

Mike DeWine
Governor**Jon Husted**
Lieutenant Governor**Dorothy Pelanda**
ODA Director**Amy Acton, MD**
ODH Director

DATE: May 3, 2019

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

RE: Recall Announcement (ODA/ODH) 2019-073

D.B.P. Distribution Issues Voluntary Nationwide Recall of Titanium 4000 Due to Presence of Undeclared Sildenafil and Tadalafil

D.B.P. Distribution is voluntarily recalling all lots of Titanium 4000 capsules to; the consumer level. FDA analysis has found this product to be tainted with sildenafil and tadalafil. Sildenafil and tadalafil are both FDA approved active ingredients used for the treatment of erectile dysfunction and are in a class of drugs called phosphodiesterase (PDE-5) inhibitors. The presence of sildenafil and tadalafil makes Titanium 4000 an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. To date, D.B.P. Distribution has not received any reports of adverse events related to this recall.

Risk Statement: Consumers who take Titanium 4000 with undeclared sildenafil and that have underlying conditions such as diabetes, hypertension or high cholesterol often take nitrates. Concomitant use of nitrates and PDE-5 inhibitors can lower blood pressure to dangerous levels which can be life threatening. Titanium 4000 is used as a male enhancement nutritional supplement and is packaged in 30 count display boxes, with single pill packs containing a red and black pill. Titanium 4000 was distributed Nationwide to users via the internet and from www.discountbonerpills.com.

D.B.P. Is notifying its distributors and customers by email and phone and is arranging for return of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using/return to place of purchase or to D.B.P. Distribution or discard.

Consumers with questions regarding this recall can contact D.B.P. Distribution by phone 818-262-9951 on Monday thru Friday 9am to 5pm PST or e-mail orders@discountbonerpills@gmail.com.

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

Company Contact Information**Consumers:**

D.B.P. Distribution

(818) 262-9951

orders@discountbonerpills@gmail.com