Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 22, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

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

AFFECTED PRODUCT: **B-Lipo Capsules**

SUMMARY: **Unclassified Recall; The recall was initiated after a sample of B-Lipo Capsules collected and tested by the FDA was found to contain Lorcaserin, a controlled substance used for weight loss.**

B-Lipo Capsules are marketed as a Natural Herbal Supplement for Weight Loss. B-Lipo burgundy and white Capsules are packaged in white plastic bottles containing 30 Capsules per bottle, and labeled with Lot # 20213 EXP DATE 12/22/2016, and bar code 160126 417509.

The product was sold to consumers online at 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, 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 B-Lipo Capsules Due to the Presence of an Undeclared Drug Ingredient

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 **B-Lipo Capsules** to the consumer level. The firm was informed by the US Food and Drug Administration (FDA) that a sample of **B-Lipo Capsules** collected and tested by the FDA was found to contain Lorcaserin, a controlled substance used for weight loss.

Adverse health consequences associated with taking Lorcaserin range from difficulty thinking, hallucinations, and feeling of intense excitement to changes in blood sugar and heart rate. More serious adverse events, which may be life-threatening, include damage to the heart valve, or serotonin syndrome particularly if Lipo-B is taken with other medications that work similarly. Excessive levels of serotonin can cause symptoms that range from mild (shivering and diarrhea) to severe (muscle stiffness, fever, and seizures). Severe serotonin syndrome can be fatal if not treated. **No illnesses or injuries have been reported to the company to date in connection with this product.**

B-Lipo Capsules are marketed as a Natural Herbal Supplement for Weight Loss. **B-Lipo** burgundy and white Capsules are packaged in white plastic bottles containing 30 Capsules per bottle, and labeled with **Lot # 20213 EXP DATE 12/22/2016**, and bar code 160126 417509.

The product was sold directly to individual customers in our New York City sales office and to consumers online at www.bethel30.com. The company has discontinued distribution of this product.

Consumers should not consume **B-Lipo 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, 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 this 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.

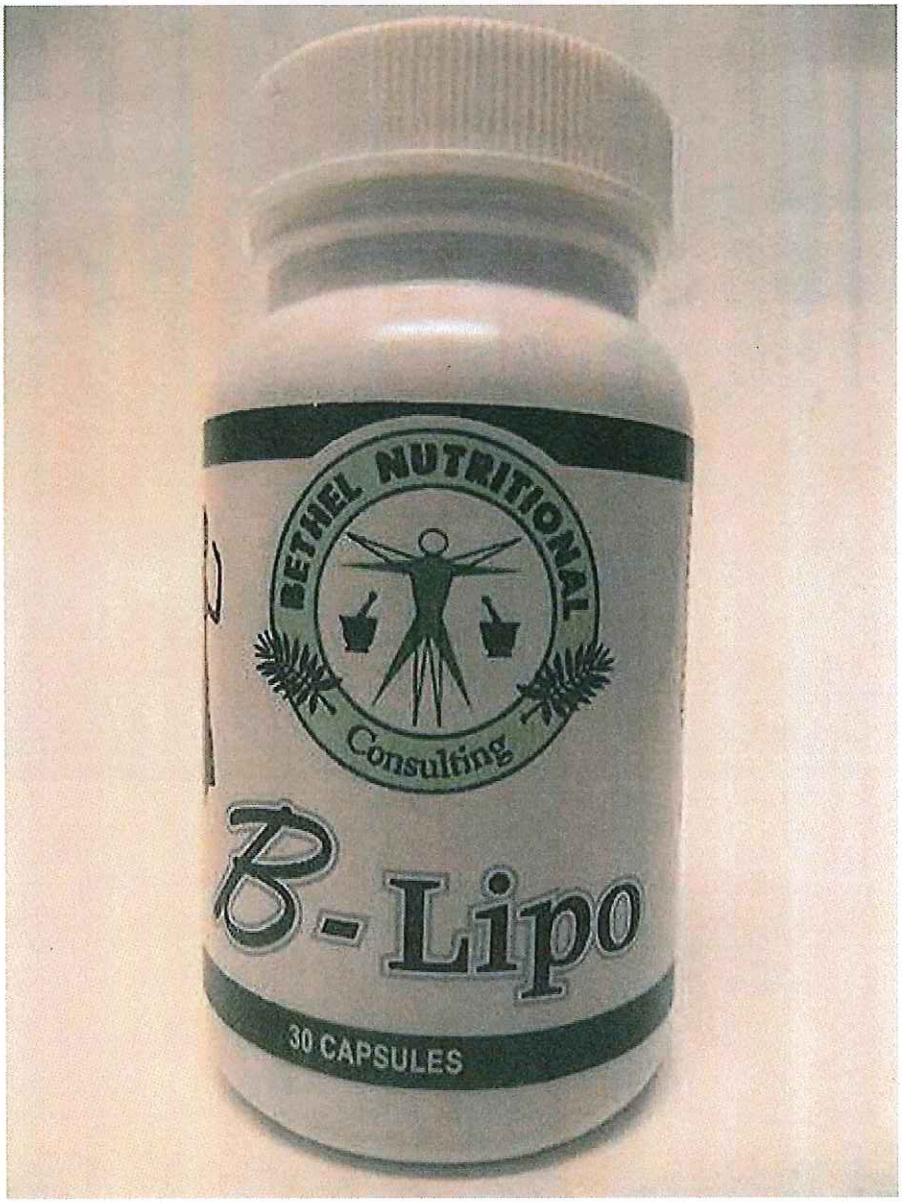
- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

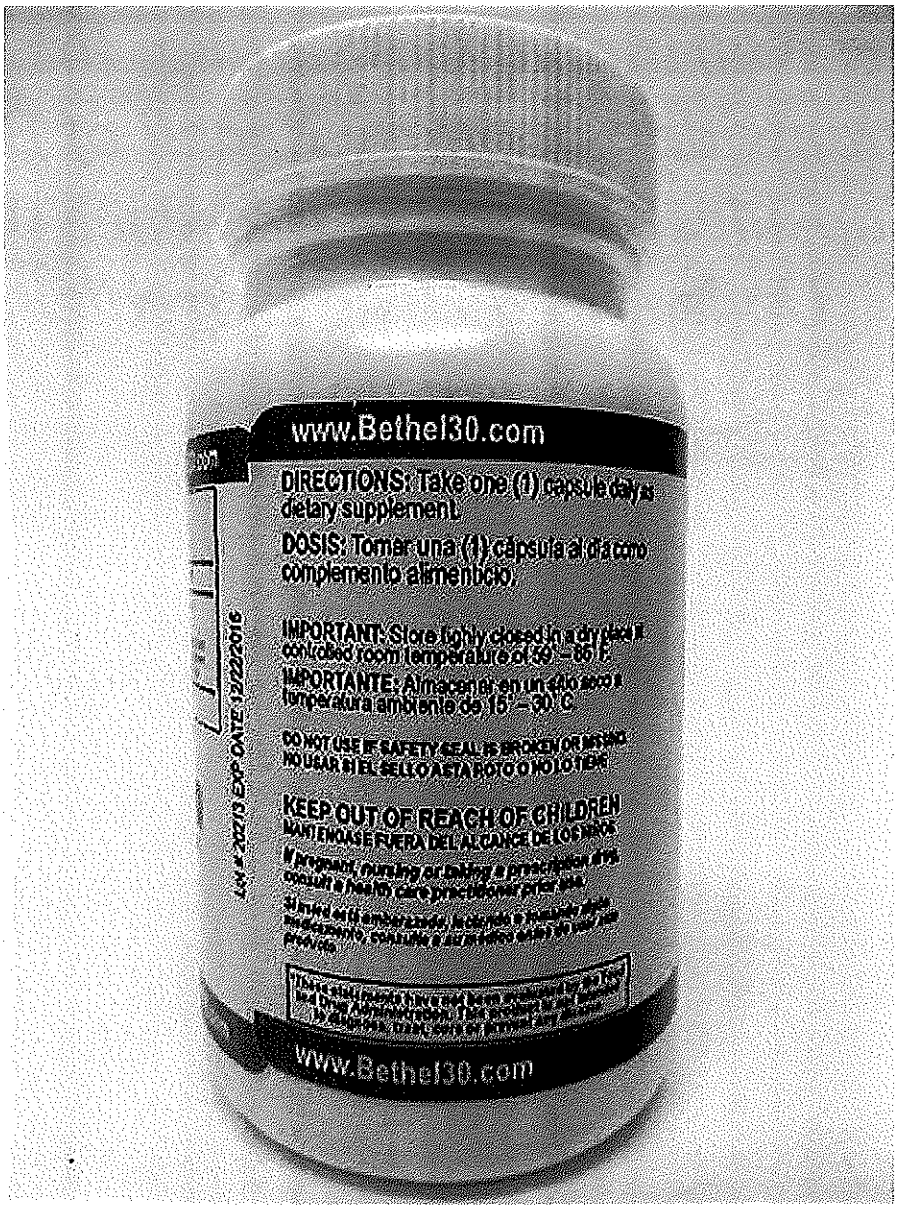
Bethel Nutritional Consulting, Inc. is taking this voluntary action because we are committed to the health and safety of our customers and to the quality of our select brand. We are working diligently to make available an appropriate Natural Herbal replacement product manufactured in the USA for all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

Bethel Nutritional Consulting, Inc. Issues Nationwide Voluntary Recall of B-Lipo Capsules Due to the Presence of an Undeclared Drug Ingredient

Photo




www.Bethel30.com
DIRECTIONS: Take one (1) capsule daily as dietary supplement.
DOSIS: Tomar una (1) cápsula al día como complemento alimenticio.
IMPORTANT: Store tightly closed in a dry place at controlled room temperature of 59° – 86° F.
IMPORTANTE: Almacenar en un lugar seco a temperatura ambiente de 15° – 30° C.
DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING
NO USAR SI EL SELLO ESTÁ ROTO O NO LO TIENE
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 use.
Si está en el embarazo, lactando, o tomando algún medicamento, consulte a su médico antes de usar este producto.
www.Bethel30.com