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

Food and Drug Administration
College Park, Maryland 20740

1/8/07

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Scott Black
BCM Direct, LP
4604 Caymen Place
Austin, Texas 78749

Ref. No. CL-07-HFS-810-243

Dear Mr. Black:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses http://www.heartguardian.com, http://www.bcmdirect.net, and http://www.cholesterblock.com, and has determined that the product "Cholesterblock" is promoted for conditions that cause the product to be a drug 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 product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web sites include:

Cholesterblock
"Quit worrying about high choles[]terol. Take care of it today."
"Have you been prescribed Lipitor®, Zocor®, or Crestor®? Ask your doctor if you can try Cholesterblock™."
"No side effects like Lipitor®, Zocor®, Crestor® …"

These claims suggest that your product is intended to treat high cholesterol. In addition, your web sites contain numerous testimonials from customers that your product treats high cholesterol.

Your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" 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.

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)).

The Act also allows certain health claims and nutrient content claims on food and dietary supplements, but only if the products comply with the requirements to bear such claims. If a firm has evidence, such as scientific research, that it believes supports a health claim or nutrient content claim, there are mechanisms available for presenting that evidence to FDA for evaluation of the claim. More information about claims allowed on conventional foods and about the mechanisms available for presenting support for a claim to FDA can be found on the Center for Safety and Applied Nutrition's website at www.cfsan.fda.gov/~dms/lab-hlth.html.

FDA has issued a regulation authorizing a health claim in the labeling of dietary supplements in soft gel form for the relationship between consumption of plant sterol/stanol esters and coronary heart disease (Title 21, *Code of Federal Regulations*, section 101.83(c)(2)(iii)(A)(2)). However, the claims cited in the FDA Warning Letters do not meet the requirements identified in that regulation or any letters we have issued regarding an exercise of enforcement discretion with respect to limited deviations from that regulation.

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. If you have evidence that you believe supports approval of your product as a new drug, information on the drug approval application process is available at http://www.fda.gov/cder/regulatory/applications/default.htm

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 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/

Vasilios H. Francos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
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and Dietary Supplements
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