



Ohio Department of Agriculture
and
Ohio Department of Health



Governor
John R. Kasich

Lieutenant Governor
Mary Taylor

ODA Interim Director
Tim Derickson

ODH Director
Lance Himes

DATE: January 8, 2019

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

RE: Recall Announcement (ODA/ODH) 2019-003

Happy Together, Inc. Issues Voluntary Nationwide Recall of Product Due to Presence of Undeclared Sildenafil and Tadalafil

Happy Together, Inc. Boynton Beach, FL is voluntarily recalling all lots within expiry of the Rhino 5k capsules to the consumer level. FDA analysis finds these products to be tainted with sildenafil and Tadalafil. Sildenafil/Tadalafil is an FDA approved drug for the treatment of erectile dysfunction, the presence of sildenafil in the Rhino 5k products renders them unapproved drugs for which safety and efficacy have not been established, therefore subject to recall.

Risk Statements: Men with diabetes, high blood pressure, high cholesterol, or heart disease, may be on medications that if taken with these products could lower blood pressure to dangerous levels that could be life threatening. The products affected are men with diabetes, high blood pressure, high cholesterol, or heart disease. To date, Happy Together Inc. has not received any reports of adverse events related to this recall.

The product is marketed as dietary supplements for male sexual enhancement and is packaged in a blister card. 30 count box. Rhino 5k was distributed to consumers nationwide via the Internet. We are notifying the public through this public announcement due to lack of ability to identify customers who may have received the product. Happy Together, Inc. is notifying its customers that have the Rhino 5k products to stop use and properly discard the product.

Consumers with questions regarding this recall can contact Happy Together, Inc. by 248-343-2013 or Happy_my@yahoo.com, 504 Muirfield Dr. Atlantis FL, 33462 Monday – Friday 9am to 9pm Eastern Standard Time 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, regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** download 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 1-800-FDA-0178

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