Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 21, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: SmartLipo365 – RECALL [Drug]

AFFECTED PRODUCT: **Smart Lipo (800, 900, 950 mg) capsules**

SUMMARY: **Unclassified Recall; FDA's analysis found the Smart Lipo products to contain undeclared sibutramine, desmethylsibutramine, and phenolphthalein.**

Smart Lipo is marketed as a dietary supplement and is packaged in bottles of 30 capsules in 800mg, 900mg, and 950mg per capsule. The affected Smart Lipo products include all expiration dates.

The recalled products were distributed nationwide via the Internet, SmartLipo365.com.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact SmartLipo365 by calling 972-757-8136 on Monday through Friday from 10 A.M. to 5 P.M. (Central time).**

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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.

SmartLipo365 Issues Voluntary Nationwide Recall of Smart Lipo Due to Undeclared Sibutramine, Desmethylsibutramine and Phenolphthalein

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December 18, 2015

Contact

Consumers

SmartLipo365
(972) 757-8136

Firm Press Release

SmartLipo365 of Dallas, TX, is voluntarily recalling all lots of Smart Lipo (800, 900, 950 mg) capsules, to the consumer level. FDA's analysis found the Smart Lipo products to contain undeclared sibutramine, desmethylsibutramine, and phenolphthalein.

Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010. 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. 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. Health risks associated with phenolphthalein could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use. These undeclared ingredients make these products unapproved new drugs for which safety and efficacy have not been established. These products may also interact in life-threatening ways with other medications a consumer may be taking.

Smart Lipo is marketed as a dietary supplement and is packaged in bottles of 30 capsules in 800mg, 900mg, and 950mg per capsule. The affected Smart Lipo products include all expiration dates:. Smart Lipo was sold in stores, Centro Naturista in Richardson, TX, SmartLipo365 in Arlington, TX, as well as distributed nationwide via the Internet, SmartLipo365.com.

Smart Lipo 365 has not received any complaints associated with this product to date.

SmartLipo365 is notifying its distributors and customers by e-mail and letter and will not continue the distribution of Smart Lipo. Distributors and retailers should check their inventory and discontinue the Smart Lipo products. Consumers should immediately discontinue the use of these products.

Consumers with questions regarding this recall can contact SmartLipo365 by calling 972-757-8136 on Monday through Friday from 10 A.M. to 5 P.M. (Central time). 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.

- 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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