

## Pharmacy\_Subscriberlist@DCA

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**From:** Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>  
**Sent:** Monday, December 21, 2015 2:34 PM  
**To:** PHARM-GENERAL@DCALISTS.CA.GOV  
**Cc:** Pharmacy\_Subscriberlist@DCA  
**Subject:** Smart Lipo: Recall - Undeclared Drug Ingredients

**AUDIENCE:** Consumer

**ISSUE:** SmartLipo365 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. 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.

Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010.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.

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

**BACKGROUND:** 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.

**RECOMMENDATION:** 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.

[12/18/2015 - [Press Release](#) - SmartLipo365]