



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-01

October 23, 1997

Kathy Connelly, President
Achievers Unlimited
777 Flager Drive
West Tower, 9th Floor
West Palm Beach, Florida 33401

Dear Ms. Connelly:

This letter is in reference to your firm's marketing, labeling (including promotional materials), and distribution of your products, "CardioForce", "Cytopro", "TranQuell", "CytoPure", "MaxiLeane", "Tri-Chromaleane", and "CytoLife".

Promotional literature for "CardioForce" include, for example, claims relating to "heart disease", "cardiovascular disease", "lowering cholesterol and reducing hardening of the arteries", "angina, heart attacks, and strokes", "arteriosclerosis", "myocardial ischemia, transplant surgeries, coronary angioplasty, muscular dystrophy, congestive heart failure, cancer, AIDS, diabetes, and Chronic Fatigue Syndrome".

"CytoPro" literature claims include, for example, reduced blood pressure, artery blockage, "asthma", "lowering cholesterol levels", "anti-inflammatory and antiarthritic", "heart disease", "arthritis", "autoimmune diseases", "cancers", "cataracts and other eye damage", "diabetes".

"TranQuell" claims include, for example, "anxiety", "ulcers", "frequent illness", "depression and mood swings", "insomnia", "chronic tension", "autoimmune disease", "high blood pressure", "chronic pain and migraine headaches".

"Tri-Chromaleane" claims include, for example, "obesity".

Among the claims for "CytoPure" are "diverticulitis", "ovarian cancer", "antifungal and antibacterial", "antimicrobial", "colitis", "fistulas", "hemorrhoids", "Chron's disease", "bacterial infections", "Chronic Fatigue Syndrome", "gastritis", "parasites", "colon cancer", "ulcers" and "liver infection".

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The promotional literature for "MaxiLeane" includes such claims as "heart disease", "high cholesterol", "clogged arteries", "high blood pressure", and "stroke".

Claims for "CytoLife" include "bone cancers", "Chronic Fatigue Syndrome", "reduce cholesterol", and "inhibit growth of certain cancers".

We regard your promotional brochures as labeling, since they make therapeutic claims for these products, the products are drugs [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)], and, 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.

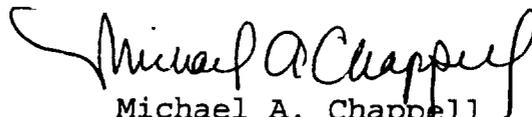
We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products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

Please notify this office in writing within 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 the Food and Drug Administration,
Florida District, 7200 Lake Ellenor Drive, Suite 120, Orlando,
Florida 32809, Attn: Martin E. Katz, Compliance Officer, telephone
no. (407) 648-6823, ext. 262.

Sincerely,

A handwritten signature in cursive script that reads "Michael A. Chappell". The signature is written in black ink and is positioned above the typed name.

Michael A. Chappell
Acting Director
Florida District