DEPARTMENT OF HEALTH & HUMAN SERVICES **Food and Drug Administration**

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

July 1, 2005

VIA FEDEX

Andy Smith
NFI Dietary Supplements
4525 Camp Ground Road
Fayetteville, North Carolina 28314

Dear Mr. Smith:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses http://www.blue-emu.com, http://www.getyourfizzon.com, and http://www.nfiproducts.com and has determined that the products "PerformaFlex™" and "EnergyFizz™" 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 sites 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 sites include:

PerformaFlex™

"PerformaFlex™ provides clinically proven ingredients that help reduce pain and inflammation associated with joint problems…."
"[F]ast, soothing, and deep penetrating pain relief formula. Sufferers of minor arthritis pain, back pain, knee pain, neck and shoulder pain, joint stiffness or muscle pain can benefit from this powerful, highly effective pain relief formula."

EnergyFizz™

"Regular consumption of green tea [an ingredient in the product] may reduce the risk of hypertension. The tannins in green tea may have antibacterial properties and can produce anti-diarrhea effects."
"Green tea is thought to confer cardiovascular protection by…decreasing LDL cholesterol and…by blocking platelet aggregation."

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 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.
Page 2 – NFI Dietary Supplements

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.

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 James C. MacLaughlin, Compliance Officer, at the address listed in the letterhead.

If you need additional information or have questions concerning this letter or products distributed through your web site, please contact James MacLaughlin at 404-253-1220.

Sincerely,

/s/

Mary H. Woleske
Director, Atlanta District