



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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October 11, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mitchell L. Tate, C.E.O.
Nonu, Inc.
d.b.a. Nonu International and Royal Farms
50 East 100 South, Suite 205
St. George, Utah 84770

Ref. # DEN-01-1

Dear Mr. Tate:

This letter is in reference to the promotion, marketing, and distribution of products by your firm. Included among these products are:

- NONU Morinda Citrifolia Dietary Supplement tablets
- NONU Children's Chewable Vitamin C with Morinda Citrifolia tablets
- NONU ROYAL NONU TEA
- NONU Nonu Juice Dietary Liquid Supplement
- NONU Nonu Juice 100% pure morinda citrifolia dietary liquid supplement
- ROYAL PACIFIC NONI Children's Chewable Vitamin C with Morinda Citrifolia tablets
- ROYAL PACIFIC NONI Morinda Citrifolia Dietary Supplement tablets
- ROYAL PACIFIC NONI HERBAL TEA
- ROYAL PACIFIC NONI JUICE Morinda Citrifolia; and
- LIQUID DIETARY SUPPLEMENT ROYAL PACIFIC NONI JUICE 100% Pure Morinda Citrifolia

Examples of the claims made for your products through various promotional literature (labeling) pieces are:

- reprints from "totalhealth FOR LONGEVITY" (used as promotional literature for both "Royal Pacific Noni" and "Nonu") include such claims as "... use this plant for a

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variety of health problems including pain relief, sinus infections, arthritis, digestive disorders, colds, flu, headaches (including migraines), infections . . . injuries, skin disorders, heart disease, diabetes II and more . . . use it for diabetes, high blood pressure, cancer, and many other illnesses . . . showed antibacterial properties against M. pyrogenes, Ps. aeruginosa, and even the deadly E. coli . . . Nonu may have turned precancer cells back into normal healthy cells . . . Nonu may inhibit tumor growth. Research indicates Nonu is useful for a wide variety of conditions, including: Producing unique anti-pain and anti-inflammatory effects . . . cellular regeneration of damaged cells . . . Fighting many types of bacteria, including E. coli . . . Inhibiting the growth of cancerous tumors . . . inhibit precancer function . . .,” “. . . documented benefits listed below . . . Pain; Headaches; Diarrhea; Intestinal worms . . . Chest infections . . . Fever with vomiting; Inflamed, sore gums; Sore throat with cough; Thrush; Abscess; Anticancer activity; Precancerous tissue; Lung cancer; Hypertension; Diabetes II (adult onset diabetes); Arthritis; Antibiotic; Antimicrobial; Abdominal pains; Backache . . . Mouth and gum infections; Sore throat; Toothaches; Wounds, fractures and boils; Urinary tract ailments; Abdominal swelling; Diaphragmatic hernia . . . Arthritis . . . Epstein-Barr virus” and “Functions of Noni: Reduces pain (analgesic), Reduces inflammation (anti-inflammatory) . . . Antibacterial, anticatarrhal, anticongestive . . . hypotensive (lowers blood pressure), . . . inhibits certain tumors and cancer growth . . .”;

- reprint from “Whole Foods magazine” (used as promotional literature for Noni, the ingredient for both of your product lines) include such claims as “. . . use this plant for a variety of health problems, including: pain relief, sinus infections, arthritis, digestive disorders, colds, flu, headaches (including migraines), infections . . . injuries, skin disorders, heart disease, type II diabetes, and more . . . lower blood pressure . . . inhibit excessive blood flow . . . inhibit the formation of blood clots . . . alleviating painful joint conditions and resolving skin inflammations . . . hypertension . . . arthritis, gastric ulcers, diabetes, and depression . . . anti-cancer activity . . . Hundreds of thousands of people the world over have reported dramatic improvements with: Pain/Arthritis symptoms. . . Diabetes; Allergy/Hay fever; Cold & Flu Symptoms . . . High Blood Pressure . . .”; and
- the “Information Mailer Royal Farms” (used as promotional literature for the “Royal Pacific Noni” product line) contains such claims as “Noni is Traditionally Used For: Pain/Arthritis symptoms . . . Migraine headaches . . . High blood pressure. . . Internal parasites; Diabetes; Tumor growths; Allergy/Hay fever; Cold & Flu symptoms; Digestive disorders; Open wounds & sores . . .”;

Based on the numerous and extensive 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 (Section 505).

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These drugs are also misbranded because the labeling fails to bear adequate directions for use [Section 502(f)(1)] 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 [Section 502(a)].

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.

In addition, we are also aware that your Internet websites www.royalnoni.com and www.nonuinc.com make claims similar to those cited above.

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 the attention of Ms. Shelly L. Maifarth, Compliance Officer, at the above letterhead address.

Sincerely,



Thomas A. Allison
District Director

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