Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, December 14, 2015 9:34 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Reesna Inc., Issues a Nationwide Recall of Fuel Up Plus and Fuel Up High Octane due to the Presence of Undeclared Hydroxythiohomosildenafil

Reesna Inc., Canoga Park, CA, is recalling all lots of Fuel Up Plus and Fuel Up High Octane particularly distributed in August 2015 due to containing undeclared hydroxythiohomosildenafil, an analogue of sildenafil. Sildenafil is an FDA-approved drug for the treatment of male Erectile Dysfunction (ED), making Fuel Up an unapproved drug. The problem was found after FDA sampled the product and the results were positive for undeclared hydroxythiohomosildenafil.

Hydroxythiohomosildenafil is close in structure to sildenafil and is expected to possess a similar pharmacological and adverse event profile. This poses a threat to consumers because sildenafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. No illnesses or injuries have been reported to the company to date in connection with this product.

Fuel Up is marketed as a dietary supplement sexual enhancer for men. The product was sold to distributors and retail stores nationwide and via internet sales.

Reesna Inc. is notifying its customers by email and telephone. Consumers should not consume Fuel Up and should return it immediately to the place of purchase for a full refund. Reesna is taking this voluntary action because of the concern for the health and safety of consumers. The company has discontinued distribution of these affected products. It sincerely regrets any inconvenience to our customers.

Consumers should contact their physician if they have experienced any problems that may be related to taking this product. Consumers with questions should contact Romy Navarro at 818-576-0576, Monday through Friday, 9:00 am to 5:00 pm, PST.

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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.

To see the recall press release go to:
http://www.fda.gov/Safety/Recalls/ucm476978.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery