



September 18 2006

Food and Drug Administration  
College Park, Maryland 20740**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Peter W. Manville  
NJP Products, Inc.  
23352 Madero Road, Suite C  
and 27525 Puerta Real #100-505  
Mission Viejo, California 92691

Ref. No. CL-06-HFS-810-239

Dear Mr. Manville:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses <http://www.noni-juice-plus.com> and <http://www.barley-green-premium.com> and has determined that the products "Noni Juice" and "BarleyGreen Premium" are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web sites establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your <http://www.noni-juice-plus.com> web site include:

**Noni Juice**

Your web site contains disease claims in the form of personal testimonials about the use your Noni Juice product for a wide variety of diseases, including chronic lymphocytic leukemia, arthritis, carpal tunnel syndrome, allergies, asthma, bipolar disorder, depression, migraines, multiple sclerosis, and others. Examples of some of the disease claims observed on your testimonials page include:

"I just want to take the time to let you know that after a month of taking the Noni Juice you supply I noticed a difference in my symptoms, you see I have Lupus Erythematosus [sic] and suffer from arthritic like symptoms. The first two weeks after taking I noticed that I did not have joint pain, the swelling in my fingers had disappeared, the fatigue disappeared and I had a lot more energy. Also, I had been suffering from chronic back pain and even that seemed to have disappeared. ... It has helped with my depression. ... It has vastly improved my irritable bowel condition. The relief from pain that I have had from arthritis [sic], fibromyalgia and lingering nerve pain (from shingles) is absolutely amazing. And I haven't had a migraine since I started taking it. My allergies have improved. And slowly, but surely, my acid reflux [sic] is getting less and less every day. ..."

"I recently broke 3 bones in my leg. ... Being depressed, and not having much circulation in my leg [sic] needed something that would benefit my situation. I was talking a friend and he told me when Terrell [sic] Owens (NFL football star) broke his ankle in the 2004-05 football season just 7 weeks prior to the Super Bowl, he took Noni juice to help him, and was back in

time for the Super Bowl where he had 7 receptions! This influenced me to start using Noni juice and after taking it for a week, it helped my depression a whole lot, help get circulation in my leg ..."

"... [A]fter my extensive back surgery, where I had two discs removed and nine pieces of titanium placed in me.... my one month post op x-rays looked like what they expected at three months. I thank the NONI juice for major assistance in healing this almost 50 yr. old spine."

“... My wife's bad knee which had been swelling for over a month, was down just two days after her first dose of Noni. ... I suffer from aches and pains as well as other symptoms of MS. The numbness in my feet and in my left pinky finger have [sic] been reduced to a point where I barely notice them after only five shots of this stuff.”

“I have suffered with severe constipation for 18 or more years. I have used every fiber and laxative on the market with little relief. After only 2 ounces of Noni I have been regular. Nothing short of a miracle! I have also suffered with reflux for several years and am glad to report that I have been cured. ...”

“I have suffered from severe indigestion and heartburn for about 8 years. Taking Pepcid all day was really getting old. A co-worker told me about how Noni juice had helped his mother with acid reflux. ... After a few days my heartburn and indigestion were completely gone. ...”

“I have been drinking Noni juice for almost 3 years now. It really helps my joint and muscle pain ...”

“I was hit by a car while riding my motorcycle about 2 years ago. I was pretty banged up and had to go through 6 months of therapy for my lower back pain. I have had to take muscle relaxers for the past year just to be able to sit still without constant pain. My nephew (a real herbalist) brought me a bottle of maximum potency noni juice and insisted that I take it daily. I did and after just 3 weeks I don't have to take pain pills anymore. I haven't even been back to refill my prescription. The cost of the noni juice is a fraction of the price of the pain medicines and it doesn't make me all groggy like the pain pills did. ...”

Examples of some of the claims observed on your “Noni Usage” page include:

“Traditional uses for Noni include:

- ADD/ADHD
- Headaches
- Asthma
- Chronic Fatigue
- Depression
- Cancer Treatment ...
- Healing from Surgery
- Cold & Flu
- Burns
- Back Pain
- Joint Pain
- Arthritis
- Lower Cholesterol
- Lower Blood Pressure
- Tendonitis ...”

Examples of some of the claims observed on your “What does Noni Help?” page include:

“What illnesses can Noni juice help? ... Conditions Reported Helped With Noni

- Allergy Symptoms lessened ...
- Pain Relief
- Headache Relief
- Cancer Symptoms Lessened
- Depression Symptoms Lessened
- Fibromyalgia [sic] Symptoms Lessened ...
- Arthritis Symptoms Lessened ...
- Diabetes (Type I and II) ...

- Decreased High Blood Pressure
- Heart Disease Lessened ...
- Aid to Help Stop Smoking”

Examples of some of the claims observed on your “What are doctors saying?” page include:

“In 1993, a Japanese research team reported in *The Cancer Letters* that Noni was the most effective of 500 tropical plant extracts at preventing the growth of tumors. ... Other studies have shown Noni to have very effective anti-inflammatory, analgesic, antibacterial properties. One study at the University of Hawaii isolated one of the 140 compounds, scopoletin, and showed that it lowered high blood pressure ... reduced inflammation, killed bacteria and fungi and prevented growth of tumors.”

“... 78% of the more than 15,000 noni users reported that it helped in some way, including fighting cancer, heart disease ... diabetes, autoimmune disorders, stroke ...” [quoting Neil Solomon, M.D., Ph.D.]

“New studies show this Hawaiian juice soothes even the worst aches and pains, helps lower high blood pressure ... and early studies indicate it may even have the ability to cure cancer.” [quoting *Alternative Medicine Magazine*]

“Scientific research now shows that constituents in noni fruit have the ability to... inhibit[] tumor growth.[’]” [quoting *Delicious Living Magazine*]

Examples of some of the claims observed on your “What is Noni?” page include:

“It was also determined to be helpful ... as an aid for injured muscles, bones, and tissue. Currently, scientists are studying possibilities in treating hypertension, cancer, high blood pressure ....”

Examples of some of the claims observed on your <http://www.barley-green-premium.com> web site include:

### **BarleyGreen Premium**

“Extracted compounds have found to have hypercholesteromic, anti-inflammatory, and anti-ulcer properties. ... Finally, studies have shown that when *Barley Green* juice is added to injured cells, the cells' DNA repair themselves more rapidly. This may contribute to preventing the changes that often lead to cancer ....”

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The

intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web sites and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web sites, please contact FDA. You may respond in writing to Linda J. Webb, Compliance Officer, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Webb at (301) 436-2375.

Sincerely yours,

/s/

Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
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