



**Indiana State  
Department of Health**  
*An Equal Opportunity Employer*

**Michael R. Pence**  
Governor

**Jerome M. Adams, MD, MPH**  
State Health Commissioner

**DATE:** February 10, 2015

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:** *Kristine Gaspi*  
Laurie Kidwell, RRT Supervisor  
Food Protection Program

**SUBJECT:** Detox Transforms Health and Nutrition – RECALL [Drug]

**AFFECTED  
PRODUCT:** Dietary Supplements

**SUMMARY:** Unclassified Recall; The recall has been initiated because they contain undeclared drug ingredients making them unapproved drugs.

The following products are being recalled:

<u>Product Name</u>	<u>Bottle Color</u>	<u>Label</u>	<u># Capsules</u>	<u>UPC</u>	<u>Lot</u>	<u>Expiration</u>
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

The recalled products were distributed nationwide via the internet and retail stores.

**SUGGESTED**

**ACTION:** For consumer inquiry only. 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.

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.



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

**Contact:**

Consumer:  
877-404-7873 or 919-341-9050

**FOR IMMEDIATE RELEASE** — January 9, 2015 — 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	
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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: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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.

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

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*Photo*





DIETARY SUPPLEMENT

**AMPD GOLD**

**BEE POLLEN CAPSULES**

350mg

**60**  
CAPSULES



by  
ent

Be  
Or  
Ca  
M  
Jo  
So  
Ko  
Lo  
Ba  
Ta  
P  
35



200 mg

DIETARY SUPPLEMENT

INSANE

BEE POLLEN  
CAPSULES

60  
CAPSULES







DIETARY SUPPLEMENT

220 mg

INDIGO

60  
CAPSULES

GOOD MANUFACTURING PRACTICE  
GMP