Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 29, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Premiere Sales Group – RECALL [Drug]

AFFECTED PRODUCT: **RHINO 7 3000 capsules and Rhino 7 Platinum 3000 Capsules**

SUMMARY: **Unclassified Recall; The recall has been initiated because these products to contain undeclared desmethyl carbondenafil and dapoxetine, making these products unapproved new drugs.**

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 products were distributed to consumers nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Premiere Sales Group by telephone at 888-550-8621 between (Monday through Friday 7:30am to 4:00pm Pacific Standard Time.**

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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.

Recall: Firm Press Release

Premiere Sales Group Issues Voluntary Nationwide Recall of All Lots of Rhino 7 3000 and Rhino 7 Platinum 3000 Capsules due to Undeclared Active Pharmaceutical Ingredients

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 28, 2015

Contact

Consumers

Name
888-550-8621

Media

Name
888-550-8621
Firm Press Release
View Product Photos

Premiere Sales Group of Santa Clarita, California 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.

Premiere Sales has not received a report of any adverse events associated with these products.

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. Premiere Sales Group has discontinued sales of these products.

Premiere Sales Group has notified its customers of this voluntary recall via e-mail and phone. Consumers that purchased these products from Premiere Sales Group should stop using them immediately and can return the products to : Premiere Sales Group, 21446 Golden Triangle Rd., Santa Clarita, CA 91350

Consumers with questions regarding this recall can contact Premiere Sales Group by telephone at 888-550-8621 between (Monday through Friday 7:30am to 4:00pm Pacific Standard Time 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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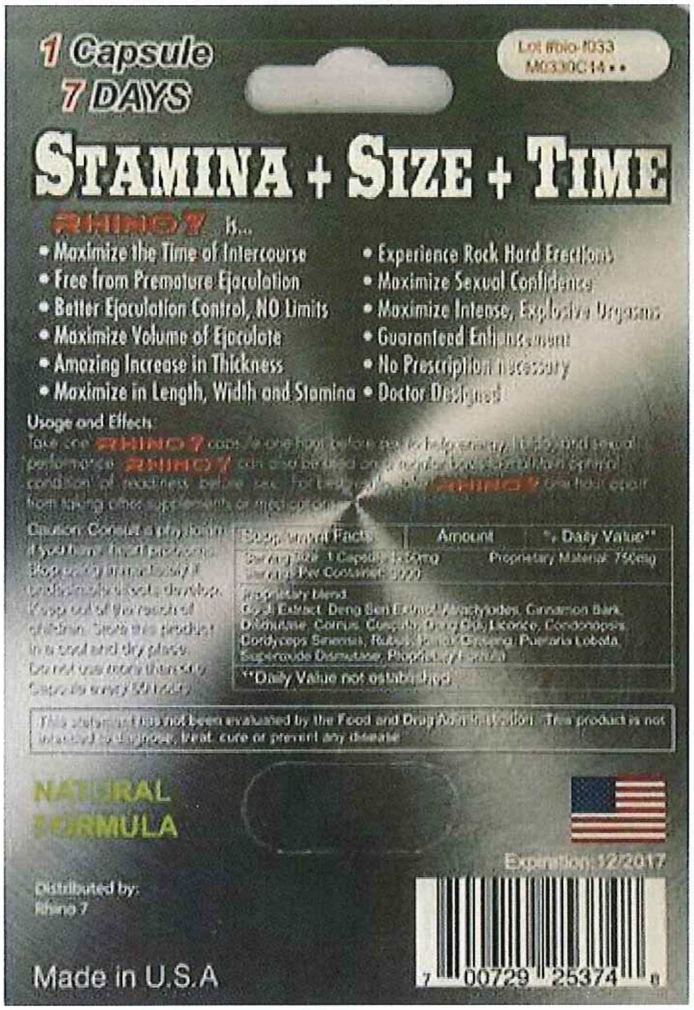
Product Photos


1 Capsule
7 DAYS
Lot #bio-f033
M0330C14
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
• Guaranteed Enhancement
• No Prescription necessary
• Doctor Designed
Usage and Effects:
Amount
Daily Value**
Proprietary Material: 750mg
Proprietary blend
Cinnamon Bark
Cordyceps Sinensis
Pueraria Lobata
**Daily Value not established
NATURAL FORMULA
Expiration: 12/2017
Distributed by:
Rhino 7
Made in U.S.A
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