



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: ^{ASG} A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: EZVille, Ltd. Solo Slim Recall

SUGGESTED ACTION: **Unclassified Recall; Sibutramine is an FDA-approved drug used as an appetite suppressant for weight loss. The FDA has not approved Solo Slim®, therefore the safety and effectiveness of the product is unknown; 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 Solo Slim® Found to Contain an Undeclared Drug Ingredient

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

FOR IMMEDIATE RELEASE - August 06, 2010 - EZVille, Ltd. of Ronkonkoma, NY, has been informed by the Food and Drug Administration (FDA) that FDA lab analysis of Solo Slim® distributed by the company was found to contain an undeclared drug ingredient. Solo Slim® was found to contain Didesmethyl Sibutramine. Sibutramine is an FDA-approved drug used as an appetite suppressant for weight loss. The FDA has not approved Solo Slim®, therefore the safety and effectiveness of the product is unknown.

FDA advises that Solo Slim® poses a threat 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 a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

EZVille, Ltd. has decided to recall Solo Slim® and Solo Slim® Extra Strength products, both marketed as dietary supplements for weight loss. Solo Slim® is packaged in white plastic bottles with blue screw-on cap containing 30 capsules per bottle and bears UPC 8 35470 00206 9. Solo Slim® Extra Strength is packaged in white plastic bottles with blue screw-on cap containing 30 capsules per bottle and bears UPC 8 35470 00220 5. **All lots of these products with expiration dates including and prior to August 2013 currently available on the market are being recalled.** The products were 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 these products.

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 Solo Slim® and Solo Slim® Extra Strength, and should return them 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 these products. Consumers with questions should contact Eric Budzinski at 1-866-673-8483, Monday through Friday, 9:00 am to 5:30 pm, EDT.

Any adverse reactions experienced with the use of these products may be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program online [at www.fda.gov/MedWatch/report.htm], by phone 1-800-332-1088 [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from the MedWatch "Download Forms" page], by mail [to address on the pre-addressed form] or fax [1-800-FDA-0178].

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

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