



September 22, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph A. Buenconsejo, President
Herbcare Corporation of America
FullLife Natural Options, Inc.
6200 Northwest Second Avenue, Suite 311
Boca Raton, Florida 33487

Ref. No. CL-05-HFS-810-187

Dear Mr. Buenconsejo:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.charanteausa.com> and has determined that the products "Charantea Ampalaya Tea," and "Charantea 500mg Capsules" 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 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:

Charantea 500mg Capsules and Charantea Ampalaya Tea

"Charantea is ... used by Asian diabetics for its hypoglycemic benefits."

"Charantea is a dietary supplement made from 100% dried, unripe fruits of the Ampalaya ..., a vegetable that has been scientifically validated to lower blood sugar levels in animal and human subjects.

Under testimonials:

"Charantea helps me lower my blood sugar level naturally. In fact, I have to lower my insulin intake by 20% when I started drinking the tea; otherwise, I would have very low blood sugar level. My HBR1C value, also improved by one percent."

"Austrian climber, in a mission to be first diabetic to climb world's highest mountains, drinks Charantea to maintain his blood sugar level under extreme condition ..."

"A national medical organization in Asia officially endorses an Ampalaya product after recognizing its benefits to diabetics ..."

"Nationwide diabetes control and prevention program recommends Ampalaya dietary supplement for diabetics ..."

"Charantia helps me control my diabetes very well and I've taken it more than one year already. I take Charantia very often and when I do my test on glucose in my blood it has achieved an all time low...."

Under the Ampalaya:

"In the Philippines, herbalists and the traditional healers called herbolarios have long used the Ampalaya as a natural remedy for any number of diseases including anemia, hypertension and viral disorders, but most particularly for diabetes."

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.

Also, please be aware that items represented as conventional foods, including beverages, may not be lawfully marketed as dietary supplements.

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 Compliance Officer Shari H. Shambaugh, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have any questions concerning this letter, please contact Ms. Shambaugh at 407-475-4730.

Sincerely yours,

/s/

Jimmy E. Walthall
Director, Compliance Branch
Florida District