Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 8, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: BeaMonstar Products Recall

SUGGESTED ACTION: **Unclassified Recall; All of SexVoltz brand, Velextra brand, and Amerect capsules to the retail level 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; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. SexVoltz, Velextra, and Amerect was distributed Nationwide to wholesalers, retail, and via internet. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Beamonstar Products Issues Voluntary Nationwide Recall of SexVoltz, Velextra, & Amerect Marketed as a Dietary Supplement, Due to Undeclared Active Ingredients

Contact:
Consumer
480-735-1424

Media
Jeff Bolanos
480-522-0566

FOR IMMEDIATE RELEASE - May 7, 2013 - Queen Creek, AZ, BeaMonstar Products is voluntarily recalling all of SexVoltz brand SKU's 626570609490, 827912089028, 626570617877, 626570615316, Velextra brand SKU's 626570619475, 626570619475, 626570619475, 626570619475 , Amerect SKU's 626570619031, 626570619598 capsules to the retail 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, and in 4 capsule and 10 capsule bottles. The affected SexVoltz brand SKU's are 626570609490, 827912089028, 626570617877, 626570615316. The affected Velextra brand SKU's are 626570619475, 626570619475, 626570619475, 626570619475. Amerect SKU's are 626570619031, 626570619598. 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 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 [1]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]
  Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

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Photo: Product Labels[5]