




Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 26, 2014

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

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

SUBJECT: Pure Edge Nutrition, LLC – RECALL [Drug]

AFFECTED

PRODUCT: Bella Vi Insane Bee Pollen Capsules, Bella Vi BTrim Ultimate Boost, Bella Vi BTrim Max, Bella Vi Extreme Accelerator, Bella Vi Insane Amp'd, and Bella Vi Amp'd Up.

SUMMARY: Unclassified Recall; The recall has been initiated because the products have been found to contain undeclared Sibutramine or a combination of both Sibutramine and Phenolphthalein.

All of the recalled products were distributed to consumers and distributors nationwide.

All affected products are marketed as dietary supplements for weight loss and were packaged and distributed as follows:

- Bella Vi Insane Bee Pollen Capsules is packaged in bottles of 60 capsules with lot # 201303 EXP: 14/03/07. Bella Vi Insane was distributed to consumers and distributors nationwide from March 1, 2013 – August 31, 2013.
- Bella Vi BTrim Max is packaged in bottles of 60 capsules with lot # BTX13 EXP: 2015/08/15. Bella Vi Btrim Max was distributed to consumers and distributors nationwide from August 31, 2013 – September 31, 2013.
- Bella Vi BTrim Ultimate Boost is packaged in bottles of 30 capsules with lot # BTRM3452 EXP: 2015/07/03. Bella Vi Btrim was distributed to consumers and distributors nationwide from July 1, 2013 – September 31, 2013.
- Bella Vi Extreme Accelerator is packaged in bottles of 30 capsules with lot # BTRX7654 EXP: 2015/07/08. Bella Vi Extreme was distributed to consumers and distributors nationwide from July 1, 2013 – September 31, 2013.
- Bella Vi Insane Amp'd is packaged in bottles of 60 capsules with lot # VINA2013 EXP: 2015/06/12. Bella Vi Insane Amp'd was distributed to consumers and distributors nationwide from June 1, 2013 – September 31, 2013.
- Bella Vi Amp'd Up is packaged in bottles of 60 capsules with lot # AU2013AB EXP: 2015/05/20 and lot #BVAU813 EXP: 2015/08/12. Bella Vi Amp'd Up was distributed to consumers and distributors nationwide from May 1, 2013 – September 31, 2013.

SUGGESTED

ACTION: For consumer inquiry only. Consumers with questions regarding this recall can contact Pure Edge Nutrition, LLC at (888) 417-3613 Monday – Friday 10:00 a.m. – 2:00 p.m. EST or email info@pureedgenutrition.com.

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.

Pure Edge Nutrition, LLC Issues Voluntary Nationwide Recall of Bella Vi Brand Products Due to Undeclared Sibutramine and Phenolphthalein

Contact

Consumer:
(888) 417-3613
info@pureedgenutrition.com

FOR IMMEDIATE RELEASE - March 26, 2014 - Toms River, NJ, Pure Edge Nutrition, LLC is voluntarily recalling one lot of each: Bella Vi Insane Bee Pollen Capsules, Bella Vi BTrim Ultimate Boost, Bella Vi BTrim Max, Bella Vi Extreme Accelerator, Bella Vi Insane Amp'd, and two lots of Bella Vi Amp'd Up to the consumer level. The products have been found to contain undeclared Sibutramine or a combination of both Sibutramine and Phenolphthalein through FDA laboratory analyses. Sibutramine a previously approved controlled substance, was removed from the US market in October 2010 for safety reasons, Phenolphthalein is used medicinally as a laxative and not approved for marketing in the US. Therefore, these products are unapproved new drugs.

Products containing sibutramine and phenolphthalein pose a threat to consumers because Sibutramine can increase blood pressure and/or pulse rate in some patients and may present a risk for those with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. To date, the company has not received any reports of adverse events related to this recall. The recall was initiated after discovering the Sibutramine and Phenolphthalein were included as ingredients by the manufacturer.

All affected products are marketed as dietary supplements for weight loss and were packaged and distributed as follows:

Bella Vi Insane Bee Pollen Capsules is packaged in bottles of 60 capsules with lot # 201303 EXP: 14/03/07. Bella Vi Insane was distributed to consumers and distributors nationwide from March 1, 2013 – August 31, 2013.

Bella Vi BTrim Max is packaged in bottles of 60 capsules with lot # BTX13 EXP: 2015/08/15. Bella Vi Btrim Max was distributed to consumers and distributors nationwide from August 31, 2013 – September 31, 2013.

Bella Vi BTrim Ultimate Boost is packaged in bottles of 30 capsules with lot # BTRM3452 EXP: 2015/07/03. Bella Vi Btrim was distributed to consumers and distributors nationwide from July 1, 2013 – September 31, 2013.

Bella Vi Extreme Accelerator is packaged in bottles of 30 capsules with lot # BTRX7654 EXP: 2015/07/08. Bella Vi Extreme was distributed to consumers and distributors nationwide from July 1, 2013 – September 31, 2013.

Bella Vi Insane Amp'd is packaged in bottles of 60 capsules with lot # VINA2013 EXP: 2015/06/12. Bella Vi Insane Amp'd was distributed to consumers and distributors nationwide from June 1, 2013 – September 31, 2013.

Bella Vi Amp'd Up is packaged in bottles of 60 capsules with lot # AU2013AB EXP: 2015/05/20 and lot #BVAU813 EXP: 2015/08/12. Bella Vi Amp'd Up was distributed to consumers and distributors nationwide from May 1, 2013 – September 31, 2013.

Pure Edge Nutrition, LLC is notifying its distributors and customers by email and is arranging for return of all recalled products. Consumers and distributors that have product which is being recalled should stop using and return products to Pure Edge Nutrition, LLC.

Consumers with questions regarding this recall can contact Pure Edge Nutrition, LLC at (888) 417-3613 Monday – Friday 10:00 a.m. – 2:00 p.m. EST or email info@pureedgenutrition.com. 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.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

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

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