



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

October 26, 2001

**VIA FEDERAL EXPRESS**

Dr. Dennis Jones  
Institute of Integrative Health  
1713 Dry Gap Pike  
Knoxville, TN 37918

**Warning Letter No. 02-NSV-02**

Dear Dr. Jones:

The U.S. Food and Drug Administration (FDA) has reviewed product labeling collected during inspection of your firm located at 1713 Dry Gap Pike, Knoxville, Tennessee 37918. Our review found that you have serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your products. You can find the Act and the food and dietary supplement labeling regulations through links in the Food and Drug Administration's world wide web home page at: <http://www.fda.gov>.

The products Colostrex™, Colostrex-D™, Echibiotic™, COQ10SODase™, Thistlex™, Tagmatol™, Marshmallow™ Herbal Cough Syrup, Lymphogen™, and St. Easewort™ include statements or suggestions that these products may be useful in the treatment of various diseases. Colostrex™ and Colostrex-D™ reference "Egret's Bio-Integrative Information," which claims that these products have "proven important in immune response excesses involving inflammation and destruction imbalances resulting in rheumatoid arthritis, lupus, multiple sclerosis, and allergies." COQ10SODase™ with reference to "Egret's COQ10SODase Bio-Integrative Information," claims "increased sperm counts in a group of infertile men," "healing of periodontal tissue," "lowered blood sugar in a group of diabetics," "may aid as a dietary supplement with congestive heart failure," "people with congestive heart failure...should not stop taking it suddenly because sudden withdrawal may exacerbate the symptoms," "improvements have been reported in people with cardiomyopathies," "reported improvement after approximately one month in people with premature ventricular beats (a form of arrhythmia) who also suffer from diabetes," "angina patients...report a greater ability to exercise without problems," "problems resulting from heart surgery occurred less," "muscle mitochondria lack ingredients found in COQ10SODase in people with muscular dystrophy," "several people with Alzheimer's disease reported that the progression of the disease appeared to be prevented for one and one-half to two years," "women with a high risk of breast cancer recurrence...show evidence of protection," and "appear to modulate blood pressure." Thistlex™ claims to act toward "chronic and toxic liver complaints, hepatitis, cirrhosis, jaundice, hyperlipidemia, and gallbladder colic." Tagmatol™ claims to be a supplement for "gastritis, gastric or duodenal ulcers, flatulence, and bloating." Marshmallow™ Cough Syrup claims to support throat irritation and dry cough." Echibiotic™ claims to provide "anti-bacterial protection," to "support the immune system of the body, especially in infection, cold, and influenza," has benefits of "treating cold and flu," to "reduced the recurrence of yeast infection," has "mild activity against Streptococci and Staphylococcus aureus," to "reduce the growth and rate of Trichomonas vaginalis," to "halt the

recurrence of *Candida albicans* infection,” “seems to prevent infection,” to “possess good anti-tumor, bacteriostatic, and anesthetic activity,” “is useful for infections of the upper respiratory tract such as laryngitis, tonsillitis, and for catarrhal conditions of the nose and sinus,” that “may be used as a mouthwash in the treatment of pyorrhea and gingivitis,” and “activates macrophages that destroy both cancerous cells and pathogens.” Lymphogen™ claims that it may be used for “chronic sinusitis.” St. Easewort™ makes claims that it has “anti-depressive, anti-anxiety, and sedative.”

Although you may be marketing these products as dietary supplements or foods, your labeling includes statements that represent or suggest that these products are intended for use in the cure, mitigation, treatment, or prevention of disease, and therefore, these products are drugs within the meaning of 201(g) of the Act. We are unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, these products are new drugs as described in section 201(p) of the Act that may not be legally marketed in the United States since no new drug application has been approved as required by section 505(a) of the Act.

These drugs are also misbranded because their labeling is false and misleading in that it suggests that there is evidence that these drugs are safe and effective for their intended uses when such evidence has not been established [section 502(a) of the Act]. These drugs are also misbranded because their labeling lacks adequate directions for use for the conditions indicated [section 502(f)(1) of the Act].

Additionally, Thistlex™, Tagmatol™, Marshmallow™ Cough Syrup, Echibiotic™, Lymphogen™, and St. Easewort™ also bear the statement “Based upon the PDR of Herbal Medicines” which also indicates intended use of these products as drugs.

The products Echibiotic™, Thistlex™, Tagmatol™, Marshmallow™ Herbal Cough Syrup, Lymphogen™, and St. Easewort™ contain 20%-60% alcohol, which is greater than the percentage of alcohol permitted in over the counter drug products [21 CFR § 328]. This alcohol content makes these products adulterated under section 501(a)(2)(B) of the Act because the methods used in the manufacture and processing of these products do not conform to good manufacturing practice requirements for safety.

Even if these products were not drugs and were marketed as dietary supplements, they would violate other provisions of the Act.

The products Colostrex™, Colostrex-D™, Echibiotic™, COQ10SODase™, Thistlex™, Tagmatol™, Marshmallow™ Herbal Cough Syrup, Lymphogen™, and St. Easewort™ are misbranded because the labels do not include the mandatory statement of identity required for dietary supplements, namely that the term “dietary supplement” appear as part of the statement of identity; or use the statements “as a dietary supplement” or “The use of this dietary supplement supports” in the instructions for use which is not a suitable alternative to the statutory requirement that a dietary supplement be “labeled as a dietary supplement” [21 CFR §101.3(g) and sections 403 (i)(1) and 403(s)(2)(B) of the Act].

The products COQ10SODase™, Colostrex™, Colostrex-D™, and Lymphogen™ are misbranded because they deviate from the prescribed labeling regulation by not separating dietary information for dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) [see 21 C.F.R. 101.36 § (b)(2)] established by regulation in section 21 C.F.R. § 101.9 (c)(8)(iv) from declared

dietary ingredients for which RDI's and DRV's have not been established [21 C.F.R. 101.36 § (b)(3)] [section 403(q)(5)(F) of the Act and 21 C.F.R. § 101.36(e)].

The products Colostrex™, Colostrex-D™, Echibiotic™, COQ10SODase™, Thistlex™, Tagmatol™, Marshmallow™ Herbal Cough Syrup, Lymphogen™, and St. Easewort™ are misbranded because they do not have "Supplement Facts" labeling as described in 21 CFR §101.36 [section 403 (q)(5)(F) of the Act].

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of the labels of your products to assure that they comply with the Act and regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your dietary products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date that you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you intend to prevent these violations from happening again. If you need more time, then let us know why and when you expect to complete your corrections.

Your written response should be directed to the attention of:

Joseph E. Hayes  
Compliance Officer  
Food and Drug Administration  
297 Plus Park Boulevard  
Nashville, TN 37217

Sincerely,

  
Carl E. Draper  
Director, New Orleans District

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