

**RAND**

research laboratories™ LLC

C/O Customer Service Distribution Center

5742 West Harold Gatty Drive  
salt Lake City, UT 84116

Phone: 1-800-898-5153

fax: 1-801-517-7001

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May 16, 2005

**VIA: Certified Mail**

CTS #  
91696

MAY 27

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 ProVactin™. This notification is on behalf of RAND Research 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**

RECEIVED  
12/27/05

This notification is being filed on behalf of RAND Research 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 **ProVactin™**.

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

- (Statement 1): "Stimulant-Free Weight Control Compound"  
(Statement 2): "For the Significantly Overweight."  
(Statement 3): "In an extraordinary, double-blind, placebo controlled clinical study, 20 overweight men and women were separated into one of three groups: Group A received the active Provactate™-CDL complex, Group B received a placebo, and Group C acted as a control (received nothing). Each group was instructed to follow a satisfying 1800 calorie meal plan and modest 3-day per week exercise program."  
(Statement 4): "Group A (the group taking the stimulant-free Provactate™-CDL complex) experienced a significant decrease in overall body weight."  
(Statement 5): "The average loss of actual body fat in the stimulant-free Provactate™-CDL complex group was just short of 10 pounds!"  
(Statement 6): "That's a loss of actual body fate 193% better than placebo."  
(Statement 7): "The stimulant-free Provactate™-CDL complex group experienced a marked reduction in fatigue levels and felt 32% more energetic."  
(Statement 8): "There's a 100% stimulant-free, clinically proven way to lose excess pounds of spongy fat and flab."

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	ProVactin™ – 90ct. Bottle
2	ProVactin™ – 90ct. Bottle
3	ProVactin™ – 90ct. Bottle

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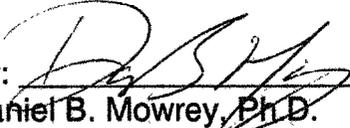
- 4 ProVactin™ – 90ct. Bottle
- 5 ProVactin™ – 90ct. Bottle
- 6 ProVactin™ – 90ct. Bottle
- 7 ProVactin™ – 90ct. Bottle
- 8 ProVactin™ – 90ct. Bottle

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	RAND Research Laboratories™, LLC	both
2	RAND Research Laboratories™, LLC	both
3	RAND Research Laboratories™, LLC	both
4	RAND Research Laboratories™, LLC	both
5	RAND Research Laboratories™, LLC	both
6	RAND Research Laboratories™, LLC	both
7	RAND Research Laboratories™, LLC	both
8	RAND Research Laboratories™, LLC	both

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

Dated this 13 day of May, 2005.

By:   
 Daniel B. Mowrey, Ph.D.  
 Consultant to RAND Research Laboratories™, LLC

## Supplement Facts

Serving Size: 2 capsules  
Servings Per Container: 45

	Amount Per Serving	% Daily Value††
<b>ProVactin™-CDL, a proprietary blend:</b>	1538 mg	
Sodium (as mono & disodium phosphate)	39 mg	2%
Potassium (as dipotassium phosphate)	67 mg	2%
Vitamin A (1000 IU as beta-carotene)	1529 IU	26%
Vitamin C	13 mg	22%
Calcium (as calcium phosphate citrate)	118 mg	12%
Vitamin E (as natural d-alpha-tocopherol)	33 IU	112%
Vitamin B1 (thiamin)	1 mg	60%
Vitamin B2 (riboflavin)	7 mg	388%
Vitamin B6	1.3 mg	96%
Folic acid	400 mcg	100%
Vitamin B12 (cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	11%
Pantothenic acid	6 mg	61%
Phosphorus (as mono & disodium, dipotassium & calcium phosphate)	119 mg	12%
Magnesium (as amino acid chelate)	13 mg	3%
Zinc (as amino acid chelate)	4 mg	27%
Selenium (as amino acid chelate)	67 mcg	95%
Copper (as amino acid chelate)	10 mcg	**
Manganese (as amino acid chelate)	690 mcg	34%
Molybdenum (as amino acid chelate)	10 mcg	13%
Compositura rhusul SE		†
Garcinia cambogia SE (HCA 125 mg)		†
L-Tyrosine		†
Phosphatidylcholine		†
Kelp Meal (0.15% iodine (15 mcg))		12%
Niacinamide		†
L-Cysteine		†
Black Pepper (fruit) SE		†
Horsetail grass (stem)		†
Gardenia root (root)		†
Nettles (herb)		†
Redish (root) extract		†

†† Percent Daily Values are based on a 2,000-calorie diet.  
\* Contains less than 2% of the Daily Value of this nutrient.  
† Daily Value not established.

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.

**Key Weight Control Components:**  
Combination of Compositura Rhusul, Garcinia Cambogia, L-Tyrosine, Monosodium Phosphate, Disodium Phosphate, Dipotassium Phosphate, Calcium Phosphate, Phosphatidylcholine

**Key Thyroid Support Components:** Kelp Meal, Zinc, Selenium, L-Cysteine, L-Tyrosine

Manufactured in the U.S.A.

Under License: U.S. patent No. 6,538,896

[www.ProVactin.com](http://www.ProVactin.com)

# ProVactin™

## Stimulant-Free Weight Control Compound\*

In an extraordinary, double-blind, placebo controlled clinical study, 20 overweight men and women were separated into one of three groups: Group A received the active ProVactate™-CDL complex, Group B received a placebo, and Group C acted as a control (received nothing). Each group was instructed to follow a satisfying 1800 calorie meal plan and modest 3-day per week exercise program.

After only 6 weeks, the verified results were astounding! Group A (the group taking the stimulant-free ProVactate™-CDL complex) experienced a significant decrease in overall body weight.\*

Even more startling was the fact that the average loss of actual body fat in the stimulant-free ProVactate™-CDL complex group was just short of 10 pounds!\* That's a loss of actual body fat 193% greater than placebo.\*

But there's more. The stimulant-free ProVactate™-CDL complex group experienced a marked reduction in fatigue levels and felt 32% more energetic.\*

What else does this scientifically validated clinical trial confirm? Simply this: Finally, there's a 100% stimulant-free, clinically proven way to lose excess pounds of spongy fat and flab.\*

**USAGE:** Take 6 capsules per day. Take 2 capsules with a large glass of water with each main meal. Do not exceed 6 capsules per day.

**CAUTION:** If you are currently taking a prescription thyroid medication, consult with your physician before using this product. If your health-care provider has any questions, ask him or her to call 1-800-898-5153. Not for use by pregnant or nursing women. Not for use by individuals under the age of 18 unless directed by a doctor. Should you desire additional information on this or any other Rand Research Laboratories™ product, please call our experienced customer service representatives at: 1-800-898-5153.

Keep out of reach of children.

Product resale allowed only through authorized representatives. International distribution not authorized without prior written approval.

For further information call toll-free:

1-800-898-5153 or visit [www.ProVactin.com](http://www.ProVactin.com)

Use only as directed.

Store at controlled room temperature

15°-30°C/59°-86°F

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.

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NBG 00555-11RK9-32

# ProVactin™

## Stimulant-Free 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 ProVactin™, please have him or her call 1-800-898-5153.

**Not to be used as  
a casual diet-aid**

## Dietary Supplement

90 Capsules

RAND Research Laboratories™ LLC  
Salt Lake City, UT 84116 • 1-800-898-5153

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