



March 12, 2001

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

Ref: 2001-DAL-WL-11

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. Winston G. Morrow, D.C., CEO
Nutrition Dynamics, Inc.
510 West Court Street
Seguin, TX 78155

Dear Mr. Morrow:

This letter is written in reference to the inspection of your facility conducted by our investigator on May 30 and 31, and June 1, 2000, and to your marketing of the products, Valerian Root, Chinese Garlic, Coenzyme Q10, Optimum Health Essentials, and Nux Vomica Homaccord. Your Internet web site promotes these products with statements which represent or suggest that these products are intended to be used in the cure, mitigation, treatment, or prevention of disease. Such claims cause the products to be drugs under Section 201(g) of the Federal Food Drug, and Cosmetic Act (the Act).

Objectionable claims for your products include, but are not limited to, the following:

VALERIAN ROOT: Cardiac Arrhythmia; Palpitations; High blood pressure; Attention Deficit Disorder (ADD); Attention Deficit Hyperactivity Disorder (ADHD); Childhood behavioral and learning disorders; Insomnia; Headaches; Emotional tension disorders; Nervous tension; Promotion of the product with the statement, "The qualities of this herb have been compared to that of Valium."; Irritable bowel; Epilepsy; Convulsions; Chest congestion; Wounds.

CHINESE GARLIC (RUSSIAN PENICILLIN): Cancer; Anti Cancer; Cancer Preventative; Prostate Cancer; Brain Tumors; Liver, Gall Bladder Tumors; Acquired Immune Deficiency Syndrome (AIDS); Cardiovascular Disease; Lowers cholesterol, Lowers blood cholesterol levels yet increases the levels of HDLs (High Density Lipoproteins); Cardiac Arrhythmia; Diabetes;

May help in diabetic therapy; Cystic Fibrosis; Antibiotic; Kill bacteria; Fight infection; Preventing infection of wounds; Preventing gangrene; Cholera; Typhus; Amoebic dysentery Antifungal; Antiviral; Anti-candida; Anti-worms; Antiparasitic; Antiprotozoan; Expectorant; Bronchitis; Asthma; Pneumonia; Reduces blood clotting; Lowers blood sugar levels; Antitoxin (carcinogens, drugs, poisons); Gastritis; Dysentery.

COENZYME Q10: Cancer; Anti-Cancer; Cancer Preventative; Prostate Cancer; Brain Tumors; Liver, Gall Bladder Tumors, Acquired Immune Deficiency Syndrome (AIDS); Cardiovascular Disease; Cardiac Arrhythmia; Coenzyme Q10 deficiency associated with heart failure, angina, congestive heart failure, and high blood pressure; Cardiomyopathy; Mitral valve prolapse; Diabetes; Muscular Dystrophy; Autism; Chronic Fatigue Syndrome and implied association with Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Herpes Simplex Viruses 1 and 2 and Human Herpes Virus 6 (HHV-6).

OPTIMUM HEALTH ESSENTIALS: Cancer; Anti Cancer; Cancer Preventative; Prostate Cancer; Brain Tumors; Liver, Gall Bladder Tumors; Acquired Immune Deficiency Syndrome (AIDS); Cardiovascular Disease; Diabetes; Cystic Fibrosis; Attention Deficit Disorder (ADD); Attention Deficit Hyperactivity Disorder (ADHD); Autism.

We are unaware of any evidence which establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, these products are also new drugs as described in Section 201(p) of the Act which may not be legally marketed in the United States since no new drug application has been approved for any of these drugs as required by Section 505 of the Act.

Objectionable claims for the following product include, but are not limited to:

NUX VOMICA-HOMACCORD: Anti-Cancer; Cancer; Attention Deficit Disorder (ADD). Diseases of the liver and gall bladder/bile duct. Based on the individual homeopathic constituents of Nux vomica-Homaccord, therapeutical possibilities result for the treatment of . . . spasmodic constipation . . . disturbances of the hepatic function . . . colitis mucosa . . . diverticulitis of the colon . . . disorders of the hepatic function and liver damage . . . pancreatitis . . .

The label and/or labeling provided with the above product states or suggests that this product is useful in treating or preventing diseases. Such labeling includes statements which represent and suggest that this article is intended to be used in the cure,

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mitigation, treatment or prevention of diseases which are neither self-limiting nor amenable to self-diagnosis and treatment by the laity. Therefore, because of the collateral measures necessary to its use, the article is not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Accordingly, the marketing of this drug is a violation of the Federal Food, Drug and Cosmetic Act (the Act) as follows. This drug is misbranded within the meanings of Section 503(b)(1) and (b)(4) of the Act in that it is not dispensed pursuant to the prescription of a practitioner licensed by law to administer such drug and in that the product label fails to bear, at a minimum, the symbol "Rx only."

Additionally, based upon its intended use, Nux Vomica-Homaccord is a new drug [Section 201(p) of the Act] that may not be legally marketed in this country without an Approved New Drug Application [section 505(a) of the Act]. This purported homeopathic drug is promoted in your Internet web site for utility against Acquired Immune Deficiency Syndrome (AIDS). We are unaware of any homeopathic product recognized in the United States as a treatment for AIDS.

All of the above drugs are also misbranded under Section 502(a) of the Act because their labeling is false or misleading. Your web site suggests that there is evidence that these drugs are safe and effective for their intended uses, but, in fact, this has not been established. These drugs are further misbranded under Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for all of their intended uses as further described under Title 21, Code of Federal Regulations, Section 201.5(a)

We request that you notify this office in writing within 15 working days of receipt of this letter stating the action you will take to discontinue the marketing of these drug products or to otherwise bring them into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

This letter does not represent a comprehensive review of all the products distributed by your firm. It also does not represent a complete review of your Internet web site nor any other product labeling or promotional materials you may use. It is your responsibility to ensure that all products distributed by your firm meet the requirements of the Act and its implementing regulations.

We strongly suggest that you review all of your labeling for all of the products you are marketing, taking particular note of the types of claims that this letter informs you cause your products to be unapproved and misbranded under the Act.

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Your reply should be directed to Brenda C. Baumert, Compliance Officer, at the address on the letterhead.

Sincerely,



Michael A. Chappel
Director, Dallas District

MAC: BCB

Cc:

Craig S. Morrow, President
Nutrition Dynamics, Inc.
510 West Court Street
Seguin, TX 78155