

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) 2018-057

'Rhino 69 Extreme 50000' Recalled due to Presence of Active Ingredient 'Tadalafil'

AMA Wholesale Inc. (Distributor/Re-seller), is voluntarily recalling Rhino 69 Extreme 50000 capsules to the consumer level. FDA analysis found the product to be tainted with undeclared tadalafil. Tadalafil is an active ingredient in a FDA-approved prescription drug that is used for erectile dysfunction.

AMA Wholesale Inc. has not received any reports of adverse events related to this recall.

Consumers who take dietary supplements for erectile dysfunction could have underlying cardiovascular disease (from diabetes, hypertension, and others). Consumers with diabetes, hypertension, high cholesterol or heart disease often take nitrates; concomitant use of nitrates and PDE5 inhibitors can lead to fatal cardiovascular collapse.

Rhino 69 Extreme 50000 is used as a sexual enhancer and is packaged in single capsule, blister packs which an expiration date of 12/2022 and UPC Code: 718122071128. The product was distributed nationwide via internet sales to the customers.

AMA Wholesale Inc. (Distributor/Re-seller) is notifying its customers by E-Mail and is arranging for return of the recalled product.

Consumers/distributors/retailers that have purchased 'Rhino 69 Extreme 50000' should immediately stop the consumption and the resale of the product. Return the product to the place of purchase for a refund.

AMA Wholesale Inc.'s customers with questions regarding this recall can contact the company by Phone: +1 (800) 689-6532 Monday through Friday from 9:00 am to 5:00 pm PST or E-Mail: amawholesale@hotmail.com. Consumers should contact their physician or health-care 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.