



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) 2008-88a

Date: December 9, 2008

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

Balanced Health Products, Inc. has expanded its voluntarily recall of STARCAPS DIET SYSTEM DIETARY SUPPLEMENT to include additional Lot Numbers 12/2009 – 82866 and 12/2010 - 83801, sold in 30 capsule plastic bottles.

The recall is effective immediately and is being undertaken because these lots of STARCAPS contain 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.

The company's investigation to date has indicated that an additional lot of raw material intended for use in the production of STARCAPS which has been stored in sealed drums since the time of its importation into the U.S. is also contaminated with Bumetanide. This information seems to indicate that the contamination occurred at the point of production of the raw material in Lima, Peru.

STARCAPS lot number 12/2009 – 82866, totaling 28,739 consumer-size bottles was distributed nationwide from 3/2006 to 4/2007 through retail outlets and online sales.

STARCAPS lot number 12/2010 - 83801, totaling 28,530 consumer-size bottles was distributed nationwide from 5/2007 to 7/2008 through retail outlets and online sales.

Consumers who purchased STARCAPS Lot Numbers 12/2009 – 82866 and 12/2010 – 83801 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.

Ohio Department of Agriculture ● 8995 E. Main Street ● Reynoldsburg, Ohio 43068-3399 ● Phone 614-728-6250 ● Fax 614-644-0720
Ohio Department of Health ● 246 N. High Street ● Columbus, Ohio 43215-2412 ● Phone 614-466-1390 ● Fax 614-466-4556

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.