



Ohio Department of Agriculture
and
Ohio Department of Health



Governor
John R. Kasich

Lieutenant Governor
Mary Taylor

ODA Interim Director
Dr. Tony Forshey

ODH Director
Theodore E. Wymyslo, M.D.

DT: February 22, 2012

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

RE: Recall Announcement (ODA/ODH) 2012-012a

Healthy People Co. is Expanding its Voluntary Recall Initiated on February 02, 2012 to Include Dietary Products Bought on or Before October 25, 2011

February 22, 2012 - Healthy People Co. announced today that is expanding its voluntary nationwide recall of the company's dietary supplements sold under the brand names described below, regardless of the lot numbers referenced herein, and to the extent these products were bought on or before October 25, 2011.

On February 02, 2011, Healthy People Co. conducted a voluntary recall because FDA lab analysis confirmed the presence of Sibutramine and Tadalafil in the products identified herein, making the following products unapproved new drugs:

MINCE BELLE (Dietary Supplement, 30 Capsules)

LOT: HPCMB/10-026, HPCMB/10-027, HPCMB/10-029, HPCMB/10-020, HPCMB/10-021, HPCMB/10-016; UPC7503013203305

EVERLAX (Dietary Supplement, 30 Capsules)

LOT: HPC EX/074, HPC EX/076, HPC EX/072, HPC EX/032; UPC7503013203046

EVER SLIM (Dietary Supplement, 30 Capsules)

LOT: HPCES-079, HPCES-070, HPCES-071, HPCES/038; UPC7503013203053

EVER SLIM Shake Mix (Dietary Supplement Strawberry Contents 17.6 oz.)

LOT: HPESSF/168; UPC7503013203084

EVER SLIM Shake Mix (Dietary Supplement Chocolate Contents 17.6 oz.)

LOT: HPESSC/061; UPC7503013203077

ACAI-MAN MANGOSTEEN Herbal Drink (Dietary Supplement Contents 16.6 oz.)

LOT: HPJAC/004; UPC7503013203015

PERFECT MEN (Dietary Supplement, 10 Capsules)

LOT: HPCPM/002; UPC7503013203190

Sibutramine is an FDA-approved drug for appetite suppressant for the treatment of obesity, making dietary supplements: Mince Belle, Everlax, Ever Slim, Ever Slim Shake Mix Dietary Supplement Strawberry, and Ever Slim Shake Mix Dietary Supplement Chocolate unapproved drugs. It is a Schedule IV controlled substance and because of the risks associated with its use, it should be taken only under the direct supervision of a qualified health care professional. Sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk to patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. Sibutramine has been withdrawn from the U.S. marketplace. The active drug ingredient is not listed on the label for the products listed above.

Tadalafil is an FDA-approved drug for the treatment of male Erectile Dysfunction (ED), making Perfect Men Dietary Supplement and Acai-man Mangosteen Herbal Drink Dietary Supplement unapproved drugs. FDA advises that this poses a threat to consumers because Tadalafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

Although there is no evidence suggesting that other lot numbers contain these substances, today Healthy People Co. announced an expanded recall of the company's dietary supplements sold under the brand names described herein, to include all lot numbers sold on or before October 25, 2011.

Healthy People Co. advises its distributors and customers in possession of the brand names listed above, to return any unused product to our store located in 13105 Ramona Blvd Ste F, Irwindale, CA, 91706. Healthy People Co. will replace any returned products of the brand names listed above, regardless of the lot numbers referenced herein, to the extent these products were bought on or before October 25, 2011. Customers can call 626-939-4132 M-F 9am-5pm (PST) for instructions on the return process.

These products were distributed nationwide.

No illnesses or adverse effects have been reported to date in connection with these products; however, immediately examine your inventory and quarantine product subject to recall.

Healthy People Co takes this opportunity to clarify the amount of capsules found in PERFECT MEN (Dietary Supplement). A prior press release stated to be 30 capsules; the correct amount of capsules in the products is 10.

Any adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: <http://www.fda.gov/MedWatch/report.htm>¹
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>². Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.