



Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

**DATE:** August 21, 2013  
**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer  
**FROM:** A. Scott Gilliam, MBA, CP-FS (LK)  
Director, Food Protection Program  
**SUBJECT:** Jack Rabbit Inc. Recall [Drug]

**SUGGESTED ACTION:**

Unclassified Recall; Jack Rabbit Inc is voluntarily recalling Lot 2510 of the dietary supplement product, "Jack Rabbit". The products have been found to contain sildenafil and tadalafil. Sildenafil and Tadalafil are active ingredients of FDA-approved drugs for erectile dysfunction (ED), making Jack Rabbit pack DIETARY SUPPLEMENT an unapproved drug. The active drug ingredients are not listed on the product label. The undeclared ingredients may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products were distributed nationwide. Products were shipped nationwide to retail stores and online. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-3213.

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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.



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317.233.1325 tdd 317.233.5577  
[www.statehealth.in.gov](http://www.statehealth.in.gov)

To promote and provide  
essential public health services.

## **Jack Rabbit Inc. Conducts Voluntary Nationwide Recall of Lot 2510 of Jack Rabbit Dietary Supplement Due to undeclared ingredient**

**Contact:**

Consumer:

[www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)<sup>1</sup>

1-800-fda-0178

**FOR IMMEDIATE RELEASE** - August 12, 2013 - Jack Rabbit Inc. announced today that it is conducting a voluntary nationwide recall of one lot of the company's dietary supplement product sold under the following name: Jack Rabbit. The product was found to contain Sildenafil and Tadalafil. No illnesses have been reported to the company to date in connection with this product.

The Company has been informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA for Lot 2510 found that the product contains sildenafil and Tadalafil. Sildenafil and Tadalafil are active ingredients of FDA-approved drugs for erectile dysfunction (ED), making Jack Rabbit pack DIETARY SUPPLEMENT an unapproved drug. The active drug ingredients are not listed on the product label. The undeclared ingredients may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

Jack Rabbit Pack is marketed as a dietary supplement for sexual enhancement. It is packaged in 4 count blister packs and distributed online and retail stores nationwide.

Customers who have this product in their possession should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product. Consumers should return any unused product to the retail location where they were purchased or email Jack Rabbit, Inc. at [JackRabbit4pack.com](mailto:JackRabbit4pack.com) for a return address, Monday-Friday, 9 am to 5 pm EDT.

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.

Online; [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)<sup>2</sup>

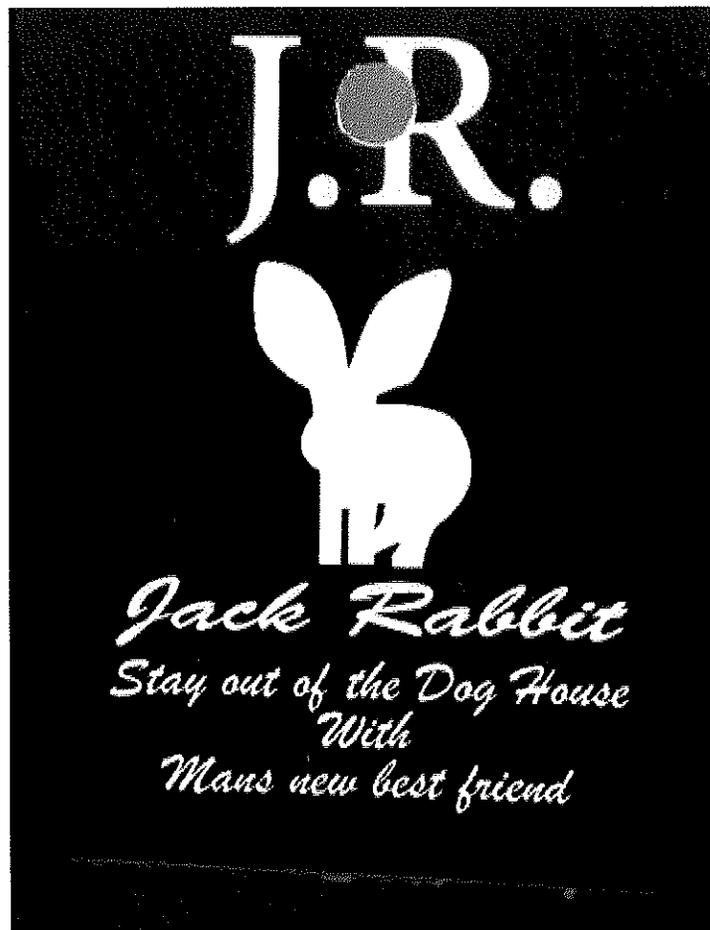
Regular mail: use postage-paid, pre-addressed form FDA 3500 available at: [www.fda.gov/medwatch/getforms.htm](http://www.fda.gov/medwatch/getforms.htm)<sup>3</sup>. Mail to address on the pre-addressed form.

Fax: 1-800-fda-0178

Jack Rabbit Inc., A Florida Corporation, is committed to providing accurate information about its products because of concerns for the health and safety of consumers. Jack Rabbit Inc. is working voluntarily with the FDA in the recall process. It sincerely regrets any inconvenience to customers.

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**Jack Rabbit Inc. Conducts Voluntary Nationwide Recall of Lot 2510 of Jack Rabbit Dietary Supplement Due to undeclared ingredient**  
**Photos**



**Dietary Supplement**

100% Money Back Guarantee

EXP DATE  
04/1/2015

Lot # 2510

**Supplement Facts**

Serving Size: 1 Tablet

Amount Per Serving	% Daily Value
Proprietary Blend	150 mg*
Epinephium	50 mg*
Rehmannia Glutitosa	40 mg*
Deer Root	30 mg*
Rhodiola Rosea	30 mg*

\* Daily value not established

[www.jackrabbitfourpack.com](http://www.jackrabbitfourpack.com)

**WARNING:** Consult physician before using this or any other dietary supplement. Do not use if you have heart problems or high blood pressure, consult physician.

**CAUTION:** Keep out of reach of children. Store in a cool, dry place.

These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Jack Rabbit, Inc.  
4355 Dow Road, Melbourne, FL 32934



084622843328

Not for use by persons under 18.  
Marketed by: Jack Rabbit, Inc.

**100% Natural**

**Order at:**  
**www.jackrabbitfourpack.com**

**All Natural**  
**-HERBAL SUPPLEMENT-**

**Jack Rabbit Tablet Indicated for:**

*Male loss of libido*  
*Short and small penis*  
*Dysfunction of erection*  
*Premature ejaculation*

**Recommended Use:**

*20-30 minutes before intimacy,*  
*with water, one tablet every*  
*3 days.*

**One tablet can last 24-72 hours,**  
**results may vary, real results.**

**Jack Rabbit Tableta Indicada Para:**

*Perdido de libido*  
*Pene pequeno y corto*  
*Disfuncion erectil*  
*Eyacuacion prematura*

**Uso Recomendado:**

*20-30 minutos antes de intimidad*  
*pasional, con agua, una tableta*  
*cada 3 dias*

**Caution:**

*Keep out of reach of children. These statements*  
*have not been evaluated by the FDA and are not*  
*intended to diagnose, cure or prevent any disease.*

