## NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA MAY 10 AND 21 CFR § 161.93



74961

This notification is being filed on behalf of Basic Reseat Evanstown Research Labs that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 402 West 5050 North, Provo, Utah 84604. 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 **CarboLean<sup>TM</sup> – 90 ct. Box.** 

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

(Statement 1):	"Weight control"
(Statement 2):	"Intended to enhance: low carbohydrate weight loss programs"
(Statement 3):	"Adding CarboLean <sup>™</sup> to your present low-carb diet plan can: Increase loss of body fat without changing what you eat."
(Statement 4):	"Adding CarboLean <sup>™</sup> to your present low-carb diet plan can: Inhibit production of prostaglandins that impede fat loss at the cellular level"
(Statement 5):	"Adding CarboLean <sup>™</sup> to your present low-carb diet plan can: Increase loss of body fat without altering your present caloric_intake or low-carb diet regimen"
(Statement 6):	"Adding CarboLean <sup>™</sup> to your present low-carb diet plan can: Dramatically elevate your energy levels"
(Statement 7):	"Adding CarboLean <sup>™</sup> to your present low-carb diet plan can: Eliminate low-carb diet fatigue"

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

Statement <u>Number</u>	Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:
1	CarboLean <sup>TM</sup> – 90 ct. Box
2	CarboLean <sup>™</sup> – 90 ct. Box
3	CarboLean <sup>™</sup> – 90 ct. Box
4	CarboLean <sup>™</sup> – 90 ct. Box
5	CarboLean <sup>™</sup> – 90 ct. Box
6	CarboLean <sup>™</sup> – 90 ct. Box
7	CarboLean <sup>™</sup> – 90 ct. Box

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

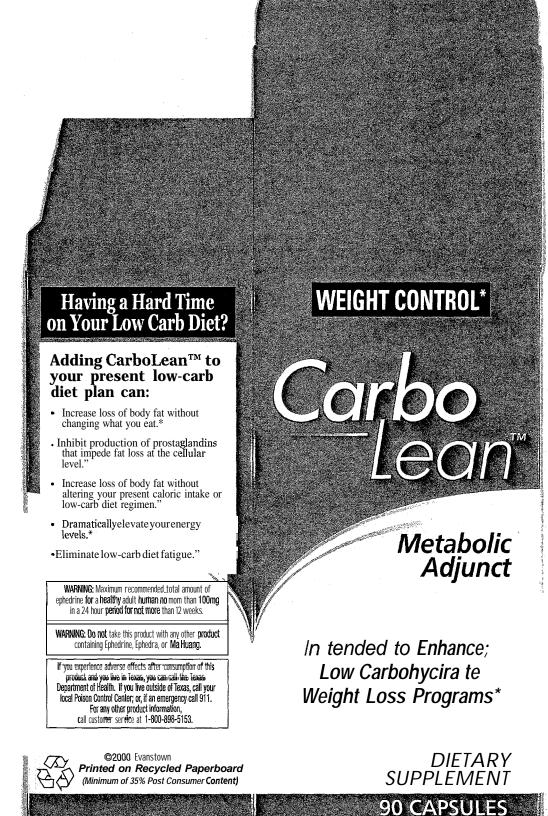
Statement		
Number	Brand Name	<u>Label or Labeling?</u>
1	Basic Research, L.L.C,	both
	dba Evanstown Research Labs	
2	Basic Research, L.L.C,	both
	dba Evanstown Research Labs	
3	Basic Research, L.L.C,	both
	dba Evanstown Research Labs	
. 4	Basic Research, L.L.C,	both
r r	dba Evanstown Research Labs	
5	Basic Research, L.L.C,	both
	dba Evanstown Research Labs	
6	Basic Research, L.L.C,	both
	dba Evanstown Research Labs	
7	Basic Research, L.L.C,	both
	dba Evanstown Research Labs	

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of Basic Research, L.L.C. dba Evanstown Research Labs. I certify that the information presented and contained in this Notification is complete and accurate, and that Basic Research, L.L.C. dba Evanstown Research Labs has substantiation that each structure-function statement is truthful and not misleading.

Dated this ( day of March , 2001.

By: -Daniel B. Mowrey, Ph.D.

Consultant to Basic Research, L.L.C. dba Evanstown Research Labs



ervings Per Container 45		
	Amount Per Serving	% Daily Value*
Ephedrine alkaloids (from standardized whole plant ma huang extract (250 mg))	20mg	t
Caffeine (26mg from standardized bissey nut (212 mg))	200mg	†
Acetylsalicylic acid	324mg	†
Proprietary Blend Glycemic Complex	241mg	
Schizonepeta (spica) Extract (	5:1)	t
Forsythia (fruit) Extract (5:	1)	1
Gymnema (leaves, stem)	100	†
Bitter Melon (seeds)		- †
Stevia (leaf)		t
Chromium polynicotinate		1

## Other Ingredients: rice flour

This product has 20 mg. of ephedrine group alkaloids per serving in the form of herbal extracts may cause serious adverse health effects. Read the label and follow directions.

\*No statement an **this** package has been reviewed by **the** Food and Drug Administration. Neither **the** specified products nor any of these writings are intended to **diagnose, treat,** cure, **or** prevent any **disease.** 

Provo, UT 84604 • 1-800-898-5153 • www.carbolean.com Manufactured in the U.S.A. Carbo Lean<sup>™</sup> Directions: Take two capsules with a full glass of water, three times per day: morning, noon and early evening. Do not exceed 6 capsules per day. NOTE: Jitters, anxiety, dry mouth or insomnia may occur during the first week of use. Reducing number of capsules per day during the first week should eliminate these mild effects. For additional information on this or any other Evanstown tabs product, please call our experienced customer service representatives at 1-800-898-5153. WARNINGS: 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 especifically directed to de so by

WARNINGS: DO NOI take in sensitive to of in allergic to aspirin. Do Noi 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 pregnancy), nursing, have ashma, 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 before taking again. DRUG INTERACTION PRECAUTION: Do not take this product if you are taking MAO inhibitors or a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis or any other prescription drug unless directed by a physician. Do not take this product if you have any of the following conditions: high blood pressure, cardiovascular disease, thyroid **disease**; prostate problems or diabetes. Improper use may be hazardous **to** your health. This product is not intended for pain relief, fever,, toothache or my other analgesic effect. Keep out of **the reach** of children. **Child**ren and teenagers should not use this **product** 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. Consult a physician or licensed health, care professional before **using** this product if you have, or have a **tamily** history of, heart disease: thyroid disease, diabetes, high blood pressure, recurrent headaches, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure counter drug containing ephedrine, pseudoephedrine,, or phenylpropanolamine (ingredients found **u** certain allergy, asthma, cough&old and weight control products). Exceeding recommended serving may cause serious adverse health effects including heart attacks and stroke. Discontinue use and call physician or li

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

Do not take if under 18 years of age.