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Food and Drug Administration
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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60 Eighth Street, N.E.
Atlanta, Georgia 30309

August 18, 2000

VIA FEDERAL EXPRESS

Jack L. Davis, President
Jack Davis & Associates, Inc.
(d.b.a. Davis Vitamin Company)
2925-4 Ledo Road
Albany, GA 31701

WARNING LETTER

00-ATL-60

Dear Mr. Davis:

This letter is in reference to your firm's marketing and distribution of the product "Noni Tahiti." Labeling for the product (promotional materials) contains drug claims for the treatment and prevention of various diseases. Examples include:

- Your promotional literature for "Noni Tahiti" includes disease claims such as "... a long list of curative properties is associated with the daily intake of 100% PURE NONI juice. The PURE juice of the NONI fruit is traditionally used on the islands for its beneficial natural antibiotic, analgesic, and anti-inflammatory properties, especially with respect to rheumatic problems ... a natural remedy to treat hypertension ... low/high blood pressure ... sore throats (gargle), colds, diarrhea ... and much more";
- Other promotional literature intended for media distribution includes such claims as "NONI is a fruit with extraordinary healing properties ... has been demonstrated to improve a variety of conditions. Some of the benefits may include: lowers high blood pressure ... acts as anti-inflammatory and anti-histaminic agent ... helps against Fibromyalgia"; and
- The label for "Noni Tahiti" includes the claim "... the regular intake of PURE NONI can produce remarkable results in the treatment of various ailments ... a remarkable alternative to aid the body's own healing process."

"Noni Tahiti" is a drug [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and a "new drug" [section 201(p) of the Act]. This product may not be marketed in the United States

without an approved new drug application [section 505(a) of the Act].

This drug is also misbranded [section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. This drug is further misbranded because the labeling is false and misleading as it suggests that the product is safe and effective for its intended use 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.

Furthermore, we are aware that your firm also promotes additional products via a catalog and other promotional material. Examples of such products include:

- "Colloidal minerals" claims include "chronic fatigue syndrome ... suicide ... haven't had any fevers, sneezes, sniffles, or coughs";
- "Colloidal Silver" claims include "kills 650 different disease organisms ... kills destructive bacteria within minutes ... hasten healing, reduce scaring and deadly infection from burns ... safe, natural remedy for many mankind illnesses ... best all-around germ fighter ..." Furthermore, Colloidal Silver is the subject of a Federal Register notice dated August 17, 1999, which established that "... all over-the-counter (OTC) drug products containing colloidal silver ingredients or silver salts for internal or external use are not generally recognized as safe and effective and are misbranded ..." (copy attached);
- "A.D.D. Therapy" implies treatment of an existing disease condition by virtue of the product name;
- "Collagen II" claims include "... providing relief in hips and joints ailing from arthritis symptoms ... A must for those who seek relief";
- "Allergy Relief" claims include the name of the product and the claims "... provide relief of nasal congestion, coughing, wheezing, itching, as well as minor skin rashes, headaches, and fatigue caused by allergies ...";
- "Easy Rub Spray" claims include "arthritis pain relief lotion ... relief of minor aches and pains of muscle associated with arthritis";
- "Colostrum" claims include "... anti-depressant ..."; and
- "Human Growth Hormone Precursor" claims include "diminishing eyesight ... skin wound healing; cellulite ... emotional instability; blood pressure, high/low; high cholesterol ... joint problems."

These products are drugs based upon their claims. They may also be new drugs and misbranded drugs.

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.

Your reply should be sent to U.S. Food and Drug Administration, Atlanta District Office, 60 8th Street NE, Atlanta, GA 30309, Attention: Karen Y. Dodson, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is written in a cursive style with a large initial "B".

Ballard H. Graham, Director
Atlanta District Office

Enclosure