

COMPANY ANNOUNCEMENT

NS NY Distributor Inc Issues Voluntary Nationwide Recall of Premium OrgaZen 7000 and Ginseng Power 5000 Due to Presence of Undeclared Sildenafil and/or Tadalafil

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:

April 08, 2021

FDA Publish Date:

April 09, 2021

Product Type:

Drugs

Reason for Announcement:

Undeclared Sildenafil and/or Tadalafil

Company Name:

NS NY Distributor Inc

Brand Name:

NS NY Distributor Inc

Product Description:

Premium Orgazen 7000 and Ginseng Power 5000 capsules

Company Announcement

NS NY Distributor Inc is voluntarily recalling all lots within expiry of Premium Orgazen 7000 and Ginseng Power 5000 capsules to the consumer level. FDA analyses has found the products to contain undeclared sildenafil and/or tadalafil. Sildenafil and tadalafil are known as phosphodiesterase (PDE-5) inhibitors found in FDA approved products for the treatment of male erectile dysfunction. The presence of sildenafil and/or tadalafil in Premium OrgaZen 7000 and Ginseng Power 5000 makes them unapproved new drugs for which the safety and efficacy have not been established and therefore subject to recall.

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Consumers with underlying medical issues who take Premium OrgaZen 7000 capsules and Ginseng Power 5000 with undeclared sildenafil and/or tadalafil may experience serious health risks. For example, PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin) lowering blood pressure to dangerous levels that may be life-threatening. Consumers with diabetes, high blood pressure, or heart disease often take nitrates. To date, NS NY Distributor Inc has not received any reports of adverse events related to this recall.

These tainted products are marketed as a dietary supplements for male sexual enhancement and are packaged in a single capsule blister foil sheet and sold in lots of 3 capsules, 5 capsules and 10 capsules. The affected lot numbers of Premium OrgaZen 7000, UPC 0 40232 18144 3, and Ginseng Power 5000, UPC 0 40232 18144 3 include all lots. Premium OrgaZen 7000 and Ginseng Power 5000 were distributed nationwide in the USA via the internet by seller account Beauty.Kor. and fulfilled by amazon at www.amazon.com (www.amazon.com).

NS NY Distributor Inc is notifying customers who purchased through Amazon seller account Beauty.Kor by this press announcement. Consumers that have Premium OrgaZen 7000 and Ginseng Power 5000 which are being recalled should stop using and destroy them. Consumers with questions regarding this recall can contact NS NY Distributors Inc by email at NSNYdistributors@gmail.com (<mailto:nsnydistributors@gmail.com>). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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.

1. Complete and submit the report Online (../../../../node/360543)
2. Regular Mail or Fax: Download form (../../../../node/360547) 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:

NS NY Distributors Inc

✉ NSNYdistributors@gmail.com (<mailto:NSNYdistributors@gmail.com>)

Product Photos







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