

Governor
John R. KasichLieutenant Governor
Mary TaylorODA Director
David T. DanielsODH Director
Richard Hodges

DATE: March 22, 2015

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

RE: Recall Announcement (ODA/ODH) 2015-35

Ultra ZX LABS, L.L.C. Issues Voluntary Nationwide Recall of Ultra ZX Since It Contains Undeclared Sibutramine and Phenolphthalein

UltraZx, Labs, L.L.C. is voluntarily recalling "**UltraZx**" weight loss supplements. This product has been found to contain undeclared Sibutramine and phenolphthalein.

FDA laboratory analysis of confirmed that UltraZx contains sibutramine and phenolphthalein. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons. The product poses 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. Phenolphthalein is a chemical that is not an active ingredient in any approved drug in the United States. Studies have indicated that it presents a cancer causing risk. This product may also interact, in life-threatening ways, with other medications a consumer may be taking.

Ultra ZX LABS, L.L.C. has not received any reports of adverse events related to this recall. UltraZx weight loss supplement is marketed as a dietary supplement used as a weight loss aid and is packaged in bottles of thirty (30) capsules of 300mg. The affected UltraZx weight loss supplement, includes all lots/bottles/packages. The products were distributed from September 2014 until February 2015.

UltraZx Labs, L.L.C. 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 product and return the product to UltraZx Labs, L.L.C.

Consumers with questions regarding this recall can contact UltraZx Labs, L.L.C. at (305) 904-9393, Monday through 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 product.

This recall is being conducted with the knowledge of the Food and Drug Administration (FDA).

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:** www.fda.gov/medwatch/report.htm
- **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.