







DATE: May 21, 2012
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: *DLG*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: West Coast Nutritionals, Ltd Recall

SUGGESTED ACTION: Unclassified Recall; all lots of FIRMİNITE, EXTRA STRENGTH INSTANT HOT ROD, AND LIBIDRON capsules to the consumer level because FDA found undeclared Tadalafil; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The affected products may have been ordered online at www.firminite.com¹ ², www.instanthotrodextrastrength.com³ ⁴, www.libidron.com⁵ ⁶, www.amazon.com⁷ ⁸ and were distributed to customers and retailers nationwide and worldwide. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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.

WEST COAST NUTRITIONALS, LTD. Issues a Voluntary Worldwide/Nationwide Drug Recall of Products FIRMİNITE, EXTRA STRENGTH INSTANT HOT ROD, AND LIBIDRON due to Undeclared Tadalafil

Contact:
Consumer:
(877) 782-6464

FOR IMMEDIATE RELEASE - May 18, 2012 - WEST COAST NUTRITIONALS, LTD is conducting a voluntary recalling all lots of FIRMINITE, EXTRA STRENGTH INSTANT HOT ROD, AND LIBIDRON capsules to the consumer level. An FDA lab analysis of FIRMINITE distributed by West Coast Nutritionals was found to contain undeclared Tadalafil. Tadalafil is an active ingredient of an FDA approved drug for Erectile Dysfunction (ED), making FIRMINITE, EXTRA STRENGTH INSTANT HOT ROD, AND LIBIDRON unapproved new drugs. All lots of these three products contain undeclared Tadalafil which can pose a serious risk to health.

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. FDA advises that Tadalafil may cause side effects such as headaches and flushing. The firm has not received any reports of adverse events related to this recall. The FDA is aware of one consumer complaint with an adverse event.

The affected products may have been ordered online at www.firminite.com¹ ², www.instanthotrodextrastrength.com³ ⁴, www.libidron.com⁵ ⁶, www.amazon.com⁷ ⁸ and were distributed to customers and retailers nationwide and worldwide. These products are marketed as dietary supplements intended for use as a male enhancement product and are as follows:

Firminite:

Firminite is sold in two count (2 ct.), four count (4 ct.), and ten count (10 ct.) individual boxes and sold in various kits and packs including but not limited to:

Intro Pack
Tester Pack
Economy Stimulus Pack
Super Performance Pack
Super Savings Pack

Firminite is sold in black and white boxes with red and yellow lettering that states, "FIRMINITE MAXIMUM STRENGTH HIGH POTENCY MALE ENHANCEMENT".

Libidron:

Libidron is sold in two count (2 ct.), four count (4 ct.), and ten count (10 ct.) individual boxes and sold in various kits and packs including but not limited to:

Intro Special
Tester Pack
Elite Silver Pack
Elite Gold Pack
Ultimate Performance Pack
Ultimate Savings Pack

Libidron is sold in blue and orange boxes with white lettering that states, "LIBIDRON HIGH POTENCY FORMULA".

EXTRA STRENGTH INSTANT HOT ROD:

Extra Strength Instant Hot Rod is sold in four count (4 ct.), and ten count (10 ct.) individual boxes and sold in various kits and packs including but not limited to:

Intro Special
Tester Pack
Silver Elite Special Pack
Gold Elite Special Pack
Platinum Elite Pack
Super Savings Elite Pack

Extra Strength Instant Hot Rod is sold in black and white boxes with red and white lettering that states, "EXTRA STRENGTH INSTANT HOT ROD".

West Coast Nutritionals is notifying its customers and retailers by email and/or phone to return all recalled products. All customers and retailers that have any of these products which are being recalled should stop using these products and return any unused products to ATTN: West Coast Nutritionals, 5670 Guhn Road, Houston, TX 77040 for a direct refund. Customers with questions can call (877) 782-6464 Mon thru Fri from 9:00 AM – 6:00 PM PST for further instructions or information with respect to the return and refund process.

Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using these products.

Any adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: <http://www.fda.gov/MedWatch/report.htm>⁹
- Regular Mail: Use postage-paid, pre-addressed Form FDA 3500 available at:
- <http://www.fda.gov/MedWatch/getforms.htm>¹⁰. Mail to the address on the pre-addressed form.
- Fax: 1-800-FDA-0178 This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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