Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: June 5, 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; The recall has been initiated because the products contain undeclared sibutramine, desmethylsibutramine, and phenolphthalein. These undeclared ingredients make these products unapproved new drugs for which safety and efficacy have not been established.**

Smart Lipo is marketed as a dietary supplement and is packaged in bottles of 30 capsules, with 22 bottles of 800mg, 77 bottles of 900mg, and 23 bottles of 950mg.The affected Smart Lipo products include the following expiration dates: 800mg capsules - 9/15/2017, 900mg capsules - 7/30/2017, 950mg capsules - 7/30/2017 & 7/30/2018.

The product was sold nationwide via the internet.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact SmartLipo365 by 1-(800)-547-6365 or info@smartlipo365.com 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

Contact:
Consumer:
1-(800)-547-6365

FOR IMMEDIATE RELEASE — June 3, 2015 — Dallas, TX, SmartLipo365 is voluntarily recalling 122 lots of Smart Lipo (800, 900, 950 mg) capsules, to the consumer level. FDA received samples of 800 and 900mg

capsules of Smart Lipo and the lab results 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Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010.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, with 22 bottles of 800mg, 77 bottles of 900mg, and 23 bottles of 950mg.The affected Smart Lipo products include the following expiration dates: 800mg capsules - 9/15/2017, 900mg capsules - 7/30/2017, 950mg capsules - 7/30/2017 & 7/30/2018. 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

SmartLipo365 is notifying its distributors and customers by e-mail and letter and will not continue the distribution of Smart Lipo. Consumers, distributors, retailers that have Smart Lipo which is being recalled should stop using the recalled product and asked to please dispose it.

Consumers with questions regarding this recall can contact SmartLipo365 by 1-(800)-547-6365 or info@smartlipo365.com 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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