



1798 6 NOV 20 12:14

NOV - 7 2006

Gale S. Rudolph, Ph.D.
Director of Functional Foods
Alpine Confections, Inc.
119 East 200 North
P.O. Box 1129
Alpine, Utah 84004-1631

Dear Dr. Rudolph:

This is in response to your letter of September 26, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Alpine Confections, Inc. is marketing the products Choco-Omeg Cardio Formula, Choco-Omeg Memory Formula, and Choco-Omeg Calcium Formula as dietary supplements.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet. 21 U.S.C. 321(ff)(2)(B). The products identified above are represented for use as conventional foods (i.e., as chocolate bars) (i.e., the immediate product wrappers describe each product as a "Premium Belgian Milk Chocolate Bar" and the outer cartoon describes the products as "Premium Belgian Chocolate Bars..."). Therefore, in that the products are represented for use as conventional foods, they are not dietary supplements within the meaning of 21 U.S.C. 321(ff) and claims made for them are not subject to 21 U.S.C. 343(r)(6).

Instead, these products appear to be conventional foods that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, they must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the products in their labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market these

97S 0163 LET 909

Page 2 - Dr. Gale S. Rudolph

products as conventional foods and you have any questions about the status of any of their ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutritionals
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

-NOTIFICATION-

DIETARY SUPPLEMENT NUTRITIONAL SUPPORT STATEMENT

Manufacturer/Packer/Distributor Name and Address:

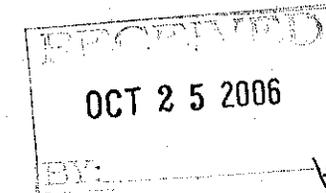
Dynamic Chocolates
1648 Derwent Way
Delta, BC Canada V3M 6R9

Dietary Supplement Name:

Choco-Omeg:

Cardio Formula
Memory Formula
Calcium Formula

Dietary Ingredient: see attached



AIMS
2006-8117

Gale S. Rudolph, Ph.D., C.N.S.
Director of Functional Foods

Alpine Confections, Inc.

119 East 200 North • P.O. Box 1129
Alpine, Utah 84004-1631

Phone (801) 763-9098

Toll Free (800) 377-4368 Ext. 450

Fax (801) 756-7791

press 5

galer@AlpineConfectionsInc.com

I hereby certify that the information presented and contained in this notice is complete and accurate. I also certify that Dynamic Chocolates has substantiation to verify that the statements listed above and on attached sheet are truthful and not misleading.

Signature

Gale S. Rudolph

Date

26 Sept 06

Print Name

Gale S. Rudolph

24

Dietary Ingredient:

Cardio Formula
200 mg omega-3

Dietary Ingredient:

Memory Formula
55 mg choline

Dietary Ingredient:

Calcium Formula
100 mg omega-3
With 500 mg calcium

Support Statement Text:

“Omega-3 supports cardiovascular and circulatory functions*”

*This chocolate is not intended to diagnose, treat, cure or prevent any disease. These statements have not been evaluated by the FDA.

Support Statement Text:

“Choline and omega-3 support memory and brain functions.*”

*This chocolate is not intended to diagnose, treat, cure or prevent any disease. These statements have not been evaluated by the FDA.

Support Statement Text:

“Calcium supports strong bones and teeth.*”

*This chocolate is not intended to diagnose, treat, cure or prevent any disease. These statements have not been evaluated by the FDA.

Martek **DHA**

Premium Belgian Milk Chocolate Bar
Real Orange Pieces

Choco-Omegs

A dietary supplement

Omega 3 • 100mg • ebsaw

Memory Formula

INGREDIENTS: MILK CHOCOLATE (SUGAR, COCOA BUTTER, WHOLE MILK POWDER, COCOA LECITHIN, NONFAT DRY MILK, BUTTER, VANILLA EXTRACT), ORANGE PIECES WITH SUGAR, SOY LECITHIN, OMEGA-3 GLUCOSE SYRUP SOLIDS, ALGAL OIL, SODIUM ASCORBATE, DIPOTASSIUM PHOSPHATE, VITAMIN B6 PYRIDOXINE HCL, FOLIC ACID, VITAMIN B12 METHYLCOBALAMIN, SOY PROTEIN, HIGH OLEIC SUNFLOWER OIL, TETRASODIUM DIPHOSPHATE, AND MIXED NATURAL TOCOPHEROLS AND MIXED NATURAL FLAVORS. CONTAINS SOY AND MILK. MAY CONTAIN TRACES OF PEANUTS AND/OR OTHER NUTS. PRODUCT OF CANADA DYNAMIC CHOCOLATES, DELTA, B.C., CANADA V3M 6R9 Martek DHA is a trademark of Martek Biosciences Corporation.

SUPPLEMENT FACTS
Serving Size 1 Bar (36g)
Servings Per Container 1

	Amount Per Serving	% Daily Value
Calories	190	
Calories from Fat	100	
Total Fat	11 g	18%
Saturated Fat	7 g	34%
+ Trans Fatty Acids	0 g	
Cholesterol	10 mg	3%
Total Carbohydrate	20 g	7%
Dietary Fiber	1 g	3%
Sugars	17 g	
Protein	2 g	
Vitamin C	19 mg	31%
Calcium	79 mg	8%
Phosphorus	97 mg	10%
Magnesium	15 mg	4%
Sodium	40 mg	2%
Potassium	135 mg	4%
Omega 3 Fatty Acids	100 mg	**
Choline	55 mg	**

** Daily Value not established.
*Percentage Daily Values based on a 2,000 calorie diet.



This chocolate is not intended to diagnose, treat, cure, or prevent any disease. These claims have not been evaluated by the FDA.

SUPPLEMENT FACTS
Serving Size 1 Bar (36g)
Servings Per Container 1

	Amount Per Serving	% Daily Value
Calories	170	
Calories from Fat	110	
Total Fat	11 g	18%
Saturated Fat	7 g	33%
+ Trans Fatty Acids	0 g	
Cholesterol	10 mg	3%
Total Carbohydrate	19 g	6%
Dietary Fiber	1 g	3%
Sugars	17 g	
Protein C	3 g	
Vitamin C	18 mg	31%
Vitamin D	137IU	34%
Calcium	694 mg	50%
Phosphorus	223 mg	23%
Magnesium	147 mg	37%
Sodium	40 mg	2%
Potassium	135 mg	4%
Omega 3 Fatty Acids	100 mg	**

** Daily Value not established.
*Percentage Daily Values based on a 2,000 calorie diet.



INGREDIENTS: MILK CHOCOLATE (SUGAR, COCOA BUTTER, WHOLE MILK POWDER, CHOCOLATE LIQUOR, NONFAT DRY MILK, BUTTER, VANILLA EXTRACT), BONE HEALTH BLEND (ALGAL OIL, SODIUM ASCORBATE, DIPOTASSIUM PHOSPHATE, GLYCERYL MONO AND DISTEARATE, SOY LECITHIN, TRICALCIUM PHOSPHATE, AND MIXED NATURAL TOCOPHEROLS / ASCORBYL PALMITATE AS ANTIOXIDANTS), SOY PROTEIN, HIGH OLEIC SUNFLOWER OIL, TETRASODIUM DIPHOSPHATE, NATURAL FLAVOR, VANILLA EXTRACT, BONE HEALTH BLEND (ALGAL OIL, SODIUM ASCORBATE, DIPOTASSIUM PHOSPHATE, GLYCERYL MONO AND DISTEARATE, SOY LECITHIN, TRICALCIUM PHOSPHATE, AND MIXED NATURAL TOCOPHEROLS / ASCORBYL PALMITATE AS ANTIOXIDANTS). CONTAINS SOY AND MILK. MAY CONTAIN TRACES OF PEANUTS AND/OR OTHER NUTS. PRODUCT OF CANADA DYNAMIC CHOCOLATES, DELTA, B.C., CANADA V3M 6R9 Martek DHA is a trademark of Martek Biosciences Corporation.

Omega 3 • 100mg • ebsaw

A dietary supplement

Choco-Omegs

Premium Belgian Milk Chocolate Bar
Crunchy Rice Crisps

Excellent Source of Calcium, Vitamin D, Magnesium and Phosphorus

Calcium Formula
With 50mg Calcium

Calcium supports strong bones and teeth*

Martek **DHA**

Premium Belgian Dark Chocolate Bar
Real Raspberry Pieces

Choco-Omegs

A dietary supplement

Omega 3 • 200mg • ebsaw

Cardio Formula

with 100mg Omega-3

Good Source of Antioxidants, Coenzyme Q10, Fiber and Vitamin C

OMEGA 3 SUPPORTS CARDIOVASCULAR AND CIRCULATORY FUNCTIONS*

Martek **DHA**

INGREDIENTS: DARK CHOCOLATE (CHOCOLATE LIQUOR, SUGAR, COCOA BUTTER, SOY LECITHIN [AN EMULSIFIER], VANILLA FLAVOR), WHOLE FLAXSEED, OMEGA-3 (GLUCOSE SYRUP SOLIDS, ALGAL OIL, SODIUM ASCORBATE, DIPOTASSIUM PHOSPHATE, GLYCERYL MONO AND DISTEARATE, SOY LECITHIN, TRICALCIUM PHOSPHATE, AND MIXED NATURAL TOCOPHEROLS / ASCORBYL PALMITATE AS ANTIOXIDANTS), VITAMIN B6 PYRIDOXINE HCL, FOLIC ACID, VITAMIN B12 METHYLCOBALAMIN, SOY PROTEIN, HIGH OLEIC SUNFLOWER OIL, TETRASODIUM DIPHOSPHATE, AND MIXED NATURAL TOCOPHEROLS AND MIXED NATURAL FLAVORS. CONTAINS SOY AND MILK. MAY CONTAIN TRACES OF PEANUTS AND/OR OTHER NUTS. PRODUCT OF CANADA DYNAMIC CHOCOLATES, DELTA, B.C., CANADA V3M 6R9 Martek DHA is a trademark of Martek Biosciences Corporation.

FACTS

	Amount Per Serving	% Daily Value
100	100	100%
200	200	200%
300	300	300%
400	400	400%
500	500	500%
600	600	600%
700	700	700%
800	800	800%
900	900	900%
1000	1000	1000%
1100	1100	1100%
1200	1200	1200%
1300	1300	1300%
1400	1400	1400%
1500	1500	1500%
1600	1600	1600%
1700	1700	1700%
1800	1800	1800%
1900	1900	1900%
2000	2000	2000%

*Percentage Daily Values based on a 2,000 calorie diet.



