



Department of Health  
Department of Agriculture

Mike DeWine, Governor  
Jon Husted, Lt. Governor

Amy Acton, MD, MPH, Director, Ohio Department of Health  
Dorothy Pelanda, Director, Ohio Department of Agriculture

DATE: March 16, 2020

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

RE: Recall Announcement (ODA/ODH) 2020-038

**Natural Remedy Store Issues Voluntary Worldwide - Recall of Active Male Due to Presence of Undeclared Tadalafil**

Natural Remedy Store is voluntarily recalling all lots of Active Male, 500mg capsules to the consumer level. FDA analysis has found the product to be tainted with undeclared tadalafil. - Tadalafil is an FDA approved drug indicated for the treatment of male erectile dysfunction. The presence of tadalafil in this product renders it an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Consumption of a product with undeclared tadalafil may pose a risk to consumers who take prescription medications containing nitrates (such as nitroglycerin). The combination of tadalafil and nitrates may lower blood pressure to dangerous levels which can be life threatening. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates and may be the population most likely to be affected. To date, Natural Remedy Store has not received any adverse events related to this recall.

The tainted Active Male product is marketed as a dietary supplement for male enhancement to boost sexual performance and is packaged in small foldable cardboard with the image of a Trojan helmet and the name Active Male with BN: Nd6332. The product was distributed at the Natural Remedy Store in San Antonio TX and through the NaturalRemedyStore.com website.

Natural Remedy Store is notifying its customers through this press release, recall letters and by displaying a sign on the retail counter of the Natural Remedy Store in San Antonio TX. and is arranging for return/replacement -of this recalled product. Consumers that have Active Male which is being recalled should stop using this product and return to place of purchase and/or should call us immediately to arrange for return.

Consumers with questions regarding this recall can contact Natural Remedy Store at (210) 798-5433 from Monday thru Saturday 10:00AM to 6:00PM central time or by e-mail address [natremedies@att.net](mailto:natremedies@att.net). 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.

1. Complete and submit the report [Online](#)
2. Regular Mail or Fax: [Download form](#) 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.