



APR - 2 2003

1715 '03 APR -4 P4:27

Mr. Tom Rumolo  
Technical Director  
National Vitamin Company, Inc.  
2075 West Scranton Avenue  
Porterville, California 93257-8358

Dear Mr. Rumolo:

This is in response to your letters of February 12, 17, 18, 20, and 25, 2003 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 National Vitamin Company, Inc. is making the following claim for the following products:

**Cayenne 450 mg Capsules**

"...rheumatic conditions;"

**Echinacea 350 mg & Golden Seal 100 mg**

"...Golden Seal may help fight infections;"

**Cold & Flu Fighter**

"...may provide mild antibiotic and antiviral activities that could help resist infections.

The product **Cholesterol Fighter** uses the claim "...maintain a healthy cholesterol profile." The product **Flaxseed Oil 1000 mg** uses the claim "support healthy cholesterol...levels for healthy heart." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claims for your products (including the name of the product, i.e., Cholesterol Fighter) about them being to "maintain a healthy cholesterol

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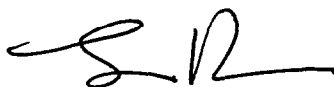
Page 2 - Mr. Tom Rumolo

profile” and “support healthy cholesterol” levels do not establish that the claims are about a blood cholesterol profile or blood cholesterol level that are already within normal limits and, therefore, imply that the products are intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease.

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 “Cholesterol Fighter and Cold and Flu Fighter) suggest that they are intended to treat, prevent, or mitigate diseases. 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-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,



Susan J. Walker, M.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-300

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

FDA, San Francisco England District Office, Office of Compliance, HFR-PA140

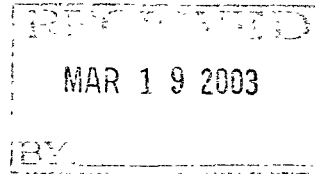


# National Vitamin Company, Inc.

2075 WEST SCRANTON AVENUE • PORTERVILLE, CALIFORNIA 93257-8358

Toll Free Inside California (800) 682-9862 • Outside California (800) 538-5828 • Fax (559) 781-8878

Food & Drug Administration  
200 C St. SW  
Washington DC 20204

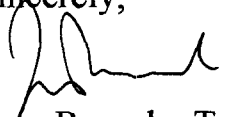


To Whom It May Concern:

Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company  
2075 W Scranton Avenue  
Porterville CA 93257
- (ii) The dietary supplement Cayenne 450mg Capsules states "The Cayenne Pepper may help with gastrointestinal disorders, muscle spasms, and rheumatic conditions."
- (iii) The name of the dietary ingredient is Cayenne Pepper (fruit) at 450mg per capsule.
- (iv) The brand label name is Nature's Blend Cayenne 450mg capsule, 90 capsules per bottle.

Sincerely,

 2/17/03

Tom Rumolo, Technical Director

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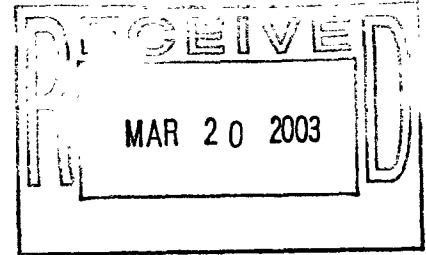


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To Whom It May Concern:

Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company  
2075 W Scranton Avenue  
Porterville CA 93257
- (ii) The dietary supplement Flaxseed Oil 1000mg states "Flaxseed Oil (Linum Usitatissimum) provides essential fatty acids, including Omega 6 as Gamma Linoleic acid which helps to maintain healthy joint function by inhibiting the body's inflammatory response as well as helping to support healthy cholesterol and Triglyceride levels for health heart".
- (iii) The name of the dietary ingredients is Flax Seed Oil at 1000mg per softgel, Omega 3 (as Alpha-Linolenic Acid) at 570mg per softgel, Omega 6 (as Linoleic Acid) at 160mg per softgel, and Omega 9 (as Oleic Acid) at 180mg per softgel.
- (iv) The brand label name is Nature's Blend Flaxseed Oil 1000mg, 90 softgels per bottle.

Sincerely,

 3/12/03  
Tom Rumolo, Technical Director

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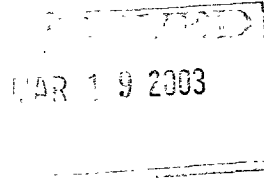


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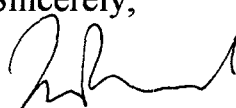


To Whom It May Concern:

Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company  
2075 W Scranton Avenue  
Porterville CA 93257
- (ii) The dietary supplement Cholesterol Fighter states "Cholesterol Fighter is specially formulated from the finest quality herbs and ingredients including natural Betaine Anthdrous-known as Trimethylglycine and natural Chitosan-Shell Fish Fiber. Cholesterol Fighter is intended for use by healthy adults whose goal is to maintain a healthy cholesterol profile."
- (iii) The name of the dietary ingredients are Niacin (from Inositol-Niacinate) at 37.5mg per capsule, Trimethylglycine at 250mg per capsule, Chitosan at 100mg per capsule, Beta-Sistosterol Complex at 50mg per capsule, and Lecithin at 50mg per capsule.
- (iv) The brand label name is Nature's Blend Cholesterol Fighter, 60 capsules per bottle.

Sincerely,

 2/18/03  
Tom Rumolo, Technical Director

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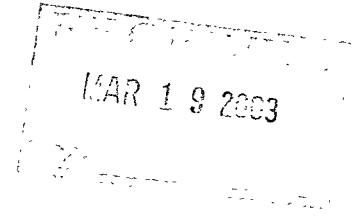


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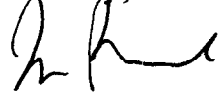


To Whom It May Concern:

Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company  
2075 W Scranton Avenue  
Porterville CA 93257
- (ii) The dietary supplement Cold & Flu Fighter states "The pure and natural unique blend of powders and standardized herbal extracts are formulated to stimulate the body's immune system. The stimulation may provide mild antibiotic and antiviral activities that could help resist infections."
- (iii) The name of the dietary ingredients are Vitamin C (as Ascorbic Acid at 30mg per capsule, Elderberry Standardized Extract Flavonoids 5% & Polyphenols 15% at 100mg per capsule, St. John's Wort Standardized Extract Hypericin .3% at 75mg per capsule, Echinacea Standardized Extract Total Phenols 4% at 50mg per capsule, Cat's Claw (bark) at 25mg per capsule, Golden Seal (root) at 25mg per capsule, and Siberian Ginseng (root) at 25mg per capsule.
- (iv) The brand label name is Nature's Blend Cold & Flu Fighter, 60 capsules per bottle.

Sincerely,

 2/20/03  
Tom Rumolo, Technical Director

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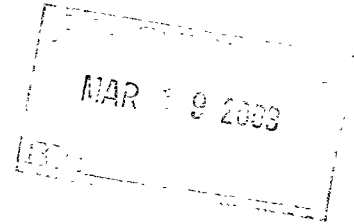


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To Whom It May Concern:

Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company  
2075 W Scranton Avenue  
Porterville CA 93257
- (ii) The dietary supplement Echinacea 350mg & Golden Seal 100mg states "Echinacea increases the body's natural immune system and Golden Seal may help fight infections."
- (iii) The name of the dietary ingredient is Echinacea Purpurea (Herb) at 350mg per capsule & Golden Seal (Root) at 100mg per capsule.
- (iv) The brand label name is Nature's Blend Echinacea 350mg & Golden Seal 100mg, 60 capsules per bottle.

Sincerely,

Tom Rumolo, Technical Director

42829