DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612·2506
Telephone (949) 608-2900

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 21, 2007

Michael Ellison, President
TriVita, Inc.
16100 North Greenway Hayden Loop, Suite 950
Scottsdale, Arizona 85260

Dear Mr. Ellison:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.trivita.com and has determined that the products "Non-Acidic Vitamin C Crystals," "GlucoBalance Formula" and "Odorless Garlic" 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:

Non-Acidic Vitamin C Crystals

"

- Provides nutrition your body needs to lower blood pressure and cholesterol

…

- Nutritionally support your body's ability to prevent heart disease and cancer"

[under the heading "Product Details"] "This non-acidic formula … brings you better absorption and longer lasting Vitamin C power to:

…

- Nutritionally support your body to help fight colds and flu
- Nourish your ability to fight bacterial infections and viral invaders"

GlucoBalance Formula

"Nutritionally supports your body's ability to:

- Reduce sugar fluctuations
- Combat sugar-related disease …"

[under the heading "Product Details"] "Today, millions of people show early risk factors of diabetes--the medical community refers to these people as pre-diabetic.

Symptoms of Diabetes and PreDiabetes include:

- Frequent urination
- Unusual thirst
- Extreme hunger
- Unusual weight loss
- Extreme fatigue
- Irritability
- Frequent infections
- Blurred vision
- Cuts/bruises that are slow to heal
- Tingling or numbness in hands or feet"

Odorless Garlic

[under the heading "Product Details"] "The most commonly claimed benefit is reduced cholesterol, although garlic is also said to reduce blood pressure … and reduce the risk of certain cancers."

In addition, we note that your web site identifies several products under the category "Diabetes, Blood Sugar & Nerves" including "GlucoBalance Formula," "Green Food Complex – Capsules," and "CoEnzymeQ-10" products, for example. Such product headings and categories cause the products listed under them to be drugs under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)] because they imply that the products are useful in the cure, mitigation, treatment or prevention of these diseases.

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 U.S. Food & Drug Administration, 19701 Fairchild, Irvine, CA 92612. If you have any questions concerning this letter, please contact MaryLynn Datoc, Compliance Officer, at (949) 608-4428.

Sincerely,

/s/

Alonza E. Cruse
District Director