DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

January 12, 2006

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Nathan Howlett
Healthy Warehouse
2011 Tammy Drive
Springfield, Tennessee 37146

Ref. No. CL-05-HFS-810-166

Dear Mr. Howlett:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.healthywarehouse.com and has determined that the products "AIM Herbal Fiberblend," and "Natures Sunshine Berry Healthy" 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 *United States Code* (USC), Section 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:

Natures Sunshine Berry Healthy

"Components of the berries function … with anti-inflammatory, antiviral, [and] antimicrobial … activity."

AIM Herbal Fiberblend

"Fiber studies show lowered cholesterol and reduced incidences of diverticulosis, colon cancer, and appendicitis."

"A variety of epidemiological (disease and population) studies have found that in populations with high-fiber diets, the incidences of colon cancer, appendicitis, and diverticulosis are very low. Industrialized countries, which largely have diets high in fat and low in fiber, have high incidences of these diseases."
In addition, the Internet labeling for AIM Herbal Fiberblend, represents that the benefits of ingesting fiber include cleansing the body of toxins and then makes the following claims:

"More specifically, a body overloaded with toxins can result in a number of symptoms. These include constipation … headaches … depression …."

"Some health practitioners relate toxins to specific diseases. R.A. Buist, M.D., (*International Clinical Nutrition*; 1988; 8:4) states that chronic fatigue syndrome may be related to toxin exposure. Multiple chemical sensitivity and fibromyalgia (muscle and joint pain) may also be environment-related diseases."

"Our body does not, however, always know how to handle the new toxins in our lives. It cannot understand how to excrete them, and they may accumulate to harmful quantities or be converted to odd, unknown substances that can interfere with metabolism. According to the textbook *Nutrition, Concepts and Controversies*, this can result in cancers or birth defects."

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.

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 Kari L. Batey, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217. If you have any questions concerning this letter, please contact Ms. Batey at (615) 781-5380, extension 112.

Sincerely yours,

/s/

H. Tyler Thornburg
District Director
New Orleans District