

FDA Talk Paper

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FDA Public Health Advisory: FDA Warns Consumers Against Taking the Following Dietary Supplements-SIGRA, STAMINA Rx and STAMINA Rx for Women, Y-Y, Spontane ES and Uroprin

Today, the Food and Drug Administration (FDA) is warning consumers not to purchase or consume the following products: SIGRA, STAMINA Rx and STAMINA Rx for Women, Y-Y, Spontane ES and Uroprin, manufactured by NVE, Inc., in Newton, N.J. and distributed by Hi-Tech in Norcross, Ga. These products, which are being marketed as dietary supplements, actually contain a prescription drug ingredient that poses possible health risks. The products are being sold over-the-counter and are claiming to increase stamina, confidence and performance.

FDA has determined that the products actually contain the prescription-strength drug ingredient, tadalafil. Tadalafil is the active ingredient in Cialis, an Eli Lilly product approved in Europe to treat male erectile dysfunction. An interaction between certain prescription drugs containing nitrates (such as nitroglycerin) and tadalafil may cause a drastic lowering of blood pressure. There is real danger that this product may be taken by patients taking nitrates since erectile dysfunction is often a common problem in people with diabetes, hypertension (high blood pressure), hyperlipidemia (high cholesterol), ischemic heart disease and in people who smoke.

FDA's Office of Criminal Investigations, with assistance from FDA's New Jersey and Atlanta Districts, executed concurrent federal search warrants in Georgia and New Jersey after finding these dietary supplements.

Consumers who have used these products and have medical concerns should consult with their health care providers.

All consumers should be aware of the risks associated with these products.

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