

Governor
John R. Kasich

 Lieutenant Governor
Mary Taylor

 ODA Director
David T. Daniels

 ODH Director
Richard Hodges

DATE: February 10, 2015

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

RE: Recall Announcement (ODA/ODH) 2015-24

Detox Transforms Health and Nutrition Issues Voluntary Nationwide Recall of Dietary Supplements Due to the Presence of Undeclared Drug Ingredients

Detox Transforms Health and Nutrition, Garner, NC announced it is conducting a voluntary recall of the following dietary supplements, to the consumer level, because they contain undeclared drug ingredients making them unapproved drugs.

Product Name	Bottle Color	Label	# Capsules	UPC	Lot	Expiration
EDGE Amplified Weight Release	White	Purple label	60	852175004174	ALL	
iNDiGO	White	Dark blue label	60	852175004044	000034	4/10/2017
AMPD Gold Bee Pollen	White	Black label	60	852175004181	ALL	
BtRim Max	White	Dark Red label	60	852175004068	00002	4/27/2017
iNSANE Bee Pollen	White	Bright Red label	60	852175004082	0000:02	6/20/2017

FDA analysis found iNDiGO and BtRim Max to contain undeclared phenolphthalein. The health risks of phenolphthalein could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use. FDA analysis found EDGE Amplified Weight Release and iNSANE Bee Pollen to contain undeclared phenolphthalein and fluoxetine. In addition to the potential adverse health consequences for phenolphthalein, the concomitant use of fluoxetine with other medications such as MAO-Inhibitors and serotonin precursors (such as tryptophans) is either contraindicated or is not recommended. Fluoxetine is an SSRI with potentially life-threatening side effects that is given to patients to treat depression, anxiety, panic attacks, obsessive-compulsive disorder, or bulimia. Even when taken as prescribed, fluoxetine has been associated with serious side effects including suicidal thinking, abnormal bleeding, and seizures. Thus, any adverse reaction that is possible with fluoxetine is possible with the fluoxetine-containing dietary supplement product. In patients on other medications for common conditions (aspirin, ibuprofen, or other drugs for depression, anxiety, bipolar illness, blood clots, chemotherapy, heart conditions, and psychosis), ventricular arrhythmia or sudden death can occur with concomitant use of fluoxetine. FDA analysis found AMPD Gold Bee Pollen to contain

undeclared sildenafil which has the potential to interact with medications. Males taking nitrates are at risk for life threatening hypotensive events. Certain medications such as ritonavir, ketoconazole, and itraconazole as well as consuming substantial amounts of alcohol can increase the effects of sildenafil.

The products were distributed nationwide via the internet and retail stores. No illnesses have been reported to date with the use of these products.

Detox Transforms has ceased distribution of the products as the company is working in close cooperation with the U.S. Food and Drug Administration (FDA) to fully resolve this issue. Detox Transforms is notifying its distributors and customers by email, telephone, and mail and is arranging for return of all recalled products. Consumers/distributors/retailers that have these products which are being recalled should stop use and return to place of purchase for a full refund.

Consumers with questions regarding this recall may contact Detox Transforms at 877-404-7873 or 919-341-9050 between the hours of 10am – 6pm (EST), Monday through Friday. 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 these 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: Detox Transforms Health and Nutrition Issues Voluntary Nationwide Recall of Dietary Supplements Due to the Presence of Undeclared Drug Ingredients 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.