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

Food and Drug Administration
College Park, Maryland 20740

JUL 7 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ronald Picardi
Health First Distributors
P O Box 629
Nanuet, New York 10954

Ref. No. CL-03-HFS-810-71

Dear Mr. Picardi :

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.myhealthfirst.com and has determined that the product "Eurocel" being offered 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 USC 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The continued marketing of this product with these claims violates the Act and may subject you or the product to regulatory action without further notice.

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

"Eurocel is the exact product that was used in a pilot study with HIV patients."

"The participating patients were diagnosed with antibodies to the Hepatitis C virus and had chronic illness for 3 to 20 years before using Eurocel. One capsule twice per day demonstrated a reduction in Hepatitis C Virus RNA in ALL 10 patients. The reduction was noted after the first month of treatment. The study lasted from 6-24 months demonstrating Hepatitis C Viral RNA to decrease by 1 million fold."

Furthermore, FDA has no information that your product is generally recognized as safe and effective for the above referenced conditions and therefore, the product may also be a "new drug" under section 201(p) of the Act [21 USC 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 USC 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 or as cosmetics if therapeutic claims 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 (DSHEA), 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 into 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 CFR) 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 may market. It is your responsibility to ensure that all products marketed by your firm are in compliance 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 APope@CFSAN.FDA.GOV, or you may respond in writing to Angela F. Pope, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement,
5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning any issue in this letter, please contact Ms. Pope at (301) 436-2375.

Sincerely yours,

/s/

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition