



Received by S. Davis 6/10/99

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 7, 1999

WARNING LETTER
99-DT-09

Margaret M. Burco, President
Nature's Vision, Inc.
7320 Garden Lane
Portage, Michigan 49002

Dear Ms. Burco,

This letter is in reference to your firm's marketing and distribution of unapproved new drugs. Promotional materials, including your product catalogs, are labeling. These catalogs makes therapeutic claims for your products which cause the products to be drugs as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Examples of claims appearing in your most recent product catalogs include the following:

Alpha Lipoic Acid: "...Helps regulate blood sugar for diabetics and possible nerve regeneration. Also used as treatment for Parkensons and Alzheimers".

Cardio Care: "...reduce chances of heart disease...".

Golden Seal: "...natural blood purifier which is shown to lower cholesterol and help rid the body of free radicals that may cause arthritis pain".

Kava Kava: "...mild sedative...alternative to prescription tranquilizers and sleeping pills...used for many types of painful conditions such as urinary tract irritations, cystitis,...for irritable coughing associated with bronchitis and asthma...".

Pregnenolone: "...help with...PMS symptoms and rheumatoid arthritis".

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Melatonin: "...aid for insomnia".

MSM (Methyl Sulfonyl Methane): "...alleviate the pain of arthritis as well as muscular aches".

Natural Progesterone Cream: "...has been shown to help reduce symptoms of PMS and menopause, such as hot flashes, migraines...".

Saw Palmetto: "...may be effective in relieving the major symptoms of benign prostatic hyperplasia (BPH)".

Shark Cartilage Plus: "...may offer relief for arthritis sufferers".

St. John's Wort: "...natural alternative to Prozac...for mild to moderate depression".

5-HTP: "...used for natural relief of depression...migraine headache reduction".

These products are "new drugs" because there is no evidence that they are generally recognized as safe and effective for their intended uses [Section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

The drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [Section 502(f)(1) of the Act]. The labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established [Section 502(a) of the Act].

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

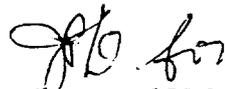
We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

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Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to Sandra Williams, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Mlecko' with a stylized flourish at the end.

Raymond V. Mlecko
District Director