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DEPARTMENT OF **HEALTH** AND **HUMAN SERVICE**

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000 FAX:
303-236-3100

August 2, 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Christopher D. Edwards
American Nutrition, Inc.
735 North Park Street, Unit E
Castle Rock , Colorado 80104

Ref. No. DEN-06-22-UTL

Dear Mr. Edwards:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.americannutrition.com and has determined that the products "American Nutrition® Odorless Garlic," "American Nutrition® Echinacea Extract," and "American Nutrition® L-5•-HTP" 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:

American Nutrition® Odorless Garlic
"Researchers have found odorless garlic to:

- Helps fight viral, fungal and bacterial infections

- Odorless Garlic may help to destroy certain viruses such as fever blisters, genital herpes, and a certain type of influenza"

American Nutrition® Echinacea Extract
"Echinacea was used by Native American Indians for wounds, infections, ..."
"Echinacea has been used ... to help speed wound healing, to reduce inflammations, and to treat colds, flu's [sic], and infections. Many of the active components of echinacea have antibacterial, antiviral, and antifungal properties. Echinacea has also been used externally to ... heal wounds, eczema, burns, psoriasis, herpes, vaginitis, canker sores, abscesses .... Recent research has indicated that echinacea has potent anti-tumor activity[.] Our Standardized Echinacea

Angustifolia Extract is produced by a European phyto-pharmaceutical company .... Like all European herbal extracts, the extraction of our Echinacea Angustifolia Extract is regulated to the same high standard as Over-The-Counter drugs."

American Nutrition® L-5-HTP
"[S]cientists have discovered that L-5-HTP helps with depression, ..."
"Other symptoms that L-5-HTP may help with include: ... migraines, obsessive-compulsive behaviors, ...
Our American Nutrition Brand 5-HTP is manufactured by European Swiss Pharmaceutical company Nuova. In Switzerland where L-5-HTP is a prescription drug."

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 do not comply 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 dieta:ry 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/—l[y]d/fr000106.htm1> (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 Ms. Regina A. Barrell, Compliance Officer at the above address.

Sincerely yours,

B. Belinda Collins Denver District
Director

cc: