



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

HFI-35

MBSSh

1990 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

JUN 22 2000

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Marysa Benjamin  
Tahiti Naturel USA, Inc  
25546 Spinnaker Drive  
San Juan Capistrano, CA 92675

W/L 65-00

Dear Ms. Benjamin:

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 "Morinda Citrifolia (Noni) Juice and its Medicinal Value" (labeling) contains such claims as "Polynesian healers used Noni juice to treat fever, infection, diarrhea, constipation, asthma ... and other ailments," "Building upon Noni's effectiveness against cancer ...," "Other researchers have documented the antibacterial and anaseptic [sic] characteristics of Noni ... effective antibacterial for the control of Pseudomonas aeruginasa, Proteus morganii, Staphylococcus aureus, Bacillus, Escherichia coli, Salmonella, and Shigella," "... effectiveness against hypertension ... arthritis, gastric ulcers, sprains and inflammation, infections ... arteriosclerosis, addictions ... burns, cancer and other maladies," "... Alzheimer's disease ...," and "... traditional healers in Polynesia have, for centuries, recognized Noni's effectiveness in treating a number of conditions such as: Digestive disorders including diarrhea and parasites. Chest infection including coughs, colds, pleurisy and tuberculosis. Eye infections including conjunctivitis, sty ... fever, mouth and throat infection ... thrush. Skin infections including abscess, boil ... elephantiasis ... wounds ... jaundice ... rheumatism ..."

- Your promotional literature "Noni Tahiti by Tahiti Naturel" 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, constipation and much more."
- The reprint "Anticancer Activity of Morinda citrifolia (Noni) on Intraperitoneally Implanted Lewis Lung Carcinoma in Syngeneic Mice" that you provide to customers implies use of Noni extract not only as an antitumor drug but also "... to treat a number of ailments such as hypertension, diabetes, arthritis, and cancer."

"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 also 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].

In addition, your Internet website contains claims which may cause your product(s) to be misbranded by establishing intended use for the product(s).

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.

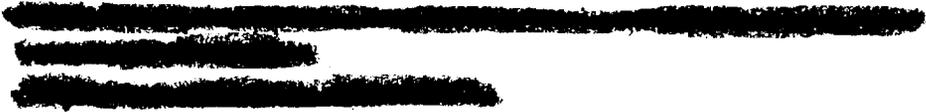
Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations 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.

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Your reply should be sent to Director, Compliance Branch, U.S. Food and Drug Administration,  
19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,

  
Acting District Director  
Los Angeles District



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bcc: HFI-35 (redacted)  
HFA-224  
HFC-210  
HFD-310  
HFR-PA240  
HFR-PA250 (Kozick)  
LOS-DO Files 3002924888  
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LOS-DO (C. Everly)