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

Food and Drug Administration
College Park, Maryland 20740

July 2, 2007

Kenton Campbell
Prime Health Direct, Ltd.
Martyn House
Victoria Street
Alderney, Channel Islands GY9 3TA
United Kingdom

Ref. No. CFSAN-OC-UL07-01

Dear Mr. Campbell:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.primehealthdirect.com and has determined that the products Doctors Ellagic Acid, DHEA, and Longevity Mix 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 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:

Doctors Ellagic Acid

"Help with the fight against cancer!"

"Ellagitannins are an all-natural extract from Meeker red raspberries that could give us some of the benefits of for example: chemo and radiation therapies, with none of the side effects. In fact, studies are indicating that Doctors Ellagic Acid taken every day could prevent some cancers from ever starting in your body." [footnote omitted]

"Working at the renowned Hollings Cancer Institute, Dr Daniel Nixon has been getting extraordinary results with Meeker red raspberries. In both lab and clinical studies, raspberry ellagitannins caused cancer cells to die naturally (apoptosis) without damaging the healthy cells."

"ASK YOUR HEALTH CARE PROFFESIONAL [sic] ABOUT USING ELLAGIC ACID AS AN ADJUNCT TO CONVENTIONAL CANCER THERAPIES"

"Doctors Ellagic Acid improves your life by:
• Providing some resistance to cancer-causing agents."

"One of the most important cancer discoverys [sic] in our lifetime"

DHEA

> "As our DHEA levels reduce with age – the low levels can trigger a host of major problems, including heart disease, breast and other cancers, Alzheimer's - and even early death."

"What are the benefits?

- Helps prevent heart disease and Alzheimer's.
- Guards against breast and other cancers."

Longevity Mix

- "Reduces the risk of Parkinson's and Alzheimer's
- Fights heart disease, stroke and diabetes …
- Fights cancer-causing free radicals"

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.

In addition, we note that your website promotes other products sold on the site to treat or prevent a variety of diseases, including arthritis, asthma, cancer, and diabetes. For example, the website identifies several products under the "Asthma" category, including Aslan Super, Colon Aid, MSM Miracle Capsules, and Aminomax AKG, among others. Product headings and categories that bear the name of a disease cause the products listed under them to be drugs under section 201(g)(1)(B) of the Act because they imply that the products are useful in the cure, mitigation, treatment or prevention of the disease.

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.

FDA is taking steps to warn U.S. citizens that drugs from foreign sources that are promoted and sold via the Internet may not be approved for marketing in this country, and that unapproved new drugs cannot be legally imported. Unapproved new drugs offered for importation into the United States are subject to detention and refusal of admission. With copies of this letter, we are advising the drug regulatory officials in the countries from which you operate that FDA considers your products Doctors Ellagic Acid, DHEA, and Longevity Mix to be unapproved new drugs that cannot be legally marketed to consumers in the U.S.

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 Kristen Moe, HFS 608, 5100 Paint Branch Parkway, College Park, MD 20740. If you have any questions concerning this letter, please contact Kristen Moe at 301-436-2064.

Sincerely,

/s/

Jennifer Thomas
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition