



**DATE:** December 22, 2014

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

**FROM:** *Kariny Ramirez*  
Laurie Kidwell, RRT Supervisor  
Food Protection Program

**SUBJECT:** Bethel Nutritional Consulting, Inc. – RECALL [Drug]

**AFFECTED  
PRODUCT:** SLIM-K Capsules

**SUMMARY:** Unclassified Recall; The recall was initiated after the product was found to contain **Sibutramine, desmethyisibutramine, and Phenolphthalein**. These undeclared ingredients make this product an **unapproved new drug for which safety and efficacy have not been established.**

SLIM-K Capsules are marketed as a Natural Herbal Supplement for Weight Loss. SLIM-K blue and white capsules are packaged in white plastic bottles containing 30 Capsules per bottle, and labeled with Lot # 140430, Expiration 12/2017, and barcode 160126417509.

The product was sold online to consumers at [www.bethel30.com](http://www.bethel30.com). The company has discontinued distribution of this product.

**SUGGESTED  
ACTION:** For consumer inquiry only. Consumers with questions should contact Kariny Ramirez by phone at (212) 568-5330 or via e-mail at [customerservice@bethel30.com](mailto:customerservice@bethel30.com), Monday - Friday, 11:00 am - 4:00 pm, ET.

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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.**

*Bethel Nutritional Consulting, Inc. Issues Nationwide Voluntary Recall of  
SLIM-K Capsules Due to Undeclared Drug Ingredients*

**Contact:**  
Consumers:  
**Kariny Ramirez**  
212-568-5330

**FOR IMMEDIATE RELEASE** – December 19, 2014 – New York, NY – Bethel Nutritional Consulting, Inc. is recalling one lot of **SLIM-K Capsules** to the consumer level. The firm was informed by the US Food and Drug Administration (FDA) that a sample of **SLIM-K** collected and tested by the FDA was found to contain Sibutramine, desmethylsibutramine, and Phenolphthalein. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010 (due to increased risk of seizures, heart attacks, arrhythmia and strokes). Phenolphthalein is an ingredient previously used in over-the-counter laxatives, but because of concerns of carcinogenicity, it is not currently approved for marketing in the United States. These undeclared ingredients make this product an unapproved new drug for which safety and efficacy have not been established.

Products containing sibutramine 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. Health risks associated with phenolphthalein could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use. **No illnesses or injuries have been reported to the company to date in connection with this product.**

**SLIM-K Capsules** are marketed as a Natural Herbal Supplement for Weight Loss. **SLIM-K** blue and white capsules are packaged in white plastic bottles containing 30 Capsules per bottle, and labeled with **Lot # 140430, Expiration 12/2017**, and barcode 160126417509.

The product was sold directly to individual customers in our New York City office and online to consumers at [www.bethel30.com](http://www.bethel30.com). The company has discontinued distribution of this product.

Consumers should not consume **SLIM-K Capsules** and should return it immediately to the place of purchase. Consumers with questions should contact Kariny Ramirez by phone at (212) 568-5330 or via e-mail at [customerservice@bethel30.com](mailto:customerservice@bethel30.com), Monday - Friday, 11:00 am - 4:00 pm, ET.

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](http://www.fda.gov/medwatch/report.htm)
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). 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.

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

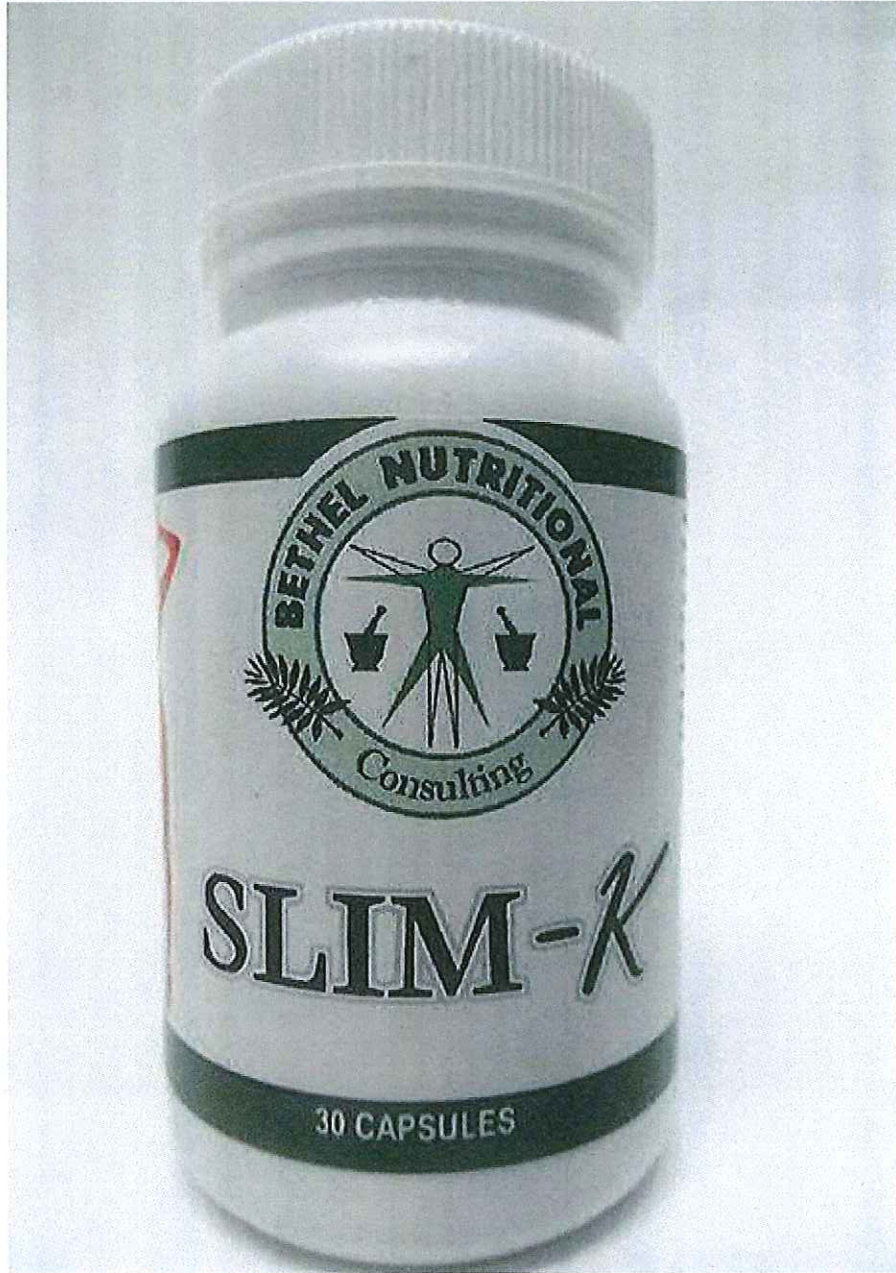
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## *Bethel Nutritional Consulting, Inc. Issues Nationwide Voluntary Recall of SLIM-K Capsules Due to Undeclared Drug*



*Ingredients*  
*Photo*



[www.Bethel30.com](http://www.Bethel30.com)

**DIRECTIONS:** Take one (1) capsule daily as dietary supplement.

**DCSIS:** Tomar una (1) capsula al dia como complemento alimenticio.

**IMPORTANT:** Store tightly closed in a dry place at controlled room temperature of 59° - 68°F.

**IMPORTANTE:** Almacenar en un sitio seco a temperatura ambiente de 15° - 30°C.

**DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING  
NO USAR SI EL SELLO ESTA ROTO O NO LO HAYE**

**KEEP OUT OF REACH OF CHILDREN**

**MANTENGASE FUERA DEL ALCANCE DE LOS NIÑOS**

If pregnant, nursing, or taking a prescription drug, consult a health care practitioner prior to use.

Si usted está embarazada, lactando o tomando algún medicamento, consulte a su médico antes de usar este producto.

None of the contents have ever been analyzed by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

[www.Bethel30.com](http://www.Bethel30.com)