



Department of
Agriculture

Ohio Department of Agriculture
and
Ohio Department of Health



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John R. Kasich

Lieutenant Governor
Mary Taylor

ODA Director
David T. Daniels

ODH Director
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DATE: July 5, 2016 2016

TO: Health Commissioners, Directors of Environment Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2016-90

Dream Body Weight Loss Issues Voluntary Nationwide Recall of Dream Body 450mg, Dream Body Extreme Gold 800mg, Dream Body Advanced 400mg Due to Undeclared Sibutramine

July 1, 2016 - **Grand Prairie, TX, Dream Body Weight Loss** is voluntarily recalling all lots of Dream Body Extreme Gold 800mg 30 gold capsules, Dream Body 450mg 30 white capsules, and Dream Body Advanced 400mg 30 purple capsules to the consumer level. The Dream Body Extreme 800mg Gold, Dream Body 450mg and Dream Body Advanced 400mg have been found to contain sibutramine after FDA sampling and testing.

Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010.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

Dream Body Weight Loss has not received any reports of adverse events related to this recall to date.

The product is used as a dietary supplement and is packaged in clear packer jars and brown foil packets. The affected Dream Body 450mg, Dream Body Extreme Gold 800mg and Dream Body Advanced 400mg with UPC codes 6903023120128 were distributed Nationwide from January 2013 to June 16, 2016 to consumers via retail sales and internet transactions.

Dream Body Weight Loss is notifying its customers via e-mail and is arranging for return of all recalled products. Consumers that have Dream Body 450mg, Dream Body Extreme Gold 800mg and Dream Body Advanced 400mg which is being recalled should stop using and discard the recalled products.

Consumers with questions regarding this recall can contact Dream Body Weight Loss by telephone at 888-882-7612 and/or e-mail at websales@dreambodyweightloss.com Monday- Friday 9am to 630pm CST. 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.