

Mitchell E. Daniels, Jr. Governor

**Gregory N. Larkin, M.D., F.A.A.F.P.** *State Health Commissioner* 

DATE:

August 19, 2010

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

A. Scott Gilliam, MBA, CP-FS Director, Food Protection Program

**SUBJECT:** 

J & H Besta Corp. Recall

## **SUGGESTED**

**ACTION:** 

Unclassified Recall; Slim-30 Herb Supplement Lot 6032101 distributed by the company was found to contain undeclared Desmethyl Sibutramine, similar in structure to Sibutramine. Sibutramine is an FDA-approved drug used as an appetite suppressant for weight loss; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. The product was sold to distributors and retail stores nationwide and via internet sales. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

\*

## 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.

J & H Besta Expands Nationwide Recall of Slim- 30 Herb Supplement to Include Lot 6032101 Found to Contain an Undeclared Drug Ingredient

Contact:

Jason Wang 516-735-1436

FOR IMMEDIATE RELEASE - August 18, 2010 - J & H Besta Corp. of Hicksville, NY, has been informed by the Food and Drug Administration (FDA) that FDA lab analysis of Slim-30 Herb Supplement Lot 6032101 distributed by the company was found to contain undeclared Desmethyl Sibutramine, similar in structure to Sibutramine. Sibutramine is an FDA-approved drug used as an appetite suppressant for weight loss. The FDA has not approved Slim-30 Herbal Supplement, therefore the safety and effectiveness of the product is unknown. On July 16, 2010, J & H Besta had recalled Lot/Code 032009 and is now expanding the recall action to include Lot 6032101.

FDA advises that this 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.

Slim-30 Herb Supplement is marketed as a Natural Herb for Weight Loss. Slim-30 Herb Supplement is packaged in plastic bottles containing 30 capsules per bottle and bears UPC 8 31457 005009 2.

The product was sold to distributors and retail stores nationwide and via internet sales.

No illnesses or injuries have been reported to the company to date in connection with this product. This recall is being conducted with the knowledge of the FDA.

J & H Besta Corp. is taking this voluntary action because of the concern for the health and safety of consumers. The company is discontinuing distribution of Lot/Code 6032101. It sincerely regrets any inconvenience to our customers.

Consumers should not consume Slim-30 Herb Supplement and should return it immediately to the place of purchase for a full refund. Consumers with questions should contact Jason Wang at 516-735-1436, Monday - Friday, 10:00 am - 5:30 pm, EDT.

Any adverse reactions experienced with the use of this product may be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program online [at www.fda.gov/MedWatch/report.htm<sup>9</sup>], by phone 1-800-332-1088 [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from the MedWatch "Download Forms<sup>10</sup>" page], by mail [to address on the pre-addressed form] or fax [1-800-FDA-0178].

###

Photo: Product Labels<sup>11</sup>