



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: February 26, 2013

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

RE: Recall Announcement (ODA/ODH) 2013-025

Olaax Corp. Issues a Nationwide Voluntary Recall of All Lots of Maxiloss Weight Advanced Softgels Dietary Supplement

Olaax Corp announced today that it is conducting a voluntary nationwide recall of the company's dietary supplement sold under the brand name MAXILOSS WEIGHT ADVANCED softgels to the user level because they contain undeclared Sibutramine. Olaax Corp. is conducting a voluntary recall after being notified by the US FDA that testing found the MAXILOSS WEIGHT ADVANCED product, to contain Sibutramine. Sibutramine was a previously approved controlled substance for the treatment of obesity that was removed from the U.S. market in October 2010 for safety reasons, making these products unapproved new drugs.

Sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk to patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. Sibutramine has been withdrawn from U.S marketplace. The active drug ingredient is not listed on the label for these products. No illnesses or injuries have been reported to the company to date in connection with this product.

The recall includes ALL authentic Lot numbers and known to be counterfeit lot numbers of authentic lots. Any packaging types that are different from listed are counterfeit. Any lot numbers not listed are counterfeit and are also part of the recall.

MAXILOSS WEIGHT ADVANCED Dietary Supplement is marketed as a Natural Herb for Weight Loss. MAXILOSS WEIGHT ADVANCED Dietary Supplement softgels are packaged in a green or blue box containing 3 X 12 blister packs per box and bears "Batch Number: 001". The product was sold to distributors nationwide and known to be counterfeit versions are sold on various online sites. This product was distributed nationwide in US from January 2011 to November 2012.

Olaax Corp. cannot guarantee the authenticity of the products in the marketplace and advises any customers in possession of any MAXILOSS WEIGHT ADVANCED, regardless of lot number to throw it away.

Consumers with questions regarding this recall can contact Olaax Corporation at 1-863-648-9581, Monday through Friday, 9:00 am to 5:30 pm, EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.

Any adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's Med Watch 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:** 1800-FDA-0178

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

Olaax Corp is committed to improving its products and avoiding future recall issues by better controlling distribution patterns.