Living Naturally 10/15/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-11-05

October 15, 2010

Emily and Dean Roberts
Green Earth Health Food Market
4 Market Street
Oneonta, NY 13820

Dear Mr. and Mrs. Roberts:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your website at the Internet address www.greenearthoneonta.com and has determined that the products "Kyolic Original Formula 100" (200 cap), "Nature's Way Sarsaparilla Root" (100 cap), "Nutrition Now PB 8 Pro-Biotic Acidophilus" (60 cap), and "Nature's Way Alfa-Max" (100 cap) are promoted for conditions that cause the products to be drugs under section 201 (g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website 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 website include:

Kyolic Original Formula 100 (200 cap)

• "Kyolic Formula 100 ... may be beneficial for ... blood pressure, cholesterol levels, heart disease ... arteriosclerosis, arthritis, asthma, cancer ... infections of the eyes, ears, throat, respiratory infections ... flu ... fungal infections, viral infections ...."

Nature's Way Sarsaparilla Root (100 cap)

• "Sarsaparilla [an ingredient in your product] may help in the treatment of congestive heart failure, high blood pressure impotence ... swelling and discomfort from rheumatism and arthritis ... psoriasis ... syphilis ...."

Nutrition Now PB 8 Pro-Biotic Acidophilus (60 cap)

• "Acidophilus [an ingredient in your product] ... has anti-fungal activity ... and play [sic] a role in yeast infections, urinary tract infections, cancer prevention, cholesterol levels ...."

Nature's Way Alfa-Max (100 cap)

• "Alfalfa [an ingredient in your product] ... may be used for allergies, anemia, arthritis, asthma, blood disorders ... high cholesterol and diabetes ...."

Your products are not generally recognized as safe and effective for the above referenced uses and therefore, the 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. Furthermore, because your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use the products safely for their intended uses. Thus, your products "Kyolic Original Formula 100" (200 cap), "Nature's Way Sarsaparilla Root" (100 cap), "Nutrition Now PB 8 Pro-Biotic Acidophilus" (60 cap), and "Nature's Way Alfa-Max" (100 cap) are also misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] in that the labeling for these drugs fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of § 301(a) of the Act, 21 U.S.C. § 331(a).

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your website, we noticed that you were promoting other products for disease treatment and/or prevention. The unlawful disease treatment and prevention claims on your website were too numerous to list in this letter. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We
advise you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your written response should be directed to the U.S. Food and Drug Administration, Attn: Winston R. Alejo, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, FL 32751. If you have any questions regarding any issues in this letter, please contact Mr. Alejo at 407-475-4731.

Sincerely,
/S/
Emma R. Singleton
Director, Florida District

cc:

Mr. David Knaggs, CEO
Living Naturally, LLC
6230 University Parkway
Suite 301
Sarasota FL 34240