



OCT 22 1997

0796 '97 DEC 16 P1:41

Rakesh M. Amin, Esq.
Dilling and Dilling
150 North Wacker Drive
Chicago, Illinois 60606

Dear Mr. Amin:

This is in response to your letter of October 20, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act) on behalf of Perfect Source Natural Products., Inc. of Fullerton, California. Your submission states that Perfect Source Natural Products, Inc. is making the following claim, among others, for the product "Fiber Plus:"

"...and may lower cholesterol."

Section 403(r)(6) of the act 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 statement that you are making for this product suggests that it is intended to treat, cure, mitigate, or prevent disease, namely hypercholesterolemia (i.e., lower cholesterol). This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is 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-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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DILLING AND DILLING
ATTORNEYS AT LAW
150 NORTH WACKER DRIVE
CHICAGO, ILLINOIS 60606

KIRKPATRICK W DILLING
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RAKESH M. AMIN, R. PH.

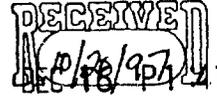
(312) 236-8417

ESTABLISHED 1917

ALBERT W DILLING
1892 - 1969

JOHN M. MANN
PATENT AND TRADEMARK
COUNSEL

0797 '97
October 20, 1997



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

Via Overnight Delivery

Re: Notification of Statements of Nutritional Support

Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

If necessary, please address future correspondence to our firm.

Sincerely yours,

DILLING AND DILLING

Rakesh M. Amin

Enclosure

75560 CALLE DEL SUR
INDIAN WELLS, CALIFORNIA 92210
(619) 568-1924
TELEFAX NO.
(619) 341-1045

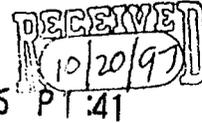
CALIFORNIA LEGAL ASSOCIATE
R CHANDLER MYERS
301 NORTH LAKE AVENUE
PASADENA, 91101
(818) 792-0007



55271
TELEFAX NO
(312) 236-8418
CABLE ADDRESS
DILGRON

October 20, 1997

Office of Special Nutritionals (HFS-450) 798 '97
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204



Re: Statements of Nutritional Support

Dear Sir:

Consider the following as notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

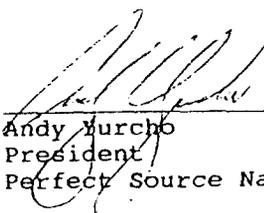
Distributor Name & Address: Perfect Source Natural Products, Inc.
4070 North Palm Street, Suite 707
Fullerton, California 92835

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
1) "Works to naturally support health and vitality"; "Barley Grass nutritionally supports the body's increased stamina and DNA repair"; "Spirulina nutritionally supports the immune system functions of the body"; "Hydroponic Sprout Complex helps the body's natural antioxidant enzyme systems"; "Vitamin C has an antioxidant role"; "Astragalus is an adaptogen and helps support the immune system"; "Ginkgo Biloba functions as a free radical scavenger and circulation aid"; "Grape Seed Extract has antioxidant properties, collagen functions and helps nutritionally support connective tissues"; and "Siberian Ginseng helps provide nutritional factors for the immune system and may help improve stamina and alertness".	Lecithin, Organic Grass Blend: (Alfalfa, Barley, Wheat Grass Juice Powders), Spirulina, Naturally Grown Phytonutrient Vegetable Blend: (Asparagus, Broccoli, Cabbage, Carrot, Celery, Red Beet, Spinach Powders), Soy Sprout Complex, Concentrated Kelp, Chlorella (Cracked Cell), Brown Rice, Acerola Berry Juice Powder (15-19% Natural Vitamin C), Royal Jelly, Bee Pollen, Dunaliella Salina (Natural Beta Carotene Source), Adaptogenic Herb Blend: (Astragalus Membranaceus, Ginkgo Biloba Extract-24% Flavone Glycosides, Grape Seed Extract and Siberian Ginseng).	Supreme Greens

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<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
2) "Aloe Vera may help in flushing toxins through the body and support the digestive process".	100% Aloe Vera Gel and Sea Life Blend: (Green Sea Lettuce, Green String Lettuce, Popping Wrack, Ribbon Kelp, Seersucker, Sugar Wrack, Turkish Towel, Wing Kelp in a 100% Aloe Vera Gel Base),	Performance Plus
3) "Nutritionally supports digestion"; "Provides mild, nutritional support for the colon system"; "Anise to help naturally expel gas and soothe the abdomen"; and "Buckthorn to nutritionally support regularity".	Senna Leaves, Buckthorn Bark, Comfrey Root, Sea Life (Green Sea Lettuce, Green String Lettuce, Popping Wrack, Ribbon Kelp, Seersucker, Sugar Wrack, Turkish Towel, Wing Kelp), Licorice Root, Psyllium Husk, Pepsin, Cascara Sagrada, Fennel Seed, Rhubarb Root, Culver Root, Anise Seed and Blue Malva Flower.	CC Tabs
4) "Absorptive properties" and "carries unwanted molecules through the digestive system and helps absorb excess liquids".	Activated Charcoal	Activated Charcoal
5) "Psyllium acts as a colon cleanser, stool softener, bulking agent and helps cleanse and soothe the intestinal track"; Apple Pectin aids in formation of intestinal bulk and promotes natural elimination and may lower cholesterol"; FOS feeds intestinal microflora and supports the body's response to toxins".	Psyllium, Rice Bran, Apple Pectin, Fructooligosaccharides (FOS).	Fiber Plus

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.



Andy Yurcho
President
Perfect Source Natural Products, Inc.