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

Food and Drug Administration

July 6, 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kevin Vokes
223 Sorrel Trail
Keller, Texas 76248

Dear Mr. Vokes:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.acai-berry.com and has determined that your products "MonaVie Original," "MonaVie Active," "MonaVie Combo," and "MonaVie Gel" 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 the claims observed on your web site include:

MonaVie Original, Active, Combo and Gel

"Imagine a juice product that combines a variety of the most powerful fruits … with additional compounds that aid in the fight against inflammation, and you'll find MonaVie …."

"Acai Berries [an ingredient in the MonaVie products] are high in essential fatty acids and omegas – 60% Oleic omega 9 – a monounsaturated essential fatty acid which helps to lower LDL (harmful cholesterol) while maintaining HDL (beneficial cholesterol). 12% Linoleic (omega 6) – a polyunsaturated essential fatty acid which has also been found to lower LDL while maintaining HDL."

"Acai also contains many valuable Phytosterols. Sterols are compounds of plant cell membranes providing numerous benefits to the Human body, namely the reduction of blood plasma cholesterol."

MonaVie Active

"MonaVie Active is MonaVie Original with two additional ingredients meant specifically to help relieve joint/muscle pain and inflammation …."

Furthermore, your MonaVie products are not generally recognized as safe and effective for the above referenced conditions and therefore, they 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.

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 Kristen Moe, Compliance Officer, 5100 Paint Branch Parkway, College Park, MD 20740. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

/s/

Jennifer A. Thomas
Acting Director
Division of Enforcement
Center for Food Safety
And Applied Nutrition

cc:
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Suite 110
Salt Lake City, UT 84095