Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

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

DATE: January 3, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

ASG

SUBJECT: PRock Marketing, LLC Recall

SUGGESTED ACTION: **Unclassified Recall; Authentic Formula Fruta Planta the weight loss dietary supplements sold and marketed contains an undeclared drug ingredient. The FDA lab analysist found the Fruta Planta to contain 15.4 mg of Sibutramine, a controlled substance that was withdrawn from the market in October 2010 for safety reasons; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. The products were sold and distributed nationwide via the internet by several different websites and can also be found in some retail locations. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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.

PRock Marketing, LLC Issues a Voluntary Nationwide Recall of All weight loss formulas and variation of formulas of Reduce Weight Fruta Planta/Reduce Weight Dietary Supplement.

Contact:
Raquel McCalla
President of PRock Marketing, LLC
Frutaplanta.com
1-877-225-1009

FOR IMMEDIATE RELEASE - [Issued December 30, 2010] PRock Marketing, LLC located in

Central Florida an authorized US distributor of the Authentic Formula Fruta Planta has been informed by the Food and Drug Administration (FDA) that the weight loss dietary supplements sold and marketed contains an undeclared drug ingredient. The FDA lab analysist of the dietary supplements found the Authentic Formula Fruta Planta to contain 15.4 mg of Sibutramine, a controlled substance that was withdrawn from the market in October 2010 for safety reasons. No illnesses or injuries have been reported to the company to date in connection with these products.

The FDA advises against taking ALL Formulas of Reduce Weigh Fruta Planta/Reduce Weight products. These products pose 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.

All lots of the Fruta Planta and Reduced Weight Fruta Planta dietary supplement products are being recalled. All these products contain the active pharmaceutical ingredient Sibutramine:

- Fruta Planta; 30 Capsules/Box
- Reduce Weight Fruta Planta; 30 capsules/Box; 30 capsules/Bottle
- Reduce Weight Fruta Planta; 30 capsules/ Pink Box;
- Reduce Weight Fruta Planta; 30 capsules/Box With GMP Sticker
- Reduce Wieght Fruta Planta; 30 Capsules/Box
- Reduce Wieght; 30 Capsules/Box

The products listed above were sold and distributed nationwide via the internet by several different websites and can also be found in some retail locations. PRock Marketing, LLC wants all consumers to know that there is NO SAFE formula on the US market and that all versions of Fruta Planta contain Sibutramine. All versions of the formula are UNSAFE and should not be purchased from any source.

PRock Marketing, LLC has taken this voluntary action because it is committed to providing accurate information to all consumers and is concerned for the health and safety of all users of Fruta Planta. PRock Market, LLC is working with the FDA in the recall process. We sincerely regret any inconvenience the recall may cause customers.

Consumers are advised to destroy the above products or return them to the companys address in Central, Florida. Consumers with questions may contact frutaplanta.com Monday through Friday 10:00 am to 4:30 pm at 877-225-1009 EST.

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.

- Online:www.fda.gov/medwatch/report.htm [9]
- Regular Mail : use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm [10]. Mail to address on the pre-addressed form.
- Fax : 1-800-FDA-0178

Photo: Product Label[13]