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

Food and Drug Administration
College Park, Maryland 20740

NOV 3 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roger Elder
Nature's R X, Inc.
PO Box 445
Paoli, Oklahoma 73074

Ref. No. CL-04-HFS-810-98

Dear Mr. Elder:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.naturesrxhq.com and has determined that the products "Grapefruit Miracle Diet Tabs (tm) 90 Tablets," "CoQ10 Rx Ultra Sorb™ 30 mg 90 Softgels," "Collodial Silver 40 ppm 4 fl oz.," "Prostate Health Rx ™ 60 Caplets," and "Colostrum Rx™ 30% IGG, 1st milking - 6 hour, 500 mg 120 Capsules" 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 USC § 321(g)(1)]. The therapeutic claims on your web site 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 web site include:

Grapefruit Miracle Diet Tabs (tm) 90 Tablets
"[G]lucomannan [an ingredient in the product] forces the body to convert cholesterol, thereby having a cholesterol lowering effect."
"Phenylalanine [an ingredient in the product] has been shown to have potent … antidepressant qualities."

CoQ10 Rx Ultra Sorb™ 30 mg 90 Softgels
"CoQ10 has been shown to promote improvements in:

- Congestive Heart
- Diastolic Dysfunction
- Ischemic Heart
- Hypertension"

Collodial [sic] Silver 40 ppm 4 fl oz.
"A natural anti-infective."

Prostate Health Rx ™ 60 Caplets
"Saw Palmetto extract [an ingredient in the product] is a potent herbal extract commonly taken for BPH."
"[R]esearch finds that Saw Palmetto extract is beneficial in BPH."
"A study of the effects of Pygeum on men having BPH has shown that men taking Pygeum Africanum [an ingredient in the product] were more than twice as likely to report an improvement in overall symptoms over the placebo group."
"Stinging Nettles extract [an ingredient in the product] has been used in Germany, as a treatment for benign prostatic hyperlasia [sic] or BPH for decades."
"Nettle root [an ingredient in the product] inhibits the binding of DHT to the prostate thereby countering prostate enlargement."

Colostrum Rx™ 30% IGG, 1st milking - 6 hour, 500 mg 120 Capsules
"[F]ight against infections and degenerative diseases."
"Colostrum helps us combat disease-causing organisms such as bacteria, viruses, yeasts and parasites…"
"Several factors exist in colostrum that work to supercharge the functioning of our immune and digestive systems. This natural boost helps the body's own defense mechanisms fight against infections and degenerative diseases."

Furthermore, these products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are "new drugs" under section 201(p) of the Act [21 USC § 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 USC 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 of disease 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 (DSHEA), 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 CFR) 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 reach FDA electronically (e-mail) at Linda.Webb@FDA.GOV, or 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/

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition