Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Thumbs Up7 Red 70K

Manassas, VA, Antoto-K is voluntarily recalling all lots of Thumbs Up 7 Red 70K, 10 capsules to consumer level. FDA analysis has found the product to contain undeclared Sildenafil and Tadalafil. Sildenafil and Tadalafil are ingredients known as phosphodiesterase (PDE-5) inhibitors found in FDA approved products for the treatment of male erectile dysfunction. The presence of Sildenafil and Tadalafil in Thumbs Up 7 Red 70K, 10 capsules makes them unapproved new drugs for which the safety and efficacy have not been established and, therefore subject to recall.

Consumers with underlying medical issues who take Thumbs Up 7 Red 70K, 10 capsules with undeclared Sildenafil and 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, Antoto-K has not received any reports of adverse events related to this recall.

This tainted product is marketed as a dietary supplement for male sexual enhancement and is packaged in foil sheet and a box containing 10 capsules. The affected lot numbers of Thumbs Up 7 Red 70K includes all lots. Thumbs Up 7 Red 70K was distributed via internet and fulfilled by amazon at www.amazon.com nationwide in the USA. On December 17, 2020, FDA issued a press release that warned consumers to avoid certain products found on Amazon, eBay and other retailers due to hidden and potentially dangerous drug ingredients. It also encouraged online marketplaces to ensure these products are not sold on their platforms.

Antoto-K is notifying its customers by this press announcement and via e-mail of this recall. Consumers that have Thumbs Up 7 Red 70K which is being recalled should stop using and destroy them. Consumers with questions regarding this recall can contact Antoto-K by email at ngtbtr.k17@gmail.com. Consumers should contact their physicians 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.

· Complete and submit the report Online

· Regular Mail or Fax: Download form 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

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