



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 27 1998

Food and Drug Administration
Washington, DC 20204

2581 '98 MAR 17 P1:40

Mr. Elwood E. Richard
President
NOW
550 Mitchell Road
Glendale Heights, Illinois 60139

Dear Mr. Richard:

This is in response to your letter of February 4, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NOW, is making the following statement for the product "Allergy Support™:"

"Allergy Support™ is a synergistic combination of vitamins, minerals, and herbal extracts for nutritionally supporting body functions, especially during the allergy season."

21 USC 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 name of this product and the statement that you are making for it suggest that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, or mitigate allergies. These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 USC 321(g)(1)(B), 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

LET 106

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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, Chicago District Office, Compliance Branch, HFR-MW140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (file)

HFS-450 (r/f, file, OSN#57057)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

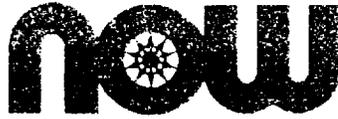
HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

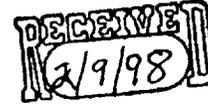
r/d:HFS-456:RMoore:2/10/98

init:GCF-1:DDorsey:2/13/98

f/t:rjm:HFS-456:2/18/98:57057.adv:disc25



Natural Products



February 4, 1998

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

Dear Sirs:

We are notifying you pursuant to the Dietary Supplement Health and Education Act of 1994 that the following structure and functions claims have been made on the following products of NOW Natural Foods. All products listed below are sold under the brand name of NOW®.

Table with 2 columns: Product and Claim. Rows include Acetyl-L Carnitine, Acidophilus Two Billion, 4 x 6 Acidophilus, and Allergy Support™.

see docket 975-0163

57057-57060

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Alpha Lipoic Acid

“Alpha Lipoic Acid is a versatile water and fat soluble metabolic antioxidant. It is a potent free radical scavenger and aids Vitamins C and E in their antioxidant activities. Vitamins C and E are added as complementary, synergistic antioxidants.”

Boron

“Boron is a biologically active trace mineral which affects calcium, magnesium and phosphorus metabolism. Boron is known to aid in bone strength and structure in animals but its significance in humans is less certain.”

Eye Support™

“NOW Eye Support™ offers a full range of antioxidant nutrients which may aid in maintaining some visual functions. Lutein, a carotenoid found in dark green leafy vegetables, is a dominant pigment in the macular region of the eye. Bilberry extract contains biologically active flavonoids which support healthy vision.”

57057
Flax Seed Oil

“Flax Oil is a rich balanced source of essential fatty acids. These beneficial fats play important roles in brain, nerve, glandular, and eye functions. In addition, they are involved in the transport and metabolism of cholesterol and triglycerides. Essential fatty acids are further metabolized into hormone-like substances in the cell known as prostaglandins. Prostaglandins are involved in the regulation of many important physiological functions.”

Glucosamine & Chondroitin

“This supplement has been formulated to provide support for joints. Glucosamine and Chondroitin are important naturally occurring structural components of healthy joints, ligaments, bones and synovial fluid.”

Grape Seed Antioxidant

“NOW Grape Seed Antioxidant is a highly concentrated natural extract derived from grape seeds. It contains a number of unique beneficial flavonoid compounds (min 90% total polyphenols) which have demonstrated free radical and oxidant scavenging activity.”

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Heart Support™

“This unique supplement has been formulated to provide superior nutritional support for the heart and cardiovascular system. This synergistic combination of B-vitamins, minerals, herbs, amino acids, and CoQ₁₀ are an excellent adjunct to an overall wellness program focused on a low fat diet and regular exercise.”

Lecithin Softgels

“Lecithin Capsules contain 15% phosphatidyl choline, which comprises a major portion of our brain and nervous system. Lecithin is also a source of essential fatty acids, choline, and inositol. Lecithin aids in emulsifying fats, enabling them to be dispersed in water.”

Lecithin Softgels-Triple Strength

“Triple strength Lecithin Capsules contain 35% phosphatidyl choline, which comprises a major portion of our brain and nervous system. Lecithin is also a source of essential fatty acids, choline, and inositol. Lecithin aids in emulsifying fats, enabling them to be dispersed in water.”

Lecithin Granules

“Lecithin contains 25% phosphatidyl choline, which comprises a major portion of all cell membranes. NOW Lecithin Granules are derived entirely from soybeans. Lecithin is also used to emulsify fats in baking and cooking, enabling them to be dispersed in water.

Phyto Flavonoids

“This comprehensive blend of potent herb and fruit extracts has been designed to provide a broad spectrum of flavonoids with scientifically demonstrated antioxidant activity and effectiveness. These herbs and fruits have been renowned throughout the world for centuries for their ability to maintain optimal well being.”

57059
Plant Enzymes

“This supplement provides a comprehensive blend of vegetarian enzymes active in a broad pH range to aid in food digestion. Protease breaks down protein, amylase breaks down starch, lipase breaks down fat, cellulase breaks down fiber, and lactase breaks down lactose (milk sugar). Papain and bromelain are primarily protein digesting enzymes.”

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Psyllium Husk Caps

“Psyllium Husks can be a convenient way to increase the intake of dietary fiber. It has the ability to swell up to 50 times its initial volume when added to liquid. This bulking action can play an important role in maintaining regularity and gastrointestinal health.”

Whole Psyllium Husks

“Whole Psyllium Husks can be a convenient way to increase the intake of dietary fiber. It has the ability to swell up to 50 times its initial volume when added to liquid. This bulking action can play an important role in maintaining regularity and gastrointestinal health.”

Shark Cartilage

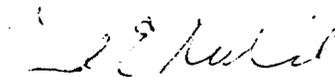
“Shark Cartilage has been researched in the U.S. and overseas. It is a rich source of nutrients including mucopolysaccharides (glycosaminoglycans) which aid in maintaining healthy connective tissue.”

57060
Soy Protein

“This product contains high levels of soy isoflavones which have been shown to aid in maintaining good health.”

I certify that the information contained in this notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Sincerely,



Elwood E. Richard
President