

Governor  
John R. KasichLieutenant Governor  
Mary TaylorODA Director  
David T. DanielsODH Director  
Theodore E. Wymyslo, M.D.

DATE: May 13, 2013

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

RE: Recall Announcement (ODA/ODH) 2013-052a

**Beamonstar Products Issues Voluntary Nationwide Recall of SexVoltz, Velextra, & Amerect Marketed as a Dietary Supplement, Due to Undeclared Active Ingredients- Expanded to Include SexVoltz 12 Capsules Bottle, SKU 626570615316.**

May 10, 2013 -Queen Creek, AZ, BeaMonstar Products is voluntarily recalling all of SexVoltz brand SKU's 626570609490, 827912089028, 626570617877, 626570615316, 626570615316 Velextra brand SKU's 626570613855, 626570619055, 626570617860, 626570617563 Amerect SKU's 626570619031, 626570619628 capsules to the consumer level. Laboratory analysis conducted by the FDA on SexVoltz and Velextra has determined these products contain undeclared tadalafil. Amerect is voluntarily recalled because it has the potential to contain undeclared tadalafil. Tadalafil are FDA-Approved drugs used to treat male erectile dysfunction (ED), making the products unapproved new drugs.

**Risk Statement:** These undeclared active ingredients 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. BeaMonstar Products has not received any reports of adverse events to date related to this recall.

The product is used as a sexual enhancement product and all 3 products are packaged in blister type packaging in 1 & 2 caps blister, and in 4, 10 & 12 capsule bottles. The affected SexVoltz brand SKU's are 626570609490, 827912089028, 626570617877, 626570615316, 626570615316. The affected Velextra brand SKU's are 626570613855, 626570619055, 626570617860, 626570617563, Amerect SKU's are 626570619031, 626570619628. The affected 'Maximum Strength' SexVoltz, Velextra, and Amerect are all lots distributed and sold from January of 2012 to May 7, 2013 and contain various expiration dates. SexVoltz, Velextra, and Amerect was distributed Nationwide to wholesalers, retail, and via internet.

BeaMonstar Products is notifying its distributors and customers by email and telephonically and is arranging for credit of all recalled products. Consumers/distributors/retailers that have Sexvoltz, Velextra or Amerect which is being recalled should return to place of purchase.

Consumers with questions regarding this recall can contact BeaMonstar Products by 480-735-1424 or [info@beamonstar.com](mailto:info@beamonstar.com) Mon-Friday from 8am-1pm (MST). 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.

- **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)<sup>1</sup>
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). 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.