Ohio Department of Agriculture and Ohio Department of Health

Mike DeWine	Jon Husted	Dorothy Pelanda	Lance Himes
Governor	Lieutenant Governor	ODA Director	ODH Interim Director

DATE: February 25, 2019

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

RE: Recall Announcement (ODA/ODH) 2019-038

Golean Detox USA Issues Voluntary Nationwide Recall of Golean DETOX Capsules Due to Presence of Undeclared Sibutramine and Phenolphthalein

Golean Detox USA, Charlotte, NC is voluntarily recalling all lots within expiry of Golean DETOX capsules to the consumer level. FDA analysis has found Golean DETOX capsules to be tainted with undeclared sibutramine and phenolphthalein. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market due to safety concerns. Phenolphthalein was once an ingredient used in over-the-counter laxatives, but because of concerns of carcinogenicity is not currently approved for marketing in the United States. The presence of sibutramine and phenolphthalein in Golean DETOX renders it an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Risk Statement: 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. Health risks of ingesting phenolphthalein could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use. These products may also interact in life threatening ways with other medications a consumer may be taking. To date, Golean Detox USA has not received any reports of adverse events related to this recall.

This tainted product is marketed as a dietary supplement for weight loss and is packaged in 14 packets containing 2 capsules per packet, a total of 28 capsules per box, UPC 8 938510 909013. Golean DETOX capsules were sold Nationwide in the USA to customers on Facebook at www.goleandetoxus.com.

Golean Detox USA is notifying its customers that have the Golean DETOX capsules and is arranging for return of all recalled products. Consumers that have Golean DETOX capsules should stop use and return the product.

Consumers with questions regarding this recall can contact Golean Detox USA by phone 704-537-2595 or goleandetox085@gmail.com Monday – Thursday, EST, 4:00 pm to 6:00 pm.

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.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm1
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm2 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

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