

2104 '03 APR 18 P1:59

APR 10 2003

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 March 13, 17, and 26, 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:

St. John's Wort Standardized Extract 300 mg

"...work as antidepressant;"

Hawthorne Berry 450 mg

"...help dilate peripheral and coronary blood vessels;"

Glucosamine Sulfate 500 mg

"...reduce osteoarthritic pain by slowing cartilage deterioration."

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 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.

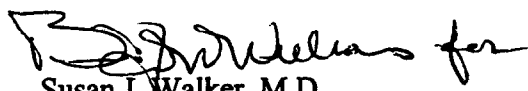
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Page 2 - Mr. Tom Rumolo

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 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

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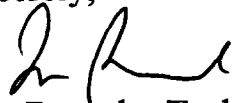
Food & Drug Administration
200 C St. SW
Washington DC 20204

To Whom It May Concern:

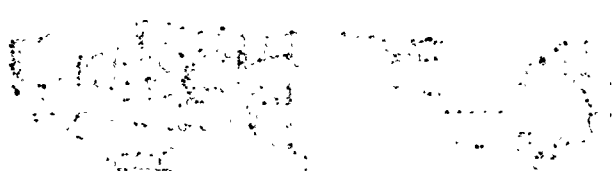
Subject: Structure/Function Claims for dietary supplement registration.

- (i) National Vitamin Company
2075 W Scranton Avenue
Porterville CA 93257
- (ii) The dietary supplement St. John's Wort Standardized Extract 300mg states "The herb may help relieve anxiety and work as antidepressant."
- (iii) The name of the dietary ingredient is St. John's Wort Standardized Extract Hypericin .3% at 300mg per capsule.
- (iv) The brand label name is Nature's Blend St. John's Wort Standardized Extract 300mg, 60 capsules per bottle.

Sincerely,

 3/26/03

Tom Rumolo, Technical Director





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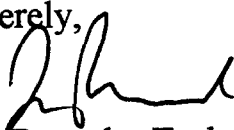
Food & Drug Administration
200 C St. SW
Washington DC 20204

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 Hawthorne Berry 450mg states "The berries are rich in flavonoids which may help to dilate peripheral and coronary blood vessels."
- (iii) The name of the dietary ingredient is Hawthorne (Berry) at 450mg per capsule.
- (iv) The brand label name is Nature's Blend Hawthorne Berry 450mg, 60 capsules per bottle.

Sincerely,

 3/17/03
Tom Rumolo, Technical Director



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


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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 Glucosamine Sulfate 500mg states
"Glucosamine Sulfate may help reduce osteoarthritic pain by slowing
cartilage deterioration."
- (iii) The name of the dietary ingredient is Glucosamine Sulfate at 500mg
per capsule.
- (iv) The brand label name is Nature's Blend Glucosamine Sulfate 500mg,
60 capsules per bottle.

Sincerely,



3/13/03

Tom Rumolo, Technical Director