DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
College Park, Maryland 20740

September 8 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Sam Chang
Perfect Health, Inc.
4872 Casitas Pass Road
Ventura, California 93001

Ref. No. CL-06-HFS-810-238

Dear Mr. Chang:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses http://www.internetnutritioncenter.com and http://www.juicing.com and has determined that the product "Noni Tahitian Plus™" 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 U.S.C. § 321(g)(1)]. The therapeutic claims on your web sites establish that the 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 at http://www.juicing.com include:

Noni Tahitian Plus™
On the page, Noni Juice FAQ :
"Noni has been used in many traditional healing cultures to alleviate a wide variety of symptoms, including those seen in arthritis … colds and flu … injuries and inflammation."
"Many people use Noni for joint or muscle stiffness and inflammation. Noni can provide relief of acute and chronic pain and headaches."
"Noni contains over 150 different compounds that … have been documented to support the body in regulating … blood pressure, assisting in the defense against specific infections …"
On the page, Noni Juice Research:
"The Hawaiian Kahunas, traditional medicine men, have used this plant and its prized fruit for a wide variety of health problems, including sinus infections, arthritis … colds, flu, headaches, infections … injuries, pain relief …"
"Dr. Isabella Abbott, a Professor at the University of Hawaii said "…use it for diabetes, high blood pressure, cancer …"
"Western research into this remarkable plant and its fruit date back at least to 1950 when the scientific journal PACIFIC SCIENCE noted that the Noni fruit showed antibacterial properties against m.pyrogenes, Ps. aeruginosa, and even the deadly E. coli."
"More specifically, the journal CANCER LETTER [73 (2-3) 1993, 161-166], reported that Keio University and The Institute of Biomedical Sciences in Japan claimed isolation of a new anthraquinone compound from Noni called damnacanthal. It caused normal morphology and cystoskeletal structure in K-ras-NRK pre-cancer cells. In layman terms, Noni may have turned pre-cancer cells into normal healthy cells."
"Important research on the medicinal uses of Noni was presented at the 83rd, 84th and the 85th Annual Meetings of the American Association for Cancer Research. A landmark paper

presented at the 83rd meeting in San Diego, California in 1992 and written up in the Proceeding of the American Association for Cancer Research was 'Anti-Tumor Activity of Morinda citrifolia on Intraperitoneally Implanted Lewis Lung Carcinoma in Mice.' The mice fed Noni fruit lived 105% - 123% longer. Some 40% of these mice lived for 50 days or more! This study was repeated numerous times, and each time Noni fruit was shown to significantly prolong the lives of cancerous mice (versus cancerous mice without Noni fruit). Simply put, Noni fruit may inhibit tumor growth."
"Another study proved Noni's analgesic (anti-pain) properties. In repeated tests by a group of researchers, and documented in Planta Medica [56 (1990) 430-434], various experiments all found Noni (Morinda citrifolia) to be beneficial for pain."

- Noni has unique anti-pain effects.
- Noni inhibits pre-cancer function & has been found to inhibit the growth of cancer tumors.
- Noni has been shown effective for many types of bacteria, including E. coli."

"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 … stroke …*""
"*'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.'*"
"*'Scientific research now shows that constituents in noni fruit have the ability to … inhibit[e] tumor growth.[']*"

In addition, we note that both of your web sites identify several products under the categories "Candida," "Cold," "Diabetes," and "Flu" respectively, including "Rainbow Light Candida Cleanse," "Nature's Herbs Cold-Sentry," "Progressive Research Labs Diabetic Nutrition Rx," and "Rainbow Light No Flush Niacin Cholesterol Balance" products, for example. Such product headings and categories cause the products listed under them to be drugs under section 201(g)(1) of the Act <u>because they imply that the products are useful in the cure, mitigation, treatment or prevention of these diseases</u>.

Your products are not generally recognized as safe and effective for the above referenced conditions and therefore, your products are "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 site 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 site, 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
Center for Food Safety
and Applied Nutrition