CardioTek, L.L.C.

43 East Lancaster Pike – Suite B
Oxford, Pennsylvania 19363
Phone: 610-998-2427

SEP 0 9 2003

August 11, 2003

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

RE: Notification of Additional Dietary Supplement Marketing Claims

Dear Sir/Madam:

Pursuant to 21 CFR §101.93 this is to notify you that CardioTek, L.L.C. will be marketing a dietary supplement containing the structure/function claims as indicated below.

1. Name and Address of Manufacturer or Distributor:

Distributor: CardioTek, L.L.C.
43 East Lancaster Pike
Suite B
Oxford, PA 19363

2. Text of Statement:

The following statement will be made in marketing the product:

"This product:

- Provides the foundation for optimal vascular, cardiac, bone, and immune system health.

MegaVim™ is a multifaceted dietary supplement that simultaneously delivers four key formulas:

- Super Antioxidant Vitamin, Mineral, and Phyto-Nutrient Formula- 3 GELATIN CAPSULES - FOUNDATION SUPPORTIVE FORMULA
- Carni-Q-Gel® with Alpha Lipoic Acid and Vitamin E Formula- 1 SOFTGEL -FOR HEART SUPPORT

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- Liquid Calcium and Magnesium Formula- 1 SOFTGEL - FOR BONE AND VASCULAR HEALTH SUPPORT
- Omega 3 Fish Oil Formula- Cholesterol Free - 1 SOFTGEL - FOR HEART, BRAIN, AND VASCULAR HEALTH SUPPORT

3. Description of Dietary Ingredient or Supplement:
The product is a dietary supplement capsule containing the ingredients described in the attached nutritional information table.

4. Name of Dietary Supplement:

"MegaVim™"

5. Certification of Accuracy:

I, Karl Zimmerman MD, General Manager of CardioTek, L.L.C., do hereby certify that the information contained in this notice is complete and accurate and that Cardiotek, L.L.C. has substantiation that the statement to be made is truthful and not misleading.

Karl Zimmerman, MD

Nutritional Table

MegaVim™ Dietary Supplement Label

Attached

Omega 3 Fish Oil Formula

Supplement Facts

Serving Size: 1 Enteric Coated Softgel

	Amount Per Enteric Coated Softgel	% Daily Value
Calories	10	
Calories from Fat	10	
Total Fat	1 g	2
Cholesterol	<25 mg	
Vitamin E (as d-alpha tocopherol & mixed tocopherols)	5 IU	17
Vitamin B-6 (pyridoxine)	1.87 mg	94
Folate (folic acid)	67 mcg	17
Vitamin B-12 (cyanocobalamin)	8.34 mcg	139
Marine Lipid Concentrate	500 mg	*
Eicosapentaenoic Acid (EPA)	150 mg	*
Docosahexaenoic Acid (DHA)	100 mg	*
Other Omega-3 Fatty Acids	25 mg	*
Garlic (odor-reduced) (bulb)	150 mg	*
Curcumin (rhizome)	42 mg	*
Ginger (as oleo-resin, extract, freeze dried) (rhizome)	14 mg	*
Rosemary Extract (leaf)	2.5 mg	*
Tocotrienols Complex	4 mg	*

‡ Percent Daily Values are based on a 2000 calorie diet. * Daily Value not established.

Other Ingredients: Gelatin, lecithin, medium chain triglycerides, glycerin, purified water, cellulose acetate phthalate, diethyl phthalate, methyl cellulose, beeswax, and titanium dioxide.

SUGGESTED USE: Adults. Take one (1) packet daily; one (1) in the morning meal.
Each packet contains three (3) foundation capsules, one (1) O-Gel® complex softgel, one (1) Calcium-Magnesium softgel, one (1) Omega-3 Fish Oil and three (3) Antioxidant Vitamin, Mineral and Phytonutrient Formula capsules. Free of: starch, sugar, yeast, salt, wheat, corn or milk. No preservatives, synthetic colors or flavors.

KEEP OUT OF THE REACH OF CHILDREN.
TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS CUT, TORN, BROKEN OR MISSING.

To preserve quality and freshness, keep bottle tightly closed. Store in a cool, dry place at controlled room temperature 18°-30°C (59°-86°F).

CardioTek Foundation Formula dietary supplement program should be combined with:
- Proper Nutrition
- Regular Exercise
- Recommended Nutritional Supplementation
  Regular visits to your Doctor or Health Professional

THE INFORMATION ON THIS LABEL HAS 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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CardioTek
Oxford, PA 19363
www.cardiotek.com
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For Retailer Only
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FOUNDATION FORMULA

MegaVim™ DAILY MULTIPLE FORMULA

Dietary Supplement

- **Super Antioxidant Vitamin, Mineral and Phyto-Nutrient Formula** - CAPSULES
  FOUNDATION SUPPORTIVE FORMULA
- **Carni-Q-Gel® with Alpha Lipoic Acid and Vitamin E**
  L-CARNITINE/COENZYME Q10 [Three (3) U.S. Patents] - SOFTGELS
  FOR HEART SUPPORT
- **Liquid Calcium and Magnesium**
  CALCIUM SUPER COMPLEX with MAGNESIUM SUPER COMPLEX - SOFTGELS
  FOR BONE & VASCULAR HEALTH SUPPORT
- **Omega 3 Fish Oils™**
  CHOLESTEROL FREE
  COMPLEX BLEND OF DHA and EPA
  - ENTERIC COATED SOFTGELS
  FOR HEART, BRAIN & JOINT HEALTH SUPPORT

60 DAY PROGRAM

RECOMMENDED BY PHYSICIANS AND HEALTH PROFESSIONALS

60 DAY SUPPLY

Antioxidant Vitamin, Mineral and Phytonutrient Formula

Supplement Facts

Serving Size: 3 Capsules

Amount Per Serving		% Daily Value
Vitamin A (as palmitate & beta carotene)	3750 I.U.	75
Vitamin C (as buffered mineral ascorbate)	125 mg	208
Vitamin D (as cholecalciferol)	250 I.U.	50
Vitamin E (as d-alpha tocopheryl acetate)	80 I.U.	266
Thiamine (vitamin B-1 as mononitrate)	10 mg	666
Riboflavin (vitamin B-2 as riboflavin & riboflavin 5 phosphate)	10 mg	588
Niacin (as niacinamide)	10 mg	50
Vitamin B-6 (as pyridoxine HCL)	10 mg	500
Folic Acid	400 mcg	100
Vitamin B-12 (as cyanocobalamin)	50 mcg	833
Biotin	75 mcg	25
Pantothenic Acid (as D-calcium pantothenate)	12 mg	120
Calcium (as carbonate, ascorbate and citrate)	167 mg	16
Iodine (from kelp)	37.5 mcg	25
Magnesium (as oxide and citrate)	67 mg	16
Zinc (as zinc ascorbate)	7.5 mg	50
Selenium (as selenomethionine)	50 mcg	71
Copper (as copper gluconate)	250 mcg	13
Manganese (as manganese gluconate)	125 mcg	6
Chromium (as chromium picolinate)	50 mcg	50
Molybdenum (as sodium molybdate)	37.5 mcg	50
Potassium (as potassium citrate)	49.5 mg	1
NAC (n-acetylcysteine)	50 mg	*
Choline bitartrate	25 mg	*
Inositol	25 mg	*

Amount Per Serving		% Daily Value
F.O.S. (fructooligosaccharides)	25 mg	*
L-Arginine HCL	25 mg	*
Hoist Yeast	25 mg	*
Acerola Powder	25 mg	*
Acerola Juice Powder	25 mg	*
Curcuma Powder (rhizome)	12.5 mg	*
Ginger Powder (rhizome)	12.5 mg	*
Cilantro Powder (stem, leaf)	12.5 mg	*
Papain (papaya enzyme)	12 mg	*
Bromelain (pineapple enzyme)	12 mg	*
Taurine	8 mg	*
Betain HCL	8 mg	*
Citrus bioflavonoid Complex	6.25 mg	*
L-Lysine HCL	5 mg	*
Rutin	5 mg	*
Hesperidin Complex	5 mg	*
Quercetin	5 mg	*
L. Sporogenes (b. coagulans)	30 Billion CFU	
Green Tea Extract (leaf, stems)	2.5 mg	*
Red Wine Extract	1.25 mg	*
Grapeseed Extract	1.25 mg	*
Grape Seed Extract	1.25 mg	*
Pine Bark Extract	1.25 mg	*
Lycopene	1 mg	*
Lutein	750 mcg	*
Aloe Vera Gel (200:1 extract)	0.625 mg	*

* Daily Value not established

Other Ingredients: Gelatin, silica, magnesium stearate and oat fiber concentrate.

Carni-Q-Gel® with Alpha Lipoic Acid and Vitamin E Formula

Supplement Facts

Serving Size: 1 Softgel

	Amount Per Softgel	% Daily Value
Vitamin E (as d-alpha tocopherol, mixed tocopherols and tocotrienols) (hydrosoluble)	15 IU	50
Coenzyme Q-10 (hydrosoluble)	5 mg	*
L-Carnitine Fumarate	75 mg	*
Alpha Lipoic Acid	25 mg	*

* Daily Value not established.

Other Ingredients: Gelatin, glycerin, sorbitol, purified water, titanium dioxide, carob extract, annatto seed extract, beeswax, plus a proprietary Bio Sol® base (polysorbate 80, hydroxylated lecithin, medium chain triglycerides).

The combination of CoQ10 and L-Carnitine is produced under a non-exclusive license from Sigma-Tau, owner of U.S. patent No. 4486232. L-Carnitine Fumarate is a stable, highly bioavailable form of L-Carnitine (U.S. patent No. 4602038).

Manufactured by the Bio Sol® Process U.S. Patent No. 6 066,671 under an exclusive worldwide agreement with Geoyles (USA), Inc.

Liquid Calcium and Magnesium Formula

Supplement Facts

Serving Size: 1 Softgel

	Amount Per Softgel	% Daily Value
Vitamin D (cholecalciferol)	33.3 IU	8
Vitamin K (phylloquinone)	3.3 mcg	4
Calcium (from carbonate, citrate, gluconate, ascorbate, malate, micronized hydroxyapatite)	333.3 mg	33
Magnesium (from oxide, aspartate, citrate)	133.3 mg	33
Boron (from gluconate)	0.3 mg	*
Horse Tail (extract) herb	8.3 mg	*

* Daily Value not established

Other Ingredients: Gelatin, purified water, glycerin, soybean oil, lecithin, oil of evening primrose, silica and titanium dioxide.

Carni-Q-Gel® Forte and Bio Sol® and Hydrosoluble™ are registered trademarks of Tishcon Corp. MegaVIM™ is registered trademark of CardioTek LLC.

Bottle: 2500cc
Size: 4 x 11
Colors: CMYK