August 9, 1990

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to: SEA 90-33

Jack T. Simms, President
Tyler Encapsulations
2200 - 4 Northwest Birdsdale
Gresham, Oregon 97030

REGULATORY LETTER

Dear Mr. Simms:

This letter is written in reference to the marketing of various products by your firm under the TYLER label and the LOVE YOUR BODY! label.

Promotional material (labeling) distributed by your firm for Cardiovascular Complex, First Intention Capsules, Cal-Plex, Adrenal Complex, Echinacea, Floramine Echinacea, Immunacea, and Hypoglycemia Complex under the TYLER label and Immune Support 1 under the LOVE YOUR BODY! label states or suggests that the products are useful in, among other conditions, the following:

Cardiovascular Complex:

Prevention of development of atherosclerosis; promotes regression of atherosclerosis in plaques; lowers serum lipid/cholesterol levels; reduces platelet adheriveness; reduces angina pectoris; reduces and controls cardiac arrhythmias; effectively treats atrial fibrillation, ventricular tachycardia, and toxic arrhythmias caused by digitalis; reduces incidence of and lowers mortality from heart attacks; prevents coronary artery spasm; increases blood flow to the heart muscle and improves cardiac performance; reduces risks of stroke and coronary artery disease; effective in cardiomyopathy and congestive heart disease; effective in hypertension and lowers blood pressure; improves vertigo, headache, tinnitus, and short-term memory loss.

First Intention Capsules:

Treating thrombophlebitis and rheumatoid arthritis; the prevention of cancer, ulcers and epinephrine-induced pulmonary edema; and has prophylactic and therapeutic effects in immune deficiency disorders, atherosclerosis, and malignancies.

Cal-Plex:

Abnormalities of blood coagulation, hormone secretion, cell membrane integrity, prevention of nervous hyperexcitability, muscular spasm, and weakness.
Adrenal Complex:

Nervous and emotional disorders, fatigue, allergies, gastric and duodenal ulcers, high blood pressure, cardiovascular and renal disturbances, inflammatory diseases such as arthritis, rheumatic and rheumatoid disorders, cancer infection, and diseases of impaired resistance in general.

Echinacea:

Conditions for which an enhanced immune response is desired, such as colds, flu, infections, inflammations of skin, mucous membranes, and epithelial tissue and wound healing.

Floramide Echinacea:

Aid in maintaining a healthy immune response against colds, flu, infections, and conditions of impaired resistance.

Immunacea:

Stimulating immune system functioning, including antibody production, phagocytosis, bacteriostatic activity, and normalized leukocyte count. Aid to healthy immune response for colds, flu, infections, and conditions of impaired resistance.

Hypoglycemia Complex:

Regulation of blood sugar. Conditions such as hypoglycemia, dysinsulinism, "carboholics," and hyperglycemia.

Immune Support 1:

Comprehensive immune system support.

Because such labeling includes statements that represent and suggest that these articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure of the body of man, these products are drugs within the meaning of Section 201(g) of the Act. Furthermore, we are unaware of any substantial scientific evidence documenting that these drugs are generally recognized as safe and effective for the above-mentioned disease conditions or any other disease conditions. The drugs are therefore new drugs within the meaning of Section 201(p). Accordingly, marketing of these drugs is a violation of the Act as follows:

SECTION 502(a) BRIEF DESCRIPTION

The articles of drug are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the treatment of the above-listed diseases or conditions.
The articles of drug are misbranded in that their labeling fails to bear adequate directions for use in the treatment of the above-listed diseases or conditions in its promotional material, and they are not exempt from this requirement under the Code of Federal Regulations, Title 21, Part 201.115 (21 CFR 201.115), since the articles are new drugs within the meaning of Section 201(p) and no approval of any application filed pursuant to Section 505(b) is effective for these drugs.

The articles of drug, Cardiovascular Complex and First Intention, are further misbranded in that their labeling does not contain adequate directions for use, as this term is defined in 21 CFR 201.5, since the conditions for which they are offered are not amenable to self-diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use these drugs safely and for the purposes for which they are intended.

These articles are drugs within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approval of any applications filed pursuant to Section 505(b) are effective for such drugs.

In addition, the labels for Cardiovascular Complex and First Intention state that the products are dietary supplements and, as such, are in serious violation of the Act as follows:

**SECTION**  
**BRIEF DESCRIPTION**

403(a)(1) & 21 CFR 101.9(1)(5) Cardiovascular Complex and First Intention are misbranded in that the labels are false and misleading since they list substances (taurine, L-carnitine, chondroitin-4-sulfate, pyridoxal-5'-phosphate, carapaegus oxycahita, Ginkgo biloba, Zingiber officinalis, and allium sativa (Cardiovascular Complex), and bromelain, bioflavonoids, and rutin (First Intention)), which are not vitamins or minerals and have no known nutritional value, in a manner which falsely implies that they have nutritional value.

403(1)(2) Cardiovascular Complex and First Intention are misbranded in that the labels fail to bear a proper designation of ingredients. We do not consider a listing of the "potency" of some of the constituents of the products as a proper designation of ingredients.
Cardiovascular Complex is adulterated within the meaning of Section 402(a)(2)(C) since it contains L-cysteine and coenzyme Q10, food additives that are unsafe within the meaning of Section 409(a) since their use and intended uses are not in conformity with regulations in effect pursuant to Section 409 which prescribes safe conditions of use.

Promotional material distributed by your firm for Immuno Complex and Buffered C Powder under the TYLER label and Essential Fatty Acid Borage Oil Formula under the LOVE YOUR BODY! label states or suggests the products are useful in, among other conditions, the following:

**Immuno Complex:**

Aid for conditions in which a normalized or heightened immune response is desired, such as bacterial, viral and fungal infections, colds, flu, inflammation of skin, mucous membranes, and epithelial tissues, wound healing, allergies, and diseases of impaired resistance in general.

**Buffered C Powder:**

Normal connective tissue formation throughout the body, blood vessel integrity, fighting infection, normal immune response, red and white blood cell function, wound healing, response to stress, and numerous other physiological processes.

**Essential Fatty Acid Borage Oil Formula:**

Assists the body in prostaglandin formation which allows for healthy skin, optimal joint mobility, strong immune function, hormonal balance throughout the menstrual cycle.

Because the labeling includes statements that represent and suggest these articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of man, these products are drugs within the meaning of Section 201(g) of the Act. We are unaware of any substantial scientific evidence documenting that these drugs are generally recognized as safe and effective for the above-mentioned disease conditions or any disease conditions. The drugs are therefore new drugs within the meaning of Section 201(p) and are misbranded under Section 502(a), in that their labeling is false and misleading, and under Section 502(f) in that their labeling fails to bear adequate directions for use.

Please advise us in writing within ten (10) days of your receipt of this letter stating the actions you have taken or intend to take. Your response should include:

1) An estimate of the quantity of drugs manufactured or received within the past twelve (12) months.
2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3) An estimate of the amount of drugs that are in inventory under your control and your estimate of the amounts in distribution channels outside your control.

4) The date of discontinuance in the event that you have already discontinued marketing these drug products.

5) Your intentions with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be sent to Richard S. Andros, Compliance Officer, at the above address.

Sincerely,

[Signature]

Joseph R. Baca
Director, Compliance Branch

cc: