DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Denis Deluca
President/Director
Biotics Research Corporation.
6801 Biotics Research Drive
Rosenberg, TX 77471

February 16, 2005

Ref. No. CL-04-HFS-810-118

Dear Mr. Deluca:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.bioticsresearch.com and has determined that the products Folate-5 plus, Lipoic Acid, and L-Arginine are promoted for conditions that cause these 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 web site establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of diseases. The marketing of these products with these claims violates the Act. Examples of some of the claims observed on your web site include:

Folate-5 plus

"Folic acid supplementation has also been shown to improve the effectiveness and/or reduce the toxicity of several pharmaceutical medications, such as fluoxetine (prozac), methotrexate, and other chemotherapy drugs."

Lipoic Acid

"Its antioxidant activities have been used in patients with diabetic neuropathy as well as those with viral hepatitis."

L-Arginine

"The role of arginine in the cardiovascular system is important due to the production of nitric oxide, which has the effect of dilating blood vessels and thereby …lowering blood pressure. [A]rginine has been used in clinical studies in men with erectile dysfunction as well as people with hypertension."

"[A]rginine also plays a role in inhibiting certain key processes that are necessary for the development of atherosclerosis."

These products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes.

Thus, your products are misbranded within the meaning of section 502(f)(1) of the Act in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)]. It is a violation of section 301(a) of the Act [21 USC 331(a)] to introduce or deliver for introduction into interstate commerce any drug that is misbranded.

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 conditions 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 reach FDA electronically (e-mail) at Kenneth.Taylor@CFSAN.FDA.GOV, or you may respond in writing to Kenneth M. P. Taylor, Ph.D., Chemist, 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 Dr. Taylor at (301) 436-1439.

Sincerely,

/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