Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: September 28, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: TF Supplements – RECALL [Dietary Supplements]

AFFECTED PRODUCT: **RHINO 7**

SUMMARY: **Unclassified Recall; The product is being recalled due to 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).**

RHINO 7 packaged in a bottle containing six (6) capsules WITH LOT# K824B719-P and in a single (1) count capsule hang card with LOT# SU-5102617*RP at the consumer level. Lot numbers are on the back top right of the (1) count and on the side of the (6) count bottle.

The product was distributed to consumers nationwide via are 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).**

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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.

TF Supplements Issues Voluntary Nationwide Recall of Dietary Supplements with Undeclared Active Pharmaceutical Ingredients

Contact:
Consumer:
866-620-3586
Media:
866-620-3586

FOR IMMEDIATE RELEASE — September 25, 2015 — Houston, TX — TF Supplements of Houston, TX, is voluntarily recalling the following product to the consumer level: RHINO 7 packaged in a bottle containing six (6) capsules WITH LOT# K824B719-P and in a single (1) count capsule hang card with LOT# SU-5102617*RP at the consumer level. 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 no reports of illness 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 are 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 http://www.fda.gov/MedWatch/report.htm; or
- Mail or fax reporting form. Download form at http://www.fda.gov/MedWatch/getforms.htm 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.

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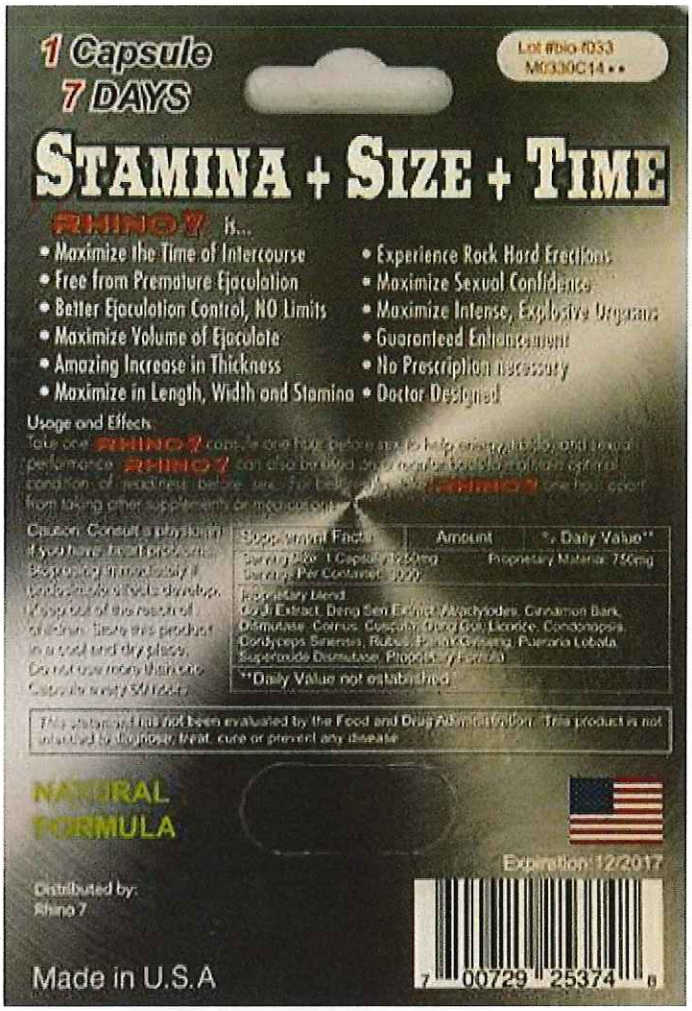
Photo


1 Capsule
7 DAYS
Lot #bio-f033
MG330C14 • •
STAMINA + SIZE + TIME
RHINO 7 is...
• Maximize the Time of Intercourse
• Free from Premature Ejaculation
• Better Ejaculation Control, NO Limits
• Maximize Volume of Ejaculate
• Amazing Increase in Thickness
• Maximize in Length, Width and Stamina
• Experience Rock Hard Erections
• Maximize Sexual Confidence
• Maximize Intense, Explosive Orgasms
• Guaranteed Enhancement
• No Prescription Necessary
• Doctor Designed
Usage and Effects
Caution: Consult a physician if you have heart problems. Discontinue immediately if undesirable effects develop. Keep out of the reach of children. Store this product in a cool and dry place. Do not use more than one capsule every 24 hours.
Supplement Facts
Amount
% Daily Value**
Proprietary Material 750mg
**Daily Value not established.
This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
NATURAL FORMULA
Expiration:12/2017
Distributed by:
Rhino 7
Made in U.S.A
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