Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: June 12, 2013

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

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

SUBJECT: Bethel Nutritional Consulting, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Bethel 30 green capsule was collected and tested by FDA in April 24, 2013. The capsules tested positive for Sibutramine and Phenolphthalein. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons; Information is provided in case of consumer inquiry.**

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. The product was sold directly to individual customers in our New York, NY, sales office and online at www.bethel30.com[2]. In addition, if any recalled products are found, please notify this office at 317-233-8475.

****

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.

Bethel Nutritional Consulting, Inc. Issues a Voluntary Recall of Weight Loss Pills "Bethel 30" Found to Contain an Undeclared Drug Ingredient

Contact
Consumer:
212-568-5330
customerservice@bethel30.com

FOR IMMEDIATE RELEASE - June 11, 2013 - Bethel Nutritional Consulting, Inc. was informed by the Food and Drug Administration (FDA) that a sample of **Bethel 30 green capsule** was collected and tested by FDA in April 24, 2013. The capsules tested positive for Sibutramine and Phenolphthalein. Sibutramine is a controlled substance that was removed from the market in

October 2010 for safety reasons. The FDA has not approved Bethel 30, green capsules as drugs; therefore the safety and effectiveness of this product is unknown.

FDA advises that these products may 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. This product may also interact, in life-threatening ways, with other medications a consumer may be taking.

Bethel 30, green capsules are marketed as a Natural Herb for Weight Loss manufactured with a pharmaceutical & Nutraceuticals laboratory. Bethel 30 Herb Supplement is packaged in plastic white bottles containing 30 capsules per bottle and bears Lot #'s 120514, with EXP: 12/05/2014.

The lot 120514 is the only one subject to recall and it will not be distributed through www.bethel30.com[1], or retail in office.

The product was sold directly to individual customers in our New York, NY, sales office and online at www.bethel30.com[2]. The company discontinued total distribution. It sincerely regrets any inconvenience to our customers.

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.

Consumers should not consume Bethel 30, green capsules, Herb Supplement and should return it immediately to the place of purchase for a refund. Consumers with questions should contact Kariny Ramirez 212-568-5330 or via email at customerservice@bethel30.com Monday - Friday, 10:00 am - 4:00 pm, EDT. 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.

- Online: www.fda.gov/medwatch/report.htm[3]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[4]. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Bethel Nutritional Consulting, Inc. is taking this voluntary action because we are committed to the health and safety of our customers and to the quality of our select brand. We are working diligently to make available an appropriate Natural Herbal replacement product manufactured in the USA for all of our affected customers. We are moving forward with new suppliers for our NEW custom formula.

We value our relationship with you and will continue to provide you with the best possible service. Thank you for your continued business and allowing us to be a trusted partner.

Photo: Product Labels[7]