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Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED****WARNING LETTER**

FLA-98-73

September 15, 1998

William E. Chase, President  
Body Systems Technology  
408 Live Oaks Blvd.  
Orlando, Florida 34100

Dear Mr. Chase:

This letter is in reference to your firm's marketing, labeling (including promotional materials), and distribution of a number of products that make disease claims. These products and examples of disease claims include:

- "Invivo": "Alzheimer's, cancer, diabetes, obesity";
- "PYC+": "Studies indicate success with Attention Deficity Disorder, improve joint flexibility and arthritis, reduce diabetic retinopathy...May help with Alzheimer's...Parkinson's, heart attack, stroke, varicose veins";
- "Una de Gato (Cat's Claw)": "treatment for a wide range of health problems"; "...there is evidence to suggest that Uncaria Tomentosa may be beneficial in the treatment of cancer, arthritis, bursitis, rheumatism, herpes, ulcers, systemic candida...many bowel and intestinal disorders, and those infected with HIV virus"; and "its remarkable ability to cleanse the entire intestinal tract and help patients suffering from Chron's disease, diverticulitis, leaky bowel syndrome, colitis, hemorrhoids, gastritis, ulcers, parasites, yeast...";
- "Shark Cartilage": "its ability to inhibit tumor growth", "advanced breast tumors", "After six weeks all the tumors had significantly reduced in size", "disappearance of their uterine fibroid tumors", and "successful in reducing pain in approximately 70% of osteoarthritis cases and 60% of the rheumatoid arthritis cases";

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- "Silver Ice": "antibiotic", "broad-spectrum...agent which can significantly reduce the length and severity of almost any type of bacteria infection";
- "Seven Flowers": "anti-hypertensive...neuro hypertension"; and,
- "Best Nogenol": "prevents incidence of stroke", "relieves diabetic retinopathy", "relieves liver and kidney disease", "reduces excessive blood sugar".

Based on the claims noted above, these products are drugs [Section 201(g) of the Federal Food, Drug, and Cosmetic Act]. Therefore, they may not be marketed in the United States without approved new drug applications [Section 505(a) of the Act].

These drugs are also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use and because 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 also object to the claims made for the following products because these claims cause them to appear to be new drugs. We strongly recommend that you address these apparent violations at this time. Examples of the products and their disease claims include:

- "Colloidal Minerals (plus)": "diabetes, arthritis, cardiovascular disease, osteoporosis, stomach ulcers, Alzheimer's, prostatitis, cardiomyopathy, stroke, aneurysm, fibromyalgia, and more";
- "Fat Trapper": "...each gram of Chitosan can safely keep 3 to 12 grams of fat out of the bloodstream";
- "Coral Waters": "Many doctors in Europe and Scandinavia are using for their patients with arthritis, osteoporosis, hiatal hernia...those needing hip replacement and those with heart disease and those with high blood pressure";
- "Energy Plus": "male impotence";

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- "Enzymes+": "joint pain and gout...yeast and fungal growth";
- "E-Z Sleep": contains melatonin. Melatonin is not generally recognized as safe and effective under the final rules concerning OTC sleep-aid drug products [21 CFR 338];
- "Herbal Cleansing Tea": "obesity, constipation and impacted colon...helps control diarrhea or constipation...helps relieve headaches";
- "Hydrilla": "anti-arthritic";
- "Polynesian Noni": "diarrhea, intestinal parasites, ulcers, tuberculosis, asthma [sic], respiratory ailments, thrush, gingivitis, toothaches, abscess, boils, wounds, infections, diabetes, high blood pressure, headache, kidney problems, bladder problems";
- "Joint Care": "osteoarthritis";
- "Restore": "rheumatism...internal bleeding...gout...breast cancer, less obesity, heart disease, rheumatism, arthritis, lower blood pressure, thyroid disease...infectious disease"; and,
- "Calcium Wafers": "lowers cholesterol levels and helps prevent cardiovascular disease...hypertension (high blood pressure), insomnia,...nervousness, numbness in the arms or legs...rheumatoid arthritis, rickets...convulsions, depression, and delusions".

We request that you take prompt action to correct these violations. Failure to promptly correct 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 injunction against the manufacturer and/or distributor of illegal products.

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. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. 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.

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Your reply should be sent to Martin E. Katz, Compliance Officer,  
U. S. Food and Drug Administration, 555 Winderley Place, Ste.  
200, Maitland, Florida 32751.

Sincerely,

  
Douglas D. Tolen  
Director, Florida District