

## COMPANY ANNOUNCEMENT

# The Protein Shoppe, LLC Issues Voluntary Nationwide Recall of the "Red- E" Male Enhancement Tablet Due to the Presence of Undeclared Sildenafil

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

September 01, 2020

**FDA Publish Date:**

September 01, 2020

**Product Type:**

Drugs

**Reason for Announcement:**

Product contains undeclared sildenafil

**Company Name:**

The Protein Shoppe, LLC

**Brand Name:**

Red-E

**Product Description:**


Red-E male enhancement tablet

## Company Announcement

The Protein Shoppe, LLC is voluntarily recalling all lots of "Red-E" (Male Enhancement tablet) to the consumer level. This recall has been initiated after an FDA laboratory analysis found the product to contain undeclared sildenafil, a Phosphodiesterase-5 (PDE-5) inhibitor which is the

active ingredient in an FDA approved drug used in the treatment of erectile dysfunction. The presence of sildenafil in Red-E renders it an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

The undeclared PDE-5 inhibitor in the product may pose serious health risks to consumers with underlying medical issues. For example, PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin) lowering blood pressure to dangerous levels that is life threatening and could result in serious adverse health consequences. Consumers with diabetes, high blood pressure, or heart disease often take nitrates. To date The Protein Shoppe, LLC has not received any reports of adverse events related to this recall.

The product, Red-E (Male Enhancement tablet), is marketed as a male enhancement nutritional supplement, the product is a scored octagonal tablet with "Red" embossed on either side of the score line on one side of the tablet which is contained in small plastic bag with a black label stapled to it, UPC. The Red-E pill was sold online at the website: [www.rgvproteinshoppe.com](http://www.rgvproteinshoppe.com) (<http://www.rgvproteinshoppe.com/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

The Protein Shoppe, LLC is notifying its customers with this press release and is arranging for return of all recalled products. Consumers that have The Red-E pill (male enhancement tablet), which is being recalled, should stop using and return to place of purchase.

Consumers with questions regarding this recall can contact The Protein Shoppe by phone at 956-687-3539, Monday through Friday from 10 AM to 6 PM CST. In addition, Consumers can email us at [theproteinshoppe@yahoo.com](mailto:theproteinshoppe@yahoo.com) (<mailto:theproteinshoppe@yahoo.com>) or send regular mail to: The Protein Shoppe, LLC, 101 E Exp. 83 Ste. A-1 Pharr, TX 78557. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the drug product.

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.

- Complete and submit the report Online (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

## Company Contact Information

### Consumers:

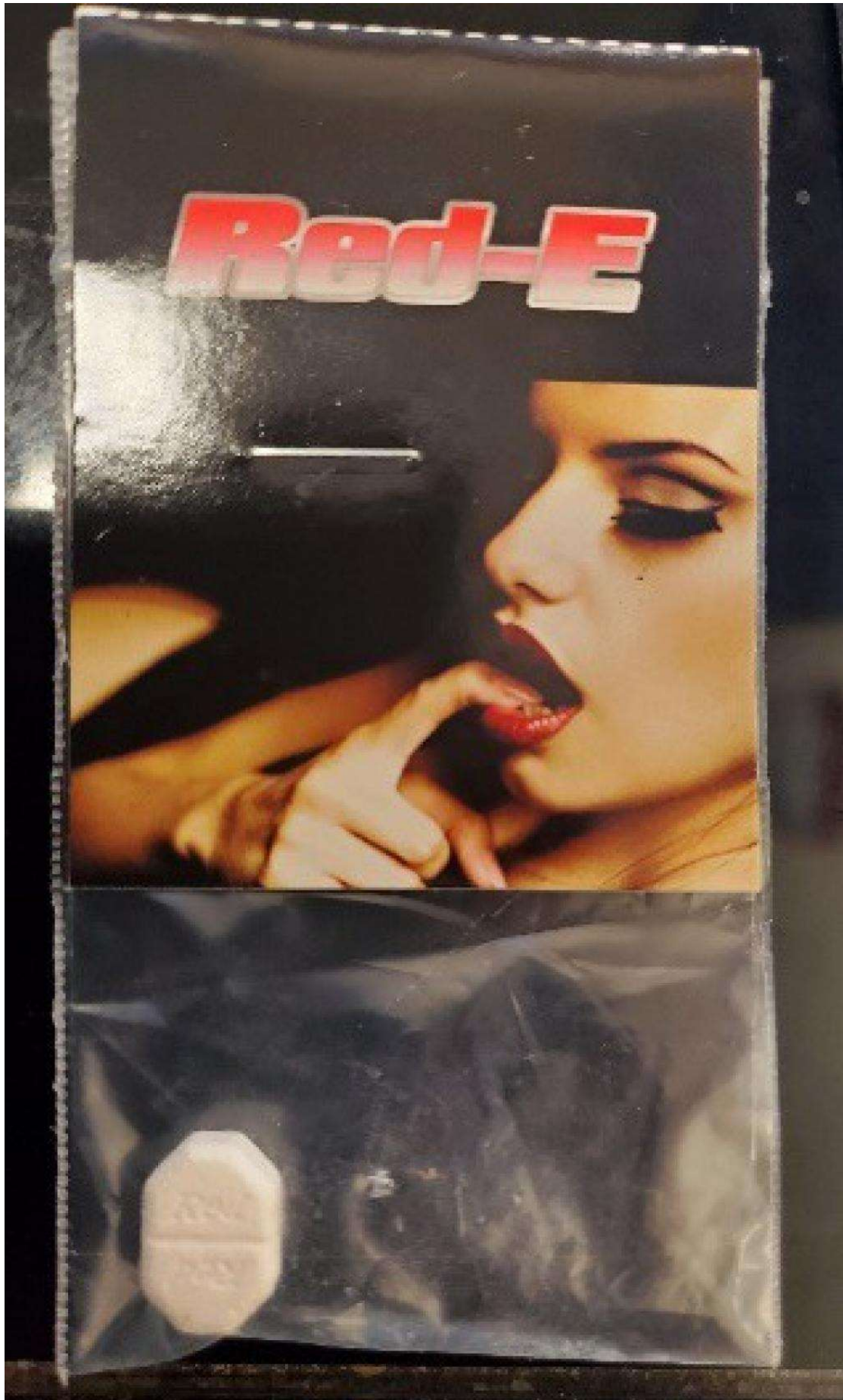
The Protein Shoppe

☎ 956-687-3539

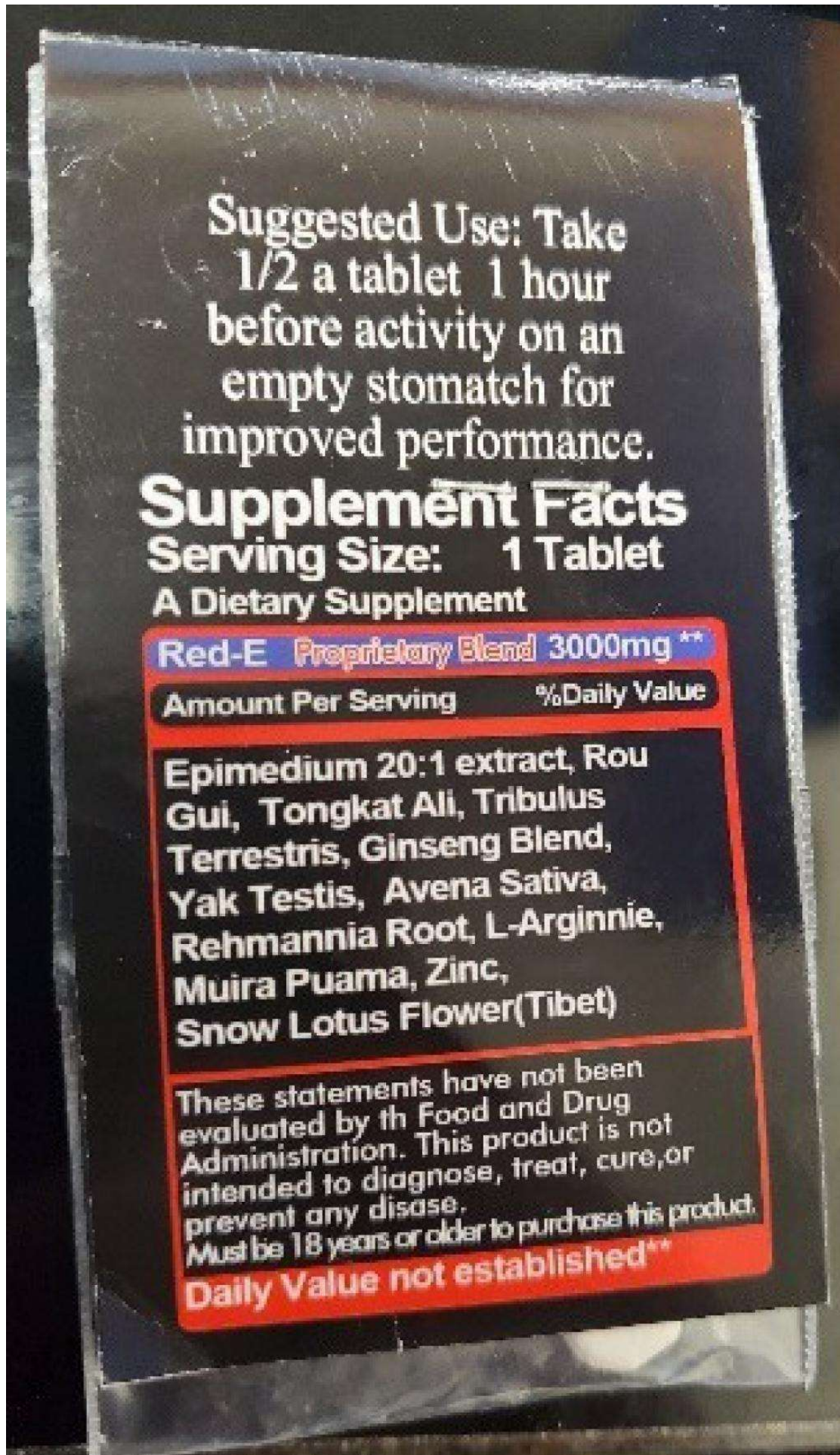
✉ [theproteinshoppe@yahoo.com](mailto:theproteinshoppe@yahoo.com) (mailto:theproteinshoppe@yahoo.com)

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## Product Photos







**Suggested Use: Take  
1/2 a tablet 1 hour  
before activity on an  
empty stomach for  
improved performance.**

**Supplement Facts**  
**Serving Size: 1 Tablet**  
**A Dietary Supplement**

**Red-E Proprietary Blend 3000mg \*\***

<b>Amount Per Serving</b>	<b>%Daily Value</b>
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<b>Epimedium 20:1 extract, Rou Gui, Tongkat Ali, Tribulus Terrestris, Ginseng Blend, Yak Testis, Avena Sativa, Rehmannia Root, L-Arginine, Muirapuama, Zinc, Snow Lotus Flower(Tibet)</b>	
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**These statements have not been  
evaluated by the Food and Drug  
Administration. This product is not  
intended to diagnose, treat, cure, or  
prevent any disease.  
Must be 18 years or older to purchase this product.**

**Daily Value not established\*\***



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