



Ohio Department of Agriculture
and
Ohio Department of Health



Governor Ted Strickland
Lieutenant Governor Lee Fisher

ODA Director Robert J. Boggs
ODH Director Alvin D. Jackson, M.D.

To: Health Commissioners, Environmental Health Directors, Nursing Directors, ODA Food Safety Specialists, and Other Interested Parties

Subject: Recall Announcement (ODA/ODH) 2008-88

Date: November 26, 2008

Balanced Health Products, Inc. Conducts Voluntary Urgent Nationwide Recall of Starcaps Dietary Supplement Capsules Found to Contain an Undeclared Drug Ingredient

Balanced Health Products, Inc. is voluntarily recalling **STARCAPS DIET SYSTEM DIETARY SUPPLEMENT, Lot 12/2011 – 84810**, sold in 30 capsule plastic bottles.

The recall is effective immediately and is being undertaken because this lot of STARCAPS contains an undeclared drug ingredient- Bumetanide – a diuretic available by prescription only. Bumetanide is also not listed on the product label as an ingredient in this product.

Bumetanide is a diuretic indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease including nephrotic syndrome. Bumetanide has been detected in STARCAPS at a level of 0.8mg per capsule. Potential risks associated with the use of Bumetanide include serious and significant fluid and electrolyte loss and an elevation in uric acid concentrations. Consumers should not take Bumetanide if they are allergic to sulfonamides. Significant drug interactions with Bumetanide, such as with digoxin and lithium, may lead to an increase risk of toxicity. Patients may also be at an increased risk of hypotension (low blood pressure), fainting (syncope) and resultant injury if they have normal blood pressure or are already taking an antihypertensive medication and take STARCAPS with undeclared Bumetanide.

The company has received no reports of illness associated with this product.

To date, this recall only applies to **Lot 12/2011 – 84810**. The company is in the process of testing other lots and will notify the FDA of its results, as well as, if additional lots are to be recalled.

The recalled lot totaling 1,974 consumer-size bottles were distributed nationwide from August 2008 to October 30, 2008 through retail outlets and online sales.

Consumers who purchased **STARCAPS Lot 12/2011 – 84810** should immediately discontinue their use and return it to Balanced Health Products, Inc at the address on the product label.

Consumers with questions may contact the company at (212) 794-9793 from 10:30am to 4pm EST Monday through Friday.

Consumers who experience adverse events with any lots of this product should seek immediate help from their physician or healthcare provider.

Retail stores are being notified by fax or registered mail to immediately stop all sales and return product to the company.

This recall is being made in cooperation with the US Food and Drug Administration.

Any adverse reactions experienced with the use of this product should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, HF-410, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch