



Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
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December 28, 2011

WARNING LETTER NO. 2012-NOL-08

**UNITED PARCEL SERVICE
Delivery Signature Requested**

James A Howenstine, MD
Natural Health Team
31240 May Street
Lacombe, Louisiana 70445-4113

Dear Dr. Howenstine;

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at www.mynaturalhealthteam.com, which automatically redirects to www.savingmyhealth.com, and your book, *A Physician's Guide to Natural Health Products That Work*, in November 2011 and has determined your products, "Alpha Lipoic Acid (ALA) 100 mg", "Arctic Omega", "Beyond Any Multiple", "Coral Calcium", "L-Lysine", "Nanonized Detoxifying Formula", "Noni Concentrate", "Oral Guard", "Samento", "Thymic Extract", "Xlear", "Zeolite", "LifeOne", and "Del Immune V", are promoted for conditions which cause the products to be drugs under Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The claims on your website and in your book establish these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of your products with these claims violates the Act. You can find the Act and FDA's regulations through links on FDA's home page at <http://www.fda.gov>.

Examples of claims observed on your www.savingmyhealth.com website, through links on the webpage titled "Online Store," include:

Alpha Lipoic Acid (ALA) 100 mg

- "Recent research has shown that high dosage of ALA (600 to 1800 mg. daily) can sometimes reverse the neuritis and eye damage seen in diabetes. Nerves have been shown to sprout new fibers."

Arctic Omega

- "Arctic Omega (AO) lowers ... cholesterol ... values. Additionally Omega 3 fatty acids have the ability to make blood less likely to clot thus warding off heart attacks and strokes."

Beyond Any Multiple

- "This product contains vitamins, antioxidants, minerals and nutrients ... Taking a supplement program gives protection against arterial disease, cancer, diabetes, arthritis, and cataracts."

Coral Calcium

- "[H]elps prevent osteoporosis, arthritis, allergic diseases and cancer."

L-Lysine

- "This essential amino acid is notable for its ability to fight cold sores and herpes virus infections; ... "

Nanonized Detoxifying Formula

- "Autism and schizophrenia have been helped by NDF."

Noni Concentrate

- "This formulation is very effective against malignancies which is not surprising as the fruit itself was very effective in treating malignancies. In a different dosage it also cures colds and influenza in hours."

Oral Guard

- "Gingivitis bacteria are a common cause for heart valve infections. Oral guard is composed of health grade hydrogen peroxide plus valuable nutrients that prevent and treat infection and promote normal cell maturation (opposes cancer). Thus OG has potential to decrease heart attacks and strokes as well as decrease the chance for heart valve infection spread from gingival bacteria and make oral cancer less likely."

Samento

- "([S]amento) is a unique preparation of this herb that has greatly improved effectiveness in treating Lyme Disease and other chronic diseases that appear to be caused by hidden (stealth) infections. Many persons misdiagnosed as fibromyalgia, chronic fatigue syndrome, amyotrophic lateral sclerosis etc. are recovering after Samento therapy. *There is now new evidence that Samento appears to have great value in treating malignancies.*"

Thymic Extract

- "Thymic extract has proven to be an effective safe therapy for systemic lupus erythematosus, rheumatoid arthritis, psoriasis, multiple sclerosis, hepatitis Band C "

On the webpage titled "Suggested Products," you list numerous diseases and the products you recommend for those diseases. Examples include the following:

- "**Asthma ... Sinusitis:** Coral Calcium, Xlear (Xylitol)"
- "**Diabetes:** Alpha Lipoic Acid (ALA) 300mg"
- "**HIV:** Thymic Extract"
- "**Malignancies:** Zeolite, Coral Calcium, Noni Concentrate"

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under Section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in Section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate the drug is safe and effective.

In addition, your website, www.savingmyhealth.com, offers for sale your book, *A Physician's Guide to Natural Health Products That Work*, which includes claims for products offered for sale through your online store. On page viii of the book's preface "Where to Obtain the Natural Health Products That I Recommend In This Book" you state, "Our own Natural Health Team offers many of the products mentioned in this book." and you list your website,

www.mynaturalhealthteam.com, and phone number, (800) 416-2806. In addition, your book's individual descriptions of Natural Health products state the products can be obtained from the Natural Health team at your website and phone number. Your book, *A Physician's Guide to Natural Health Products That Work*, establishes your LifeOne and Del Immune V products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease [21 U.S.C. § 321(g)(1)(B)]. Under Title 21, Code of Federal Regulations, Part 201.128, "intended use" is defined in part as "the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by ... labeling claims, advertising matter, or oral or written statements by such persons or their representatives."

Examples of the claims for your LifeOne and Del Immune V products in your book, *A Physician's Guide to Natural Health Products That Work*, include:

LifeOne

Under the heading "LifeOne Therapy of AIDS Patients" on page 292-293:

- "LifeOne is able to kill viruses, which made it a logical substance to be tried in HIV infections."
- "[A]verage fall in viral counts were 70% in 38 days. Lymphocyte counts increased significantly. Blood sugar values fell by an average of 14%. No side effects were seen on LifeOne therapy, and all subjects regained good health. This therapy is infinitely safer than highly active anti-retroviral drugs "
- "In HIV patients the LifeOne preparation increases lymphocyte numbers, increases CD4 and CDS lymphocytes, while decreasing viral numbers by 70% in 42 days."

Under the heading "Cancer of the Bladder" on page 399-400:

- "All patients with bladder cancer have a urinary tract infection. Recovery from the bladder cancer cannot occur until the bacterial bladder infection is cured LifeOne will begin to work more effectively after the bladder infection is eliminated "

DelImmuneV

- On page 125-126: "DIV has proven effective in quickly healing damaged immune systems. Patients with malignancies, autoimmune diseases, recurring frequent infections ... chronic fatigue states ... HIV, and non-healing bone fractures have all been helped by DIV."
- On page 126: "**Case 1** A 47 year old woman with a swollen abdomen from ovarian cancer was started on DIV one month before her surgery. The pathologic specimen revealed evidence of ovarian tumor spread into fat tissue and lymph nodes. She continued on DIV. Her blood marker for ovarian cancer returned to normal and she had no evidence of ovarian cancer two years later."
- On page 126: "**Case 2** A 19 year old male with cystic fibrosis was ill with a lung infection. He took DIV to improve his immune system. All his lung symptoms cleared "

Your "LifeOne", "Del Immune V", "Alpha Lipoic Acid (ALA) 100 mg", "Arctic Omega", "Beyond Any Multiple", "Coral Calcium", "L-Lysine", "Nanonized Detoxifying Formula", "Noni Concentrate", "Oral Guard", "Samento", "Thymic Extract", "Xlear", and "Zeolite" products are offered for conditions which are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so a layperson can use these drugs safely for their intended purposes. Thus, these products are misbranded within the meaning of Section 502(1)(1) of the Act [21 U.S.C. § 352(1)(1)], because the labeling fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of Section 301(a) of the Act [21 U.S.C. § 331(a)].

The above violations are not meant to be an all-inclusive list of violations that exist in connection with your products and their labeling. It is your responsibility to ensure all of your products and labeling are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations described above and

prevent their future recurrence. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to assure similar violations do not occur. Your response should include any documentation necessary to show correction has been achieved. If you cannot complete all corrections within fifteen days, please explain the reason for the delay and state the date by which the corrections will be completed.

Please send your reply to the attention of Mark W. Rivero, Compliance Officer, Food and Drug Administration, at the address above. If you have any questions regarding any issue in this letter, please contact Mr. Rivero at (504) 832-1290, extension 1103.

Sincerely,
/S/

Patricia K. Schafer
District Director
New Orleans District