



Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: August 9, 2010
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: EZVille, Ltd. Recall

SUGGESTED

ACTION: Unclassified Recall; Undeclared Tadalafil. Tadalafil is an FDA-approved drug for the treatment of male Erectile Dysfunction (ED); Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The product was sold to distributors and retail stores nationwide and via internet sales. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

EZVille, Ltd. Issues a Voluntary Nationwide Recall of Revivexxx® Extra Strength Found to Contain an Undeclared Drug Ingredient

Company Contact:
Eric Budzinski,
Tel: 866-673-8483

FOR IMMEDIATE RELEASE - August 06, 2010 - EZVille, Ltd. of Ronkonkoma, NY, has been informed by the US Food and Drug Administration (FDA) that FDA lab analysis of Revivexxx® Extra Strength distributed by the company was found to contain undeclared tadalafil. Tadalafil is an FDA-approved drug for the treatment of male Erectile Dysfunction (ED), making Revivexxx® Extra Strength an unapproved drug.

FDA advises that this poses a threat to consumers because tadalafil 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.

Revivexxx® Extra Strength is marketed as a dietary supplement sexual enhancer for men. Revivexxx® Extra Strength is packaged in a single dose blister pack containing one oral tablet and bears UPC 8 35470 00207 9. **All lots of this product with expiration dates including and prior to August 2013 currently available on the market are being recalled.** The product was sold to distributors and retail stores nationwide and via internet sales.

No illnesses or injuries have been reported to the company to date in connection with this product.

EZVille, Ltd. 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 not consume Revivexxx® Extra Strength and should return it immediately to the place of purchase for a full refund. Consumers should contact their physician if they have experienced any problems that may be related to taking this product. Consumers with questions should contact Eric Budzinski at 1-866 -673-8483, Monday through Friday, 9:00 am to 5:30 pm, EDT.

Consumers and health care professionals should report adverse events that may be related to the use of this product to the FDA's MedWatch Adverse Event Reporting program online at www.fda.gov/medwatch/report.htm⁹, by phone at 1-800-FDA-1088 or by returning the postage-paid FDA form 3500 which may be downloaded from www.fda.gov/MedWatch/getforms.htm¹⁰ by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax to 1-800-FDA-0178.

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

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