

GENERIX LABORATORIES™, LLC

5742 W. Harold Gatty Dr.
Salt Lake City, UT 84116
Phone (801)517-7000
Fax (801)517-7003

November 10, 2004

NOV 30 2004

VIA: Certified Mail

Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

Re: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product Leptopril™. This notification is on behalf of Generix Laboratories™, LLC.

Please review the information at your earliest convenience. Please contact me with any questions or if there is any further information I can provide regarding this matter.

Sincerely,



Heather Sprik
Legal Assistant

Enclosure

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**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93**

This notification is being filed on behalf of Generix Laboratories™, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5742 W Harold Gatty Dr. Salt Lake City, Utah 84116. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **Leptopril™**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): "Acute Metabolic Regulator"
(Statement 2): "Weight Control Compound for the Significantly Overweight"

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

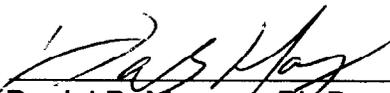
<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Leptopril™ – 95 ct. Box
2	Leptopril™ – 95 ct. Box

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Generix Laboratories™, LLC	both
2	Generix Laboratories™, LLC	both

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of Generix Laboratories™, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that Generix Laboratories™, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 10th day of November, 2004.

By: 
Daniel B. Mowrey, Ph.D.
Consultant for Generix Laboratories™, LLC

Generix Laboratories™ LLC

"Providing Affordable, Generic Versions of
the World's Most Popular Formulations"

Free Online Support From Generix Laboratories™

Congratulations for choosing Generix Laboratories™ as your weight control specialist! You have made the right choice.

Our commitment to you goes far beyond supplying you with the most effective weight control compounds on the face of the Earth. Unlike those distant distributors of so-called "diet pills" who disappear once they got your money, we at Generix Laboratories don't leave you standing alone at the cash register once the money is in the till.

We stand by you throughout your entire weight loss experience, to ensure you achieve the success you most definitely deserve. So log on to www.LeptoprilSupport.com where you will find:

FREE! Customized, easy-to-follow, balanced meal plans designed just for you.

FREE! Detailed, mistake-proof, easy-to-follow, weekly shopping lists that take the guesswork out of meal planning.

FREE! Insider advice from our certified fitness trainers, nutritionists, and registered dietitians, keeping you up-to-date on every new diet trick, innovative weight-loss shortcut, cellulite reducer, spot-reducer, exercise device and state-of-the-art research breakthrough.

FREE! Confidential chat rooms and message boards that let you share your unique experiences, knowledge, and wisdom with others striving to accomplish the same goals. Articles, news releases, research papers, and links to the latest up-to-the-minute information on diet, exercise, and all the other health issues you need to know about — stress, sex, menopause, aging, energy, and all the newest, most innovative drugs, dietary supplements, cosmetics, and other lotions and potions designed to make your life better... many months before the information becomes available to the general public.

Join today! www.LeptoprilSupport.com
It's easy, it's private, and it's **FREE!**

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MFS 12635-10BK9-84

LEPTOPRIL™

(Acute Metabolic Regulator*)

STIMULANT / NON-EPHEDRA

Weight Control Compound For The Significantly Overweight*

Notice: Before starting this or any weight-control program, check with your health-care provider to make sure you are in overall good health. If your health-care provider has any questions regarding Leptopril™, please have him or her call 1-800-898-5153.

Not to be used as a casual diet-aid

95 capsules

Dietary Supplement **Compare to**
Generix Laboratories™ LLC **Leptoprin-SD**
and Save

Supplement Facts

Serving Size: 2 capsules
Servings Per Container: 47

	Amount Per Serving	% Daily Value*
Niacin	20mg	100%
Calcium (as calcium amino acid chelate)	39mg	4%
Copper (from copper amino acid chelate)	0.5mg	50%
Leptopril™	1178mg	
A proprietary blend containing:		
Yerba Maté (leaf) SE		†
Guarana (seed) SE		†
Caffeine		†
Damiana (leaf) SE		†
L-Tyrosine		†
Acetylsalicylic acid	81mg	†
Green Tea (leaf) SE		†
Kola nut SE		†
Eucommia (bark)		†
Schizonepeta (spice) SE		†
Piper nigrum (fruit)		†
Hoelen (aerial parts)		†
Polygonum (root)		†
Turmeric (rhizome)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other Ingredients: Rice Flour

Distributed by: Customer Service Distribution Center
Salt Lake City, UT 84116 • 1-800-898-5153

This product is manufactured to be within all acceptable industry variances. Standardized Extract (SE) means an extraction process providing the highest quality compound manufactured to acceptable industry variances.

Weight Control Components: Yerba Maté, Guarana and Damiana
Protected by U.S. Patent No. 5,945,107
Energy Components: Xanthines

Product resale allowed only through authorized representatives. International distribution not authorized without prior written approval. Manufactured in the U.S.A. Under License, U.S. Patent No. 5,536,506

www.Leptopril.com

Leptopril™ Directions: For maximum weight loss, take two capsules with a full glass of water 15 minutes before each meal. Do not exceed 6 capsules per day.

NOTE: For persons sensitive to the effects of xanthines (i.e., caffeine and caffeine-like stimulants), start by taking only 1 capsule twice a day and gradually build up to the full, 2-capsule serving. Limit the use of caffeine-containing medications, foods or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasionally, rapid heart beat.

For free personalized diet and exercise programs designed to be used in conjunction with Leptopril formulations, as well as information and support, visit www.LeptoprilSupport.com.

WARNING: This product contains a significantly potent xanthine (i.e., caffeine and caffeine-like stimulants) mixture. In excess of 200 mg per regular 2-capsule serving. Therefore, Leptopril™ is not intended for use by pregnant or lactating women. Consult your physician before use. For occasional use only. If your health-care provider has any questions, ask him or her to call 1-800-898-5153.

Keep out of reach of children.

For additional information on this or any other Generix Laboratories™ product, please call our experienced customer service representatives at 1-800-898-5153.

WARNINGS: Not for use by individuals under the age of 18 unless directed by a doctor. Before using this product consult your health-care provider. Do not take if sensitive to or if allergic to aspirin. Do not use if pregnant (it is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery), nursing, have asthma, or have stomach problems (such as heartburn, upset stomach or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a physician. If ringing in the ears or temporary loss of hearing occurs, consult a physician before taking again.

DRUG INTERACTION PRECAUTION: Do not take this product if you are taking a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis, or any other prescription drug unless directed by a physician. This product is not intended for pain relief, fever, toothache, or any other analgesic effect.

Keep out of the reach of children. Children and teenagers should not use this product, or any other product containing aspirin, for chicken pox or flu symptoms before a physician is consulted about Reye Syndrome, a rare but serious illness reported to be associated with aspirin. In case of overdose, get medical help or contact a Poison Control Center right away.

Read the label and follow directions. Discontinue use and call a physician or licensed health-care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms.

ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your physician whether you should take aspirin. Aspirin may cause stomach bleeding.

*These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.