



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3848n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

MAY 22 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michel Guillemet
Polynesian Natural Health Products, LLC
1030 Calle Cordillera, Suite 106
San Clemente, CA 92674

W/L 54-00

Dear Mr. Guillemet:

This letter is in reference to your firm's marketing and distribution of the product "Pol'Noni." Labeling for the product contains numerous therapeutic claims that cause the product to be a drug [section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. Labeling includes product labels, brochures, Internet sites, and other promotional literature which you distribute in connection with your products.

Objectionable claims for "Pol'Noni" include the following:

- Your Internet website contains extensive disease claims that include "natural 'cures' for illnesses," "Native 'healers' used it to treat many health problems such as: respiratory ills, weak immune system, fevers, allergies, digestive problems, colds, heart disease, infections, stroke, depression, burns, diabetes, kidney problems, arthritis, parasites, obesity, headache, smoking [nicotine addiction], high blood pressure, sinusitis, pain, and other maladies," "...has reported positive results in the treatment of high blood pressure... and swelling of the prostate," and "... fights the detrimental effects of illness."

- Your brochure titled "Over 2,000 years ago medicine men of Tahiti discovered a plant with powerful healing properties" contains such disease claims as "... has used noni juice to treat ailments of some of her patients including high blood pressure... and swelling of the prostate...", "... works as an analgesic...", and "... used to treat many ailments such as: digestive and respiratory problems, infections of the mouth, throat, and skin, fevers, arthritis, high blood pressure, headaches"; and
- The booklet "Nature's Amazing Healer Noni" is liberally distributed to consumers as promotional literature (labeling) intended to establish the intended uses for "Pol'Noni" which include such disease claims as "lowers high blood pressure; fights cancer; reduces arthritis symptoms/pain ..."

"Pol'Noni" is also a "new drug" [section 201(p) of the Act] which 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 and because the labeling is false and misleading as it suggests that the product is safe 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 assure that all products marketed by your firm are labeled in compliance with the Act and its implementing regulations.

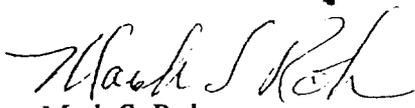
We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and for injunction against the manufacture and/or distributor of illegal products.

In addition, your website also includes disease claims for your intended product "Tamanu Oil" which include "...healing balm for many skin ailments such as burns... dermatitis, small wounds, eczema... psoriasis and other skin problems" and "... many skin ailments including burns, cuts, wounds, rashes, dermatitis... psoriasis... earaches..." We note that you did not have this product during the inspection (02/08/00). However, if you do have this product in the future, such Internet claims may cause the product to be misbranded.

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 Director, Compliance Branch, U.S. Food and Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,



Mark S. Roh
Acting District Director
Los Angeles District

