

Governor
John R. Kasich**Lieutenant Governor**
Mary Taylor**ODA Director**
David T. Daniels**ODH Director**
Lance D. Himes

DATE: April 17, 2018

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

RE: Recall Announcement (ODA/ODH) 2018-059

Epic Products, LLC, Issues Voluntary Nationwide Recall of All Lots of Euphoric Capsules Due to Presence of Undeclared Sildenafil and Tadalafil

Overland Park, KS, Epic Products, LLC is voluntarily recalling all lots of Euphoric capsules, packaged in 1 count blister cards, 3 count bottles, and 12 count bottles to the consumer level. FDA analysis found samples of Euphoric to be tainted with undeclared sildenafil and tadalafil, active ingredients in two FDA-approved prescription drug products, also known as phosphodiesterase 5-inhibitors (PDE-5 inhibitors), used to treat male erectile dysfunction (ED). The presence of sildenafil and tadalafil in Euphoric renders it an unapproved drug for which safety and efficacy have not been established and, therefore subject to recall.

Consumers who take this product for ED could have underlying cardiovascular disease. Consumers with diabetes, hypertension, high cholesterol or heart disease often take nitrates; concomitant use of nitrates and PDE-5 inhibitors can lead to fatal cardiovascular collapse. To date, Epic Products, LLC has not received any reports of adverse events related to this recall.

This tainted Euphoric product is marketed as a dietary supplement for male sexual enhancement and is packaged in 1-count blister cards (UPC 6-9685928646-9), 3 count bottles (UPC 6-9685928646-6), and 12 count bottles (UPC 6-9685928648-3). All lots of Euphoric are included in this recall. Euphoric was sold to consumers nationwide in the USA via retail stores. Epic Products, LLC has discontinued sales of these products.

Epic Products is notifying its distributors and customers by email and phone calls and is arranging for return of all recalled products. Consumers/Distributors/retailers that have Euphoric which is being recalled should stop use/distribution and return to place of purchase.

Consumers with questions regarding this recall can call 1-800-589-1470 between the hours of 9:00am and 6:00pm CST. 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.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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