufacturer.

The Classic Zi Xiu Tang Bee Pollen product is marketed as a dietary supplement used as a weight loss aid and is packaged in bottles of 60 capsules. The affected Classic Zi Xiu Tang with UPC 6937000700019, includes the following lot numbers - lots 04/15/2012, 05/15/2012, 06/15/2012 and 07/15/2012. Classic Zi Xiu Tang was distributed Nationwide to consumers and distributors. The products were distributed from May 1, 2012 to October 17, 2012.

The Ultimate Formula product is also marketed as a dietary supplement used as a weight loss aid and is packaged in bottles of 48 capsules. The affected Ultimate Formula with UPC 793573041401, includes the following lot numbers – 05/25/2012, 07/29/2012 and 08/05/2012. The Ultimate Formula was distributed Nationwide to consumers and distributors. The products were distributed from May 1, 2012 to October 17, 2012.

Zi Xiu Success, LLC is notifying its distributors and customers by letter and is arranging for return of all recalled products. Consumers and distributors that have product which is being recalled should stop using the products and return the product to Zi Xiu Success, LLC.

Zi Xiu Success, LLC regrets any inconvenience to their customers. This recall is being voluntarily conducted out of concern for the health and safety of consumers.

Consumers with questions regarding this recall can contact Zi Xiu Success, LLC at (800) 764-0120 or info@zixiutangsuccess.com Monday - Friday from 9:00am-5:00pm Est. 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:** www.fda.gov/medwatch/report.htm¹¹
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm²². 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.