Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 30, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: National Video Supply – RECALL [Drug]

AFFECTED PRODUCT: **RHINO 7 3000 Platinum Capsules**

SUMMARY: **Unclassified Recall; The recall is being conducted because these products 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.**

RHINO 7 3000 Platinum Capsules packaged in single 1 count blister hang tab cards with UPC # 700729253748 ALL LOT NUMBERS WITHIN EXPIRY. Lot numbers are located on the back top right of the (1) count and on the side of the 6 count bottles.

The recalled products were distributed to retail stores nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact National Video Supply by Telephone at 800-586-1915.**

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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

National Video Supply 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 29, 2015

Contact

Consumer

800-586-1915

Media

800-586-1915

Firm Press Release

National Video Supply located in Santa Clarita, California is voluntarily recalling the following product to the consumer level: RHINO 7 3000 Platinum Capsules packaged in single 1 count blister hang tab cards with UPC # 700729253748 ALL LOT NUMBERS WITHIN EXPIRY. Lot numbers are located on the back top right of the (1) count and on the side of the 6 count bottles. 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 increase 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.

National Video Supply 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 single 1 count blisters and 6 count bottles and distributed to retail stores nationwide. National Video has discontinued sales of these products.

National Video Supply has notified its customers of this voluntary recall via e-mail and phone. Consumers that purchased these products from National Video Supply should stop using them immediately and can return the products to: 21100 Centre Pointe Park Way, Santa Clarita, Ca. 91350

Consumers with questions regarding this recall can contact National Video Supply by Telephone at 800-586-1915 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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