

Michael R. Pence Governor

Jerome M. Adams, MD, MPH State Health Commissioner

DATE:

October 14, 2015

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

Laurie Kidwell, RRT/Supervisor

Food Protection Program

SUBJECT:

TF Supplements - RECALL [Drug]

**AFFECTED** 

PRODUCT:

RHINO 7 3000 capsules and Rhino 7 Platinum 3000 Capsules

**SUMMARY:** 

Unclassified Recall; The recall has been initiated because FDA analysis found these products to contain <u>undeclared</u> desmethyl carbondenafil and dapoxetine. Desmethyl carbondenafil is a phosphodiesterase PDE-5 inhibitor which is a class of drugs used to treat male erectile dysfunction, making these products unapproved new drugs. Dapoxetine is an <u>active ingredient not approved by the U.S. Food and Drug Administration (FDA).</u>

RHINO 7 3000 capsules packaged in a bottle containing six (6) capsules UPC: 616453150126 ALL LOT NUMBERS WITHIN EXPIRY and Rhino 7 Platinum 3000 Capsules packaged in a single (1) blister packs hang card count UPC: 700729253748 ALL LOT NUMBERS WITHIN EXPIRY. Lot numbers are on the back top right of the (1) count and on the side of the (6) count bottle.

the (1) count and on the side of the (b) count bottle.

The recalled products were distributed to consumers nationwide via our retail website tfsupplements.com.

SUGGESTED

ACTION:

For consumer inquiry only. Consumers with questions regarding this recall can contact TF Supplements by

telephone at 866-620-3586 between (Monday - Friday 9:00am to 5:00pm CST).

\*

## Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

October 9, 2015

Contact

**Consumers** 

866-620-3586



## Media

866-620-3586

Firm Press Release
View Product Photos

## Original Press Release issued 9/25/2015

TF Supplements of Houston, TX, is voluntarily recalling the following product to the consumer level: RHINO 7 3000 capsules packaged in a bottle containing six (6) capsules UPC: 616453150126 ALL LOT NUMBERS WITHIN EXPIRY and Rhino 7 Platinum 3000 Capsules packaged in a single (1) blister packs hang card count UPC: 700729253748 ALL LOT NUMBERS WITHIN EXPIRY. Lot numbers are on the back top right of the (1) count and on the side of the (6) count bottle. FDA analysis found these products to contain undeclared desmethyl carbondenafil and dapoxetine. Desmethyl carbondenafil is a phosphodiesterase PDE-5 inhibitor which is a class of drugs used to treat male erectile dysfunction, making these products unapproved new drugs. Dapoxetine is an active ingredient not approved by the U.S. Food and Drug Administration (FDA).

Desmethyl carbondenafil may pose a threat to consumers because this PDE-5 inhibitor may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels that can be life threatening. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

Dapoxetine has not been approved by the FDA and therefore its safety or efficacy has not been established. Chemically, dapoxetine belongs to a class of drugs known as selective serotonin reuptake inhibitors (SSRIs) used to treat depression. Studies have shown that antidepressants increased the risk of suicidal thinking and behavior in children, adolescents, and young adults when compared to placebo. Therefore, consuming these products presents a health risk which could be life threatening.

TF Supplements has received a report of one (1) adverse event associated with these products to date.

These products are marketed as dietary supplements for sexual enhancement and packaged in (6) count bottle and (1) count hanging card and distributed to consumers nationwide via our retail website tfsupplements.com. TF Supplements has discontinued sales of these products.

TF Supplements is notifying its customers via e-mail of this voluntary recall. Consumers that purchased these products from TF Supplements should stop using them immediately and can return the products to:

TF Supplements 6666 Gulf Freeway Houston, TX 77087

Consumers with questions regarding this recall can contact TF Supplements by telephone at 866-620-3586 between (Monday - Friday 9:00am to 5:00pm CST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these products. Consumers can report adverse reactions or quality control problems to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax as follows:

Complete and submit reporting form online at <a href="http://www.fda.gov/MedWatch/report.htm">http://www.fda.gov/MedWatch/report.htm</a>; or Mail or fax reporting form. Download form at <a href="http://www.fda.gov/MedWatch/getforms.htm">http://www.fda.gov/MedWatch/getforms.htm</a> or call 1-800-332-1088 to request a reporting form. Complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-1078.

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

## **Product Photos**







