



JUN -9 2003

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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 letter of May 13, 2003 to the Food and Drug Administration (FDA). Your letter responded to our letter dated April 2, 2003 that raised concerns about claims that you intended to make for some of your dietary supplements. Your previous letters and your May 13, 2003 letter were submissions made pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In our previous letter to you, we stated that statements being made for the products **Cayenne 450 mg Capsules, Echinacea 350 mg & Golden Seal 100 mg, Cold & Flu Fighter, Cholesterol Fighter, and Flaxseed Oil 1000 mg**, as well as the product names "Cholesterol Fighter and Cold and Flu Fighter," were claims that suggested that these products were intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that were subject to regulation under the drug provisions of the Act. Your current letter contained revised claims that you propose for the products named above. The revised claims appear to resolve the issues we raised in our April 2, 2003 letter.

Please contact us if we may be of further assistance.

Sincerely yours,

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

975-0163

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

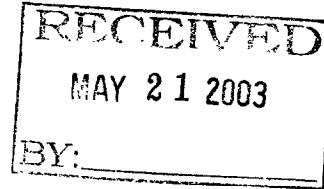


National Vitamin Company, Inc.

2075 WEST SCRANTON AVENUE • PORTERVILLE, CALIFORNIA 93257-8358

Toll Free Inside California (800) 682-9862 • Outside California (800) 538-5828 • Fax (209) 781-8878

May 13, 2003
Susan J. Walker, M.D.
Food and Drug Administration
College Park, MD 20740



Dear Susan J. Walker, M.D.:

Thank you for your letter dated April 2, 2003 concerning our structure/function claims for the following products:

Cayenne 450mg capsules, Echinacea 350mg & Golden Seal 100mg capsules, Cold Flu Fighter capsules, Cholesterol Fighter capsules, Flaxseed 1000mg softgels.

Enclosed you will find a revision to either the structure/function claim and/or to the name of the Dietary Supplement. Our intent is to market our products as dietary supplements and not as Drug Products.

Please let me know if our revisions meet your regulations and approval. If so, we will update our labels immediately.

Sincerely,

Tom Rumolo
Technical Director
National Vitamin Company, Inc.

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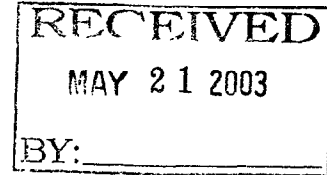


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Food & Drug Administration
200 C St. SW
Washington DC 20204



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 to support the body's gastrointestinal system."
- (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,

 5/14/03

Tom Rumolo, Technical Director

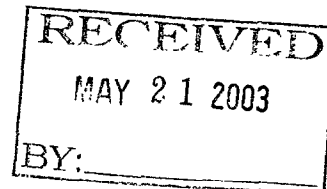


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To Whom It May Concern:

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 and Golden Seal may help to support ones immune system."
- (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,

 5/14/03

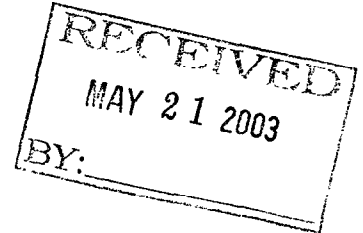
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To Whom It May Concern:

Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company
2075 W Scranton Avenue
Porterville CA 93257
- (ii) The dietary supplement Immune Support capsule states "The pure and natural unique blend of powders and standardized herbal extracts are formulated to help support the body's immune system."
- (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 Immune Support capsules, 60 capsules per bottle.

Sincerely,

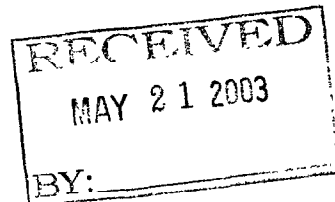
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To Whom It May Concern:

Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company
2075 W Scranton Avenue
Porterville CA 93257
- (ii) The dietary supplement Cholesterol Maintenance capsule states
"Cholesterol Maintenance is specially formulated from the finest
quality herbs and ingredients including natural Betaine Anthdrous-
known as Trimethylglycine and natural Chitosan-Shell Fish Fiber.
Cholesterol Maintenance is intended for use by healthy adults whose
goal is to maintain healthy cholesterol levels that are already within
normal range."
- (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 Maintenance
capsules, 60 capsules per bottle.

Sincerely,

 5/14/03

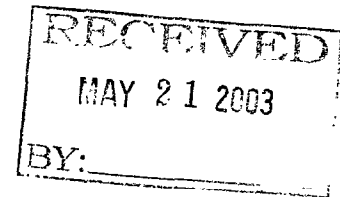
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To Whom It May Concern:

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 may help to maintain healthy joint function by inhibiting the body's inflammatory response as well as helping to support healthy Cholesterol and Triglyceride levels that are already within normal range."
- (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,


Tom Rumolo, Technical Director