

Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, December 23, 2015 10:03 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Various Products Distributed for Weight Loss by Bee Extremely Amazed: Recall - Undeclared Drug Ingredients

AUDIENCE: Consumer

ISSUE: Bee Extremely Amazed LLC, Jewett, OH is recalling various products marketed for weight loss to the consumer level due to findings of undeclared drug ingredients including sibutramine and/or 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Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010.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.

To date, Bee Extremely Amazed is not aware of any adverse event reports related to these products. See the Firm [Press Release](#) for a complete list of the recalled products.

BACKGROUND: The affected products were sold nationwide between 4/29/2014 - 12/17/2015 via distribution/resale via the U.S. Postal service with the return addressee referenced as Bee Extremely Amazed, LLC or through any association with the email address sales@beeextremelyamazed.com and websites www.beeextremelyamazed.com, www.beefitamy.com, www.slimtrim.diet, www.Storeenvy.com.

RECOMMENDATION: Bee Extremely Amazed LLC is notifying its customers to stop using these products immediately and dispose of or return all recalled products to Bee Extremely Amazed 85205 Sportsmans Club Road Jewett Ohio 43986. Consumers with questions regarding this recall can contact Bee Extremely Amazed by email to sales@beeextremelyamazed.com or 1-844-427-6553 Monday - Friday 8:00 am - 4: 00 pm EST. Consumers should contact their physician or healthcare provider if they have any health questions or have experienced any problems that may be related to taking or using this product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- [Download form](#) 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.

[12/22/2015 - [Press Release](#) - Bee Extremely Amazed LLC]