



Clifton Health Department Food Recall Notification



Food/Drug/Pet Recall: Bit & Bet, LLC

Bit & Bet LLC is voluntarily recalling all lots of Thumbs Up 7 Blue 69K 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 Blue 69K capsules make 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 Blue 69K 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, Bit & Bet has not received any reports of adverse events related to this recall.

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This tainted product is marketed as a dietary supplement for male sexual enhancement and is packaged in blister foil sheets in a box labeled with UPC 6 17135 89467 3. Each box contains 10 capsules. The affected lot numbers of Thumbs Up 7 Blue 69K includes all lots. Thumbs Up 7 Blue 69K 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, e Bay 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.

Bit & Bet LLC is notifying its customers by this press announcement and via email of this recall. Consumers that have Thumbs up 7 Blue 69K, which is being recalled should stop using and discard them. Consumers with questions regarding this recall can contact Bit & Bet LLC by phone at (201) 208-2836 Monday to Friday from 9AM to 5PM or e-mail thumbsup7blue@gmail.com. For more information, please visit www.thumbsup7blue.comExternal Link Disclaimer. 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



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- 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

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