



**Indiana State
Department of Health**
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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*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: New Life Nutritional Center - RECALL [Drug]

**AFFECTED
PRODUCT:** "Super Fat Burner capsules, Maxi Gold capsules and Esmeralda softgels"

SUMMARY: Unclassified Recall; The recall has been initiated because the products contain undeclared active pharmaceutical ingredients: sibutramine, phenolphthalein or a combination of both sibutramine and phenolphthalein.

These products are used as weight loss aids and are packaged in 30 capsule bottles. All lots of these products are being recalled. See labels below.

New Life Nutritional Center distributed these products to customers through internet sales through their website at www.newlifnutritional.com.

**SUGGESTED
ACTION:** For consumer inquiry only. Consumers with questions should contact Nilson Rosado at 646-209-9846 Monday – Friday 8am to 6 pm ET or via e-mail at rosadohow@aol.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.



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To promote and provide
essential public health services.

New Life Nutritional Center Issues Voluntary Nationwide Recall of Super Fat Burner, Maxi Gold and Esmeralda Dietary Supplements Due to the Presence of Undeclared Sibutramine and Phenolphthalein

Contact

Consumer:
646-209-9846
rosadohow@aol.com

Media:
Nilson Rosado
646-209-9846

FOR IMMEDIATE RELEASE - March 25, 2014 - New Life Nutritional Center is recalling all lots of "Super Fat Burner capsules, Maxi Gold capsules and Esmeralda softgels" to the user level after FDA analysis revealed the products contain undeclared active pharmaceutical ingredients: sibutramine, phenolphthalein or a combination of both sibutramine 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Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010 (due to increased risk of seizures, heart attacks, arrhythmia and strokes).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 these products unapproved new drugs for which safety and efficacy have not been established. At this time no illnesses or injuries have been reported to New Life Nutritional Center in connection with these products.

These products are used as weight loss aids and are packaged in 30 capsule bottles. All lots of these products are being recalled. New Life Nutritional Center distributed these products to customers residing in NY, NJ, LA, TX, VA, and MA via retail stores and internet sales through their website at www.newlifenuitritional.com.

New Life Nutritional Center is notifying its customers by letter. Customers are advised to immediately discontinue use of these products and should return the products immediately to New Life Nutritional Center 714 West 181st Street NY, NY 10033 for a refund.

Consumers with questions should contact Nilson Rosado at 646-209-9846 Monday – Friday 8am to 6 pm ET or via e-mail at rosadohow@aol.com.

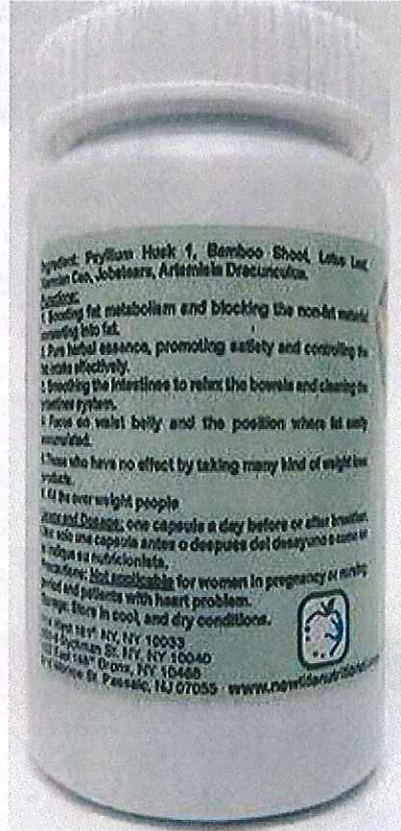
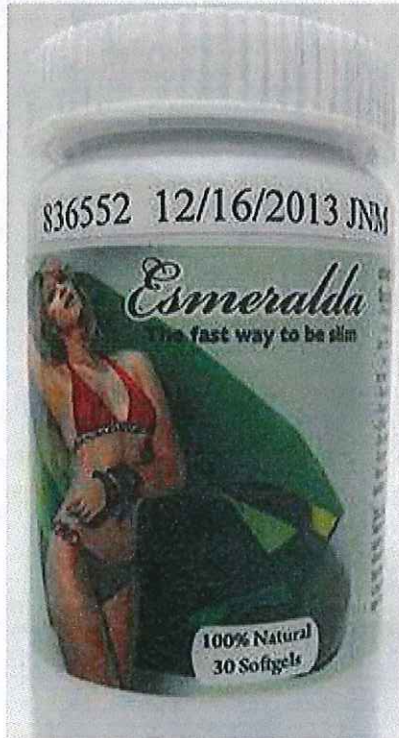
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

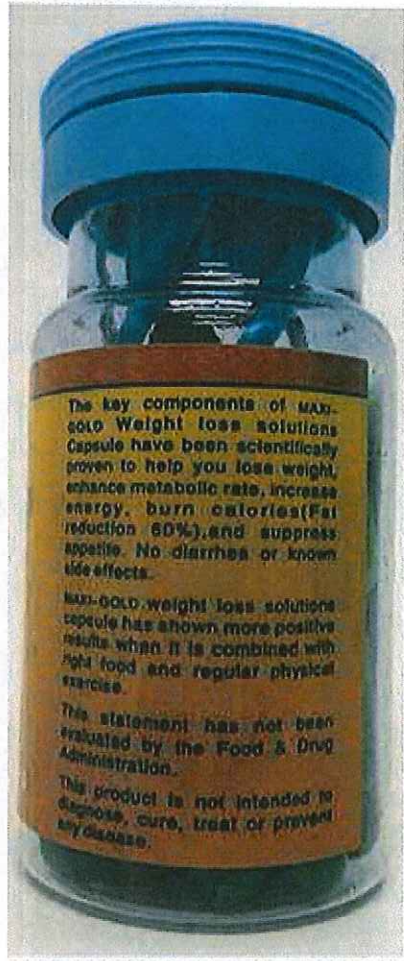
- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular mail or fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

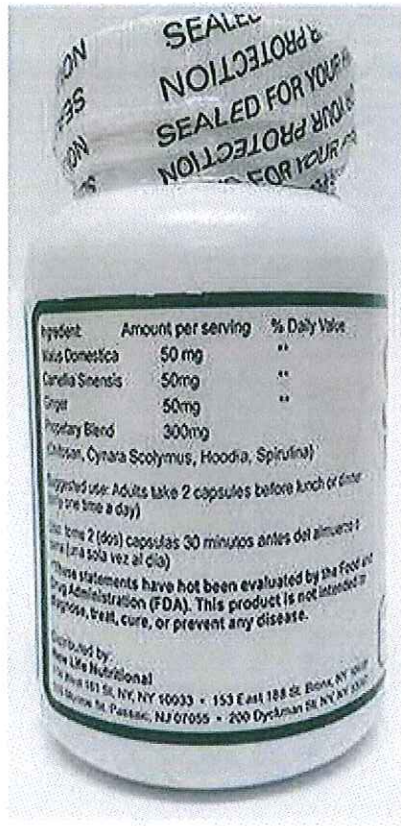
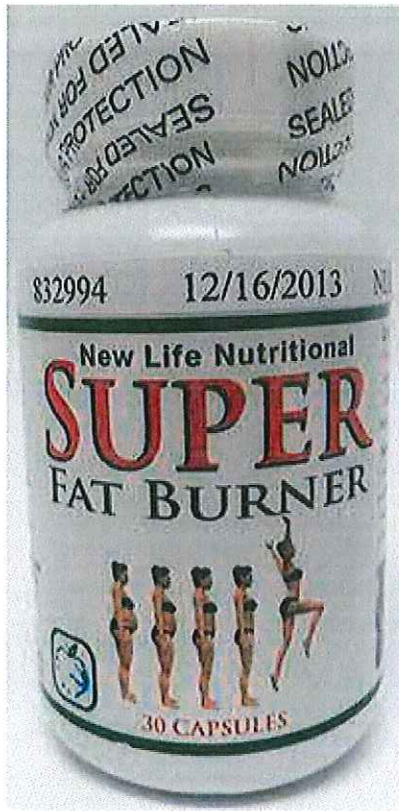
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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**Undeclared Sibutramine and Phenolphthalein
Photo**







[Return to Firm Press¹](#)

