



June 18, 1998

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

Ref: 98-DAL-WL-38

WARNING LETTER

VIA FEDERAL EXPRESS

Dr. Philip A. Duterme, CEO
Ayurvedic Concepts, Ltd.
6950 Portwest Drive, Suite 170
Houston, TX 77024

Dear Dr. Duterme:

This letter follows inspections of your firm on February 2, and March 9, 1998, by investigators of the Food and Drug Administration, and is in reference to the promotion, marketing, and distribution of products by your firm.

Promotional literature for your products make the following claims:

- **"HeartCare"** claims include: "helps normalize blood pressure", "lowers blood pressure and heart rate" and "A wide range of 'at risk' individuals will benefit from taking this product daily ... family history of cardiac problems, hypertension or hypercholesterolemia";
- **"ImmunoCare"** claims include: "distinctly different antimicrobial, particularly useful for sinus and skin disorders", "... offer a natural alternative to strengthen the body's resistance against infections", "strong disinfecting properties", "useful against fever and rheumatism", "antibacterial, antiviral, and analgesic activity", and "provides effective protection against minor infections";
- **"ProstaCare"** claims include: "In prostatic enlargement, ProstaCare potentiates the action of Adrenaline, reduces the size of the prostate and relieves prostatic congestion. ProstaCare treatment has been often beneficial in avoiding surgery ... increases sperm count and motility and corrects factors linked to infertility", "Parkinson's disease", "ideally suited for men who wish to guard against the unpleasant symptoms and risks of deterioration", "ProstaCare is a unique herbomineral formula that has shown excellent results in cases of common benign prostatic enlargement, a condition known as BPH (Benign Prostatic Hyperplasia, affecting more than half the men above 50)", "helps reduce the size of the prostate, relieves the urinary discomfort of congestion, allows freer urinary flow";

- **"LaxaCare"** claims include: "chronic constipation", and "motion sickness";
- **"VigorCare"** claims include: "... has been proven effective in cases of impotence, without the side-effects usually associated with testosterone therapy";
- **"GlucoCare"** claims include: "increases insulin secretions by repair and regeneration of pancreas beta cells", "helps regulate blood sugar levels and prevent other vascular consequences", and "lowers blood sugar levels";
- **"JointCare"** claims include: "strong disinfecting properties", "antibacterial, antiviral, and analgesic activity", "rheumatoid arthritis", "an overall improvement was recorded in 70% of patients with rheumatoid arthritis. Swelling and tenderness of the joints was greatly lowered. ... Results are equally impressive in case of knee injuries which responded very well to JointCare treatment", "for many elderly people suffering from chronic and painful deterioration of their joints, JointCare has remarkable anti-inflammatory properties", "The conclusion was that JointCare is an effective agent in Rheumatoid Arthritis", "relieving discomfort caused by morning stiffness", and "... have recognized the value of natural products such as JointCare in the treatment of low back pain, one of the most common chronic orthopedic problems";
- **"Abana"** claims include: "normalize blood pressure", "lowers blood pressure and heart rate";
- **"Septilin"** claims include: "distinctly different antimicrobial, particularly useful for sinus and skin disorders", "strong disinfecting properties", "useful against fever and rheumatism", and "antibacterial, antiviral, and analgesic activity";
- **"Rumalaya Natural Joint Support"** claims include: "antibacterial, anti-fungal, and analgesic";
- **"Pilexim"** claims include: "strong anti-bacterial ... properties" and "strong disinfecting properties";
- **"Cystone"** claims include: "decreases risk factors causing stone formation", "shown to be effective in treatment of urolithiasis (calculi)", "anti-infective acting", and "assists in control of infections of the genito-urinary systems";
- **"Glucosim"** claims include: "helps regulate high blood sugar levels and prevent other vascular consequences", "not only lowers blood sugar levels but may also

help regenerate pancreas beta cells", "the herb of choice for gentle and safe glycemic management (sugar level in the blood stream)", and "strong disinfecting qualities";

- **"Gasex"** claims include: "used for pain in the bowels and an antihelmintic. Useful against diarrhea and vomiting.", "relieves hyperacidity in functional dyspepsia", "prevents nausea or uneasiness after heavy meals", and "motion sickness";
- **"Prostane"** claims include: "helps reduce the size of the prostate, relieves urinary discomfort of congestion, allows freer urinary flow"; "mild diuretic also helps dilate coronary arteries", and "dopamine-like action investigated in Parkinson's Disease";
- **"Tentex forte"** claims include: "dopamine-like action investigated in Parkinson's Disease" and "mild diuretic that also helps dilate coronary arteries";
- **"LiverCare"** claims include: "chronic alcohol users particularly found that LiverCare helped them alleviate the detrimental effects of alcohol on liver functions", "it protects against arteriosclerosis", "LiverCare provides considerable protection against a wide range of hepatotoxic agents", "ensures the protection of the hepatic parenchyma and acts as a powerful detoxification agent", and "for the occasional consumer of alcohol, it offers the perfect protection against many health risks associated with alcohol consumption and hepatic damage.";
- **"MindCare"** claims include: "tranquilizer", "treat anxiety and other disorders", "... was shown to be effective for emotionally disturbed who demonstrated a distinct improvement in behavior and social attitudes", "cognitive defects", "may also have some relevance in Alzheimer's disease (AD) research", and "patients suffering from anxiety neurosis ... and depression";
- **"VeinCare"** claims include: "strong disinfecting properties", "famous antibacterial effective for various skin and blood conditions";
- **"UriCare"** claims include: "... has been shown to reduce the susceptibility to infections of the urinary tract and to reduce stone formation", "decreases risk factors causing stone formation", "checks calcium absorption", "shown to be effective in treatment of urolithiasis (calculi)", and "controls urinary composition which prevents stone formation and helps dissolve preformed stones or prevents recurrence ... also reduces susceptibility to infections caused by common urinary pathogens";
- **"GastriCare"** claims include: "in specific cases of people with conditions such as asthma, heart deficiencies or obesity, where gastro-intestinal gas may increase the

discomfort and aggravate symptoms such as shortness of breath ... ", "heartburn and hyperacidity", and "prevents nausea or uneasiness after heavy meals";

- **"LeanCare"** claims include: "... a unique herbomineral formula that regulates the metabolism of fats and has shown excellent results in cases of obesity", "regulates the sugar content in the bloodstream", "strong disinfecting properties", "not only lowers blood sugar levels but may also help regenerate pancreas beta cells", "helps protect overweight people against possible consequences of excess lipids, such as adult-onset diabetes, hypertension and other cardiovascular problems"

Your promotional literature "Ayurvedic Medicine Ancient Roots, Modern Branches" and "Companion Guide" contain numerous disease claims and third-party references that also make disease claims for your products. An example of such claims are those made in "Ayurvedic Medicine" for "Indian Madder" : "treat tumors, kidney stones, heart disease, hepatitis and urinary problems", "cancer treatment ... similar to the effects of the chemotherapeutic drug 5-fluorouracil", and "treating several types of cancer, including lung, blood (leukemia) and skin (melanoma)."

Some of your products are subject to 21 CFR 330 regarding Over-The-Counter (OTC) Human Drugs. Examples include, but are not limited to, "GastriCare" and "Gasex" which are subject to the "Final Rule for Antacid Products for OTC Human Use" which became effective June 4, 1974 (21 CFR 331). "MindCare" and "Mentat" are subject to the "Final Rule for Stimulant Drug Products for OTC Human Use" which became effective February 29, 1988 (21 CFR 340).

Based on the claims made for these products and their intended uses, these products are drugs [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. They are also new drugs [Section 201(p) of the Act] and may not be legally marketed in the United States without approved New Drug Applications (§505).

These drugs are also misbranded [Section 502(f)(1)] because the labeling fails to bear adequate directions for use and is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established [502(a)].

In addition, the promotional literature contains numerous references to "Himalaya Drug Company", "...holistic system of diagnosis and treatment", "herbal medicine", "...truly amazing understanding of pharmacology", "...a return to natural products in ... pharmaceuticals...", and "consistency that only modern pharmaceutical technology can provide", which could cause the products to be considered to be drugs.

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Furthermore, the promotional literature "Companion Guide" includes, in addition to numerous disease claims, a section titled "Pharmacology of the Major Components Used in Ayurvedic Concepts' Natural Formulas". The use of the word "Pharmacology" is not appropriate for dietary supplements because the word is defined as "the science of drugs". The section also makes extensive disease claims for your ingredients.

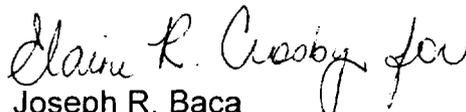
This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct the 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 proceedings 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.

Your reply should be sent to the attention of James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely,


Joseph R. Baca
Director, Dallas District

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