#### **COMPANY ANNOUNCEMENT**

# Jongu 4308 Issues Voluntary Nationwide Recall of Hydro Pineapple Burn Due to the Presence of Undeclared **Sibutramine**

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:** 

August 11, 2021

**FDA Publish Date:** 

August 11, 2021

**Product Type:** 

**Dietary Supplements** 

Drugs

**Reason for Announcement:** 

undeclared sibutramine

**Company Name:** 

Ebay Seller-John Nguyen

**Brand Name:** 

Max Health

**Product Description:** 

Hydro Pineapple Burn

### **Company Announcement**

Houston, Texas, eBay Seller ID: jongu 4308 is voluntarily recalling all lots of Hydro Pineapple Burn to consumer level. FDA analysis has found the product to contain undeclared sibutramine. Sibutramine was an FDA approved drug used as an appetite suppressant for weight loss but was withdrawn from the market because of safety issues. The presence of sibutramine in Hydro Pineapple Burn renders it an unapproved drug for which safety and efficacy has not been established and therefore subject to recall. To date, jongu 4308 has not receive any report of adverse events related to this recall.

Risk Statement: product containing sibutramine pose a health risk to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

This tainted product is marketed as a dietary supplement for weigh losst and is packaged in a box containing ten 20g sachets. Hydro Pineapple Burn was distributed by eBay via internet at www.ebay.com (https://www.ebay.com/) (http://www.fda.gov/about-fda/websitepolicies/website-disclaimer) nationwide in the USA (from 05/29/2021 to 07/27/2021). On August 03, 2021, FDA issued a press release (/news-events/press-announcements/fdawarns-consumers-avoid-certain-male-enhancement-and-weight-loss-products-soldthrough-amazon-ebay) that warned consumers to avoid certain products found eBay, Amazon, 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.

eBay Seller ID: jongu 4308 is notifying its customers by this press announcement and via email of this recall. Consumers that have Hydro Pineapple Burn, which is being recalled should stop using and destroy them. Consumers with questions regarding this recall can contact eBay Seller ID: jongu 4308 by messaging on eBbay or email: johnnyvn100@yahoo.com (mailto:johnnyvn100@yahoo.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 (/safety/medwatch-fda-safety-informationand-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: <u>Download form (/safety/medical-product-safety-</u> 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:**

eBay Seller ID: jongu 4308

<u> iohnnyvn100@yahoo.com (mailto:johnnyvn100@yahoo.com)</u>

# **Product Photos**



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