



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV - 8 1999

Mr. Matthew R. Spolar
New Product Development Manager
Atkins Nutritionals, Inc.
152 East 55th Street
New York, New York 10022

Dear Mr. Spolar:

This is in response to your letter received by the Food and Drug Administration (FDA) on November 5, 1999. Your letter was submitted to 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 Atkins Nutritionals, Inc. is making the following statements, among others, for the products:

Dr. Atkins Cholesterol

“...provides natural dietary support for the lowering of elevated cholesterol”

Dr. Atkins Cold & Flu

“...provides natural dietary support in connection with the relief of cold and flu conditions”

Dr. Atkins Allergy

“...provides natural dietary support in connection for the relief of seasonal allergies”

Dr. Atkins Emotional Aid

“...provides natural dietary support [sic] the relief of mild depression”

Dr. Atkins Blood Pressure

“...provides natural dietary support for the lowering of elevated blood pressure”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products, including the product names “Dr. Atkins Cold & Flu” and “Dr. Atkins Allergy,” suggest

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that they are intended to prevent, treat, cure, or mitigate diseases, namely the common cold, influenza, allergies, hypercholesterolemia, hypertension, and depression. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B) and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New York District Office, Office of Compliance, HFR-NE140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file, r/f)
HFS-450 (file, r/f)
HFD-3 10 (BWilliams)
HFD-3 14 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
GCF- 1 (Dorsey, Barnett, Nickerson)
f/t:HFS-456:rjm: 11/8/99:docname:67970.adv:disc42



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ATKINS NUTRITIONALS, INC.



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

Ladies and Gentleman:

Atkins Nutritionals, Inc., the address of which is set forth below, has included one or more of the statements listed in Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act on the labels of various of dietary supplement products, which it distributes. The text of each such statement, the name of the dietary ingredient that is the subject of such statement, and the name (including brand name) of the dietary supplement on whose label such statement appears, are set forth on Exhibit A.

The undersigned certifies on behalf of Atkins Nutritionals, Inc. that the information presented and contained in the notice is complete and accurate, and that Atkins Nutritionals, Inc. has substantiation that the statements are truthful and not misleading.

By:

Matthew R. Spolar
New Product Development Manager
Atkins Nutritionals, Inc.



ATKINS NUTRITIONALS, INC.

Exhibit A

Brand Name	Label Copy	Ingredient(s) related to claim
Atkins Diet Basic #3	“Each tablet contains an exclusive all-natural digestion-supporting base.”	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Atkins Diet Basic #3	“This Basic #3 multi-vitamin is specifically designed to provide effective nutritional support during the weight loss phases of The Atkins Diet.”	Vitamin A (as acetate) Vitamin A (as natural Beta-Carotene with mixed carotenoids) Vitamin C (as calcium ascorbate) Vitamin D-3 (as cholecalciferol) Vitamin E (as d-alpha tocopherolsuccinate) Vitamin B 1 (as thiamine HCl) Vitamin B2 (as riboflavin) Niacin (as niacinamide) Vitamin B-6 (as pyridoxine HCl) Folate (as folic acid) Vitamin B- 12 (as cyanocobalamin) Vitamin K Biotin Pantothenic Acid (as d-calcium pantothenate) Calcium (as phosphate, ascorbate, and citrate) Magnesium (as glycinate) Zinc (as monomethionine) Selenium (as selenomethionine) Manganese (as glycinate) Chromium (as polynicotinate) Molybdenum (as glycinate) Potassium (as citrate) Inositol hexanicotinate Choline bitartrate Para Amino Benzoic Acid Vanadyl (as bis maltolato oxovanadium) N-Acetyl-L-Cysteine Pantethine (a co enzyme A precursor) Quercetin Boron (as calcium borogluconate) Grape Seed Extract Green Tea (20% polyphenols)



ATKINS NUTRITIONALS, INC.

Exhibit A Cont.

Brand Name	Label Copy	Ingredient(s) related to claim
Atkins Diet Basic #1	“This Basic #1 multi-vitamin formula is specifically designed to provide effective nutritional support during the on-going maintenance phase of The Atkins Diet.”	Vitamin A (as acetate) Vitamin A (as natural Beta-Carotene with mixed carotenoids) Vitamin C (as calcium ascorbate) Vitamin D-3 (as cholecalciferol) Vitamin E (as d-alpha tocopherolsuccinate) Vitamin B 1 (as thiamine HCl) Vitamin B2 (as riboflavin) Niacin (as niacinamide) Vitamin B-6 (as pyridoxine HCl) Folate (as folic acid) Vitamin B- 12 (as cyanocobalamin) Vitamin K Biotin Pantothenic Acid (as d-calcium pantothenate) Calcium (as phosphate, ascorbate, and citrate) Magnesium (as glycinate) Zinc (as monomethionine) Selenium (as selenomethionine) Manganese (as glycinate) Chromium (as polynicotinate) Molybdenum (as glycinate) Potassium (as citrate) Inositol hexanicotinate Choline bitartrate Pare Amino Benzoic Acid Vanadyl (as bis maltolato oxovanadium) N-Acetyl-L-Cysteine Pantethine (a co enzyme A precursor) Quercetin Boron (as calcium boroglucarate) Grape Seed Extract Green Tea (20% polyphenols)
Atkins Diet Basic #1	“Each tablet contains an exclusive all-natural digestion-supporting base.”	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)



ATKINS NUTRITIONALS, INC.

Exhibit A Cont.

Brand Name	Label Copy	Ingredient(s) related to claim
Atkins Diet Dieters' Advantage	"This formula. .contains key vitamins and food extracts that help to naturally manage appetite, stabilize blood sugar, and make fat available in the body as an energy source."	Citrin (55% hydroxycitric acid) L-Carnitine (as USP 95%) ChromeMate™ (as chromium picolinate) Magnesium (as carbonate)
Atkins Diet Dieters' Advantage	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Essential Oils	"This formula. .provides the body with essential fatty acids to support proper metabolic functioning."	Vitamin E (from mixed tocopherols) Alpha Linolenic Acid (from flaxseed oil) Gamma Linolenic Acid (from borage seed oil) Eicosapentaenoic Acid (from fish oil) Docosahexaenoic Acid (form fish oil) Linoleic Acid (from flaxseed, borage seed and fish oils) Oleic Acid (from flaxseed, borage seed and fish oils)
Dr. Atkins Essential Oils w/CLA	"This formula. .provides the body with essential fatty acids and CLA to support proper metabolic Functioning."	Conjugated Linolenic Acid (from sunflower seed oil) Gamma Linolenic Acid (from borage seed oil) Alpha Linolenic Acid (from flaxseed oil) Eicosapentaenoic Acid (from fish oil) Docosahexaenoic Acid (form fish oil) Linoleic Acid (from sunflower seed, borage seed, flaxseed, and fish oils) Oleic Acid (from sunflower seed, borage seed, flaxseed, and fish oils)
Dr. Atkins Multivitamin	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Nutra-Pak	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)



ATKINS NUTRITIONALS, INC.

Exhibit A Cont.

Brand Name	Label Copy	Ingredient(s) related to claim
Dr. Atkins Anti-Ox	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Anti-Ox	"This formula.. provides natural dietary support for neutralizing damaging free radicals in the body."	Vitamin A (as natural beta carotene) Vitamin C (as calcium ascorbate) Vitamin E (as succinate) Opti-Zinc® (as zinc monomethionine) Selenium (as selenomethionine) N-Acetyl-L-Cysteine Quercetin Alpha-Lipoic Acid Activin® (grape seed extract) Lycopene
Dr. Atkins Cholesterol	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Cholesterol	"This formula.. provides natural dietary support for the lowering of elevated cholesterol."	Vitamin E Ginger (5% gingerols) Garlic L-Arginine Tocotrienols
Dr. Atkins Prostate	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Prostate	"This formula.. provides natural dietary support for prostate health."	Saw Palmetto Extract Fygeum Africanum (12- 13% phytosterols)
Dr. Atkins Menopause	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Menopause	"This formula is.. designed to meet the specific nutritional needs of menopausal women."	Black cohosh (<i>Cimicifuga racemosa</i>) (2.5% triterpenes) Soy isoflavones concentrate (23.6% genistein/genistin, 3.8% daidzin/daidzein) Soy Phosphatidylcholine Gamma Oryzanol

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ATKINS NUTRITIONALS, INC.

Exhibit A Cont.

Brand Name	Label Copy	Ingredient(s) related to claim
Dr. Atkins PMS	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins PMS	"This formula.. provides natural dietary support for the relief of PMS symptoms."	Vitex Angus-Castus (chaste berry) Soy Phosphatidylcholine Inositol Vitamin B6
Dr. Atkins Arthri-Joint™	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Arthri-Joint™	"This formula.. provides natural dietary support for healthy joint function."	Glucocamine sulfate Chondroitin sulfate Sea Cucumber Extract (beche-de mer) Turmeric (95% cm-cumin)
Dr. Atkins Bone Care	"This formula.. provides natural dietary support for increasing bone density and protecting against bone loss."	Calcium (as carbonate/citrate/glycinate) Ostivone™ Ipraflavone (7-isopropoxyisoflavone) Vitamin D
Dr. Atkins Bone Care	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Cold & Flu	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Cold & Flu	"This formula., provides natural dietary support in connection with the relief of cold and flu conditions."	Opti-Zinc® (as zinc monomethionine) Vitamin C Vitamin A
Dr. Atkins Allergy	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)

see
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ATKINS NUTRITIONALS, INC.

Exhibit A Cont.

Brand Name	Label Copy	Ingredient(s) related to claim	
Dr. Atkins Allergy	"This formula .provides natural dietary support for the relief of seasonal allergies."	Vitamin C Vitamin B 12 Quercetin	see deck et 975-0163
Dr. Atkins Memory	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)	
Dr. Atkins Memory	"This formula...provides natural dietary support for memory function."	Phophatidylserine (PS) Ginkgo Biloba (24% flavone glycosides, 6% terpenes) Acetyl-L-Carnitine Octacosanol	
Dr. Atkins Emotional Aid	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin. Bioperine™, and acidophilus (lactal and bifido bacterium)	
Dr. Atkins Emotional Aid	"This formula.. provides natural dietary support the relief of mild depression."	Trimethylglycine (betaine) St. John's Work (0.3% Hypercin) SAME (providing 52% s-adenosyl-l-methionine)	see deck et 975-0163
Dr. Atkins Blood Pressure	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)	
Dr. Atkins Blood Pressure	"This formula.. provides natural dietary support for the lowering of elevated blood pressure."	Taurine Vitamin C Inositol Garlic Hawthorn (1.5% vitexin conc.)	see deck et 975-0163
Dr. Atkins Blood Sugar	"Each tablet contains an exclusive all-natural digestion-supporting base."	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)	



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Brand Name	Label Copy	Ingredient(s) related to claim
Dr. Atkins Blood Sugar	“This formula.. provides natural dietary support the balancing of blood sugar levels.”	Chromium Biš-Glycinato Oxovanadium Complex (BGOV) Alpha-Lipoic Acid
Dr. Atkins Heart Care	“Each tablet contains an exclusive all-natural digestion-supporting base.”	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Heart Care	“. .vita-nutrient protocol for heart health.”	Vitamin C Vitamin E Taurine Bromelain Cayenne
Dr. Atkins Pantethine	“Each tablet contains an exclusive all-natural digestion-supporting base.”	Lecithin extracts, garlic, DGL licorice, bromelain, pantethine, spirulina, inulin, lactoferin, Bioperine™, and acidophilus (lactal and bifido bacterium)
Dr. Atkins Pantethine	“. .Pantethine aids in such broad based bodily functions as cholesterol/blood lipid management, the manufacturer of anti-inflammatory hormones and even in the conversion of the food we eat to e n e r g y . ”	Pantethine Pantothenic Acid