



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94958d

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

August 26, 2004

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-43

Thomas O. Greither, President  
Flora, Inc.  
P.O. Box 73  
Lynden, Washington 98264

**WARNING LETTER**

Dear Mr. Greither:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.florahealth.com> and has determined that the product Pure Hawaiian Noni Juice is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)(1)]. The therapeutic claims on your web site establish that this product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site under the heading "What Does Noni Do?" include:

- "[S]tudies have shown the fruit juice to contain several healing attributes including...Scopoletin, which lowers blood pressure and may help in the reduction of arthritic pain, Damnacanthal, a proven inhibitor of ras (pre-cancer) cells..."
- "According to Dr. Isabella Abbott, an expert in botanical sciences, the more common uses of noni include to control diabetes, high blood pressure and cancer."
- "Biochemist Dr. Ralph Heinicke has reported noni being used to treat ...arthritis, gastric ulcers, ... mental depression, ... atherosclerosis, and drug addictions."

And under the heading "Benefits":

- Lowers high blood pressure...
- Relieves arthritis
- Eliminates gastric ulcers...

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Flora, Inc., Lynden, Washington  
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- Prevents mental depression
- Lessens atherosclerosis
- Helps drug addiction
- Heals burns
- Inhibits pre-cancer cell growth
- Decreases chest infections
- Improves eye infections...
- Eliminates mouth and throat infections
- Decreases skin infections"

Your product is misbranded under section 502(f)(1) of the Act [21 USC 352(f)(1)] in that the labeling for this drug fails to bear adequate directions for use. It is a violation of section 301(a) of the Act [21 USC 331(a)] to introduce or deliver for introduction into interstate commerce any drug that is misbranded.

This letter is not intended to be an all-inclusive review of your web site and products your firm may market. 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 actions without further notice. These actions include seizure and/or obtaining a court injunction against further marketing of your products.

Please respond in writing within (15) fifteen days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state the time at which corrections will be completed. Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421.

Sincerely,



for  
Charles M. Breen  
District Director

cc: WSDA with disclosure statement