



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: July 24, 2015
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: Life & More, L.L.C. – RECALL [Drug]

AFFECTED PRODUCT: Akttve High Performance Fat Burner Gold capsules weight loss supplements

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

Akttve High Performance Fat Burner Gold weight loss supplement capsules are marketed as a dietary supplement for weight loss. Akttve High Performance Fat Burner Gold capsules are packaged in aluminum bottles containing 30 gold capsules per bottle and labeled with Lot #000185004400, UPC 859189005005, Expiration 12/17. The products were distributed from January 2012 until July 2015.

The recalled product was sold nationwide.

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions regarding this recall can contact Life & More, L.L.C. at 01157-300-487-0534 or e-mail info@akttve.com, Monday through Friday from 9:00am - 5:00pm EST.

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.

Life & More, L.L.C. Issues Nationwide Voluntary Recall of Akttve High Performance Fat Burner Gold Capsules Due to Undeclared Drug Ingredients

Contact:
Consumer:
E-mail: info@akttve.com

FOR IMMEDIATE RELEASE - July 23, 2015 - Miami, Florida - Life & More, L.L.C. is voluntarily recalling 783 Bottles from Lot #000185004400 Akttve High Performance Fat Burner Gold capsules weight loss supplements. The firm was informed by the US Food and Drug Administration (FDA) that a sample of Akttve



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To promote and provide
essential public health services.

High Performance Fat Burner Gold capsules 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 Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010 (due to increased risk of seizures, heart attacks, arrhythmia and strokes).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 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 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.**

Akttive High Performance Fat Burner Gold weight loss supplement capsules are marketed as a dietary supplement for weight loss. **Akttive High Performance Fat Burner Gold** capsules are packaged in aluminum bottles containing 30 gold capsules per bottle and labeled with **Lot #000185004400, UPC 859189005005, Expiration 12/17**. The products were distributed from January 2012 until July 2015.

The product was sold directly to distributors and online to consumers at www.akttive.com and shipped to the following states: NV, FL, NY, AZ, MA, NJ, CA, MD, TX, VA and MI.

Life & More, L.L.C. is notifying its distributors and customers by letter and is arranging for return of all recalled products. Consumers should not consume Akttive High Performance Fat Burner Gold weight loss supplement Capsules and should return it immediately to the place of purchase.

Consumers with questions regarding this recall can contact Life & More, L.L.C. at 01157-300-487-0534 or e-mail info@akttive.com, Monday through Friday from 9:00am - 5:00pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using 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.

- 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 US Food and Drug Administration.

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SHILLING EXPERIENCE!!!

IKTIVE™

PERFORMANCE FAT BURNER

DIETARY SUPPLEMENT | 30 CAPSULES

INDICATED FOR: Healthy adults 18-65 years of age seeking to reduce unwanted body fat.

Supplement Facts

Serving Size: 1 tablet
Number of servings per container: 30

	Amount per Serving
Green Tea (leaf) Extract (Camellia sinensis L.) Standardized to 98% polyphenols, 75% catechins, 85% EGCG	160mg
Triphala (root) Standardized to 0.8% eleuthoside (B&E)	90mg
Yohimbinum (fruit) Standardized to 30% synephrine	80mg
Cassia (seed) 10:1 Extract (Cassia obtusifolia L.) Standardized	70mg
Coffeine Extract Standardized to 20% caffeine	15mg
Morus (leaf) (Morus alba)	20mg
Guggul (stem) Extract (Commiphora mukul) Standardized to 3% guggul sterones	10mg
Forskohli (root) Extract Standardized to 10% forskohlin	5mg

Other Ingredients: Gelatin, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Croscarmellose Dioxide, Magnesium Stearate.

RECOMMENDED USE: As a dietary supplement, take 1 tablet per day, on an empty stomach 20-35 minutes before breakfast or protein shake. DO NOT exceed recommended dosage.

WARNING: Do not use by individuals under the age of 18 years. Do not use if you have or develop diarrhea, loose stools, or abdominal discomfort. Consult your physician if you have frequent diarrhea, if you are pregnant, nursing, taking medication or have a medical condition. Store in a cool dry place.

KEEP OUT OF REACH OF CHILDREN AND PETS. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure, treat, or prevent any disease.

Number of tablets per container: 30
Distributor: [illegible]