



DATE: February 14, 2014

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

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

SUBJECT: MyNicKnaxs, LLC [Drug]

**AFFECTED
PRODUCT:** Reduce Weight Fruta Planta

SUMMARY: Unclassified Recall; This drug is being recalled because it contains Phenolphthalein, an undeclared active pharmaceutical ingredient.

All lots of the Reduce Weight Fruta Planta products are being recalled.

This product is sold online Nationwide.

**SUGGESTED
ACTION:** For consumer inquiry only. Customers are advised to immediately discontinue use and Consumers with questions should contact mynicknaxs at 386-337-8142 or via e-mail at nicknaxs@yahoo.com Monday - Friday, 2pm - 7:00 pm, EDT.

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.

MyNicKnaxs, LLC. Issues a Voluntary Nationwide and International Recall of All Weight Loss Formulas of Reduce Weight Fruta Planta

Contact
Consumer:
386-337-8142

FOR IMMEDIATE RELEASE - February 4, 2014 - MyNicKnaxs, LLC., located in Florida is announcing a recall of **Reduce Weight Fruta Planta** because the products contain an undeclared active pharmaceutical ingredient: Phenolphthalein. The FDA lab analysis of the product found **Reduce Weight Fruta Planta** to contain 10.2 mg of Phenolphthalein. No illnesses or injuries have been reported to MyKnickKnaxs, LLC., in connection with these products.

Phenolphthalein was once an ingredient used in over-the-counter laxatives, but because of concerns of carcinogenicity is not currently approved for marketing in the United States. This undeclared ingredient makes **Reduce Weight Fruta Planta** an unapproved new drug for which safety and efficacy have not been established. Consumption of this product could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use.

All lots of the **Reduce Weight Fruta Planta** products are being recalled.

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

Customers are advised to immediately discontinue use and Consumers with questions should contact mynickknaxs at 386-337-8142 or via e-mail at nicnaxs@yahoo.com Monday - Friday, 2pm - 7:00 pm, EDT.

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

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