



JULY 19, 2005

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Donald Lapre  
President/CEO  
Torica Productions, Inc.  
14809 S 25<sup>TH</sup> Way.  
Phoenix, AZ 85048

Ref. No. CL-05-HFS-810-169

Dear Mr. Lapre:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the following Internet addresses <http://www.greatestvitaminintheworld.com> and <http://www.thegreatestvitaminintheworld.com> and has determined that the product The Greatest Vitamin in the World is promoted for conditions that cause this product to be a drug 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 this product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of the product with these claims violates the Act. Examples of some of the claims observed on your web sites include:

**Blood Sugar Diabetes**

"If you have diabetes, please monitor your glucose requirements closely to see what reduction you have after taking these vitamins. The results may shock you. There are many other ingredients included in this vitamin supplement that are known to assist the body in areas which help assist in blood glucose levels."

"If you or someone you know has diabetes or at risk of getting diabetes, spread the word and make sure they understand the critical importance of protecting their body from this deadly disease. [N]utritionally support the body with the best absorbed form of nutrients available with The Greatest Vitamin in The World."

**Stroke**

"The Greatest Vitamin in the World only contains these nutrients in the forms proven to effectively reduce the risk for heart disease and lower cholesterol levels. Additionally, the nutrients contained in this formula are the most bioavailable forms on the market, ...ensuring that your risk for heart disease and your cholesterol levels are lowered."

### **Heart Disease Cholesterol**

"The Greatest Vitamin in the World only contains these nutrients in the forms proven to effectively reduce the risk for heart disease and lower cholesterol levels. Additionally, the nutrients contained in this formula are the most bioavailable forms on the market, ... therefore lowering your risk for heart disease and high cholesterol."

### **Sleep**

"Habitual sleeplessness is classified as insomnia. A sleep disorder known as sleep apnea affects about 20 million more Americans.... When sleep deprivation robs the body of nutrients, serious deterioration in performance and the onset of disease ensues.... Supplementation of Magnesium, Zinc, and vitamin B[, ingredients in the product,] nutritionally help the body to have deeper and more restful sleep. In addition, garlic[, an ingredient in the product,] has been shown to improve serotonin levels, which are involved in the regulation of sleep."

### **Probiotics**

"[Probiotics, an ingredient in the product,] promote health by secreting ... antibiotic-like substances.... These substances... have a wide range of activity against bad bacterial strains of salmonella, pseudomonas, E. Coli, and other food-borne bacteria."

"As friendly bacteria in the bowel are depleted, the body is subject to numerous diseases, including colitis, diabetes, meningitis, rheumatoid arthritis, thyroid disease and even bowel cancer. A deficiency in friendly bacteria can bring on a host of additional problems associated with bowel toxicity.... What is the answer then, if our lifestyles and environmental factors are taking away from our supply of friendly bacteria? The Greatest Vitamin in the World provides a constant supply."

### **Depression**

"Certain nutrients can also greatly benefit those suffering from depression, such as B vitamins [, an ingredient in the product,] which are the most potent anti-stress vitamin and necessary for the normal functioning of the brain and nervous system. Folic acid[, an ingredient in the product,] is particularly found to be deficient in those suffering from depression. Vitamin C [, an ingredient in the product,] ... also aids in preventing depression. Garlic [, an ingredient in the product,] ... maintains balance in the brain, preventing depression."

"The vitamins and minerals contained in The Greatest Vitamin in the World are the highest quality nutrients found on the market....When taken along with a healthy diet, the symptoms and triggers of depression will be dramatically reduced."

## **Cancer**

“Cancer is a terrible disease that many of us are at risk for. The Greatest Vitamin in the World works to help lower that risk by providing you with 100% of the daily needs of all essential nutrients along with some of the most researched cancer prevention nutrients known.”

## **Kidney/Liver**

“When toxins build up in the system, the liver and kidneys are unable to function optimally and the body begins to store toxins in the tissues. As the toxins build up, common symptoms occur, such as...insomnia, depression, ...allergies, ...and over time may even lead to chronic illnesses like cancer, arthritis and Alzheimer’s disease. The Greatest Vitamin in the World contains several different valuable nutrients, such as milk thistle, which aids in removing toxins from the body.”

## **Men’s Health**

“It is well established that men have a greater problem with degeneration of discs and joints due to heavy use. Please be sure to read our section on arthritis/joint pain to see how the Greatest Vitamin in the World will help you deal with this prevalent issue.”

## **Arthritis Joint Pain**

“Glucosamine[, an ingredient in the product,] works to stimulate joint ...repair. It is most effective in treating osteoarthritis, the most prevalent form of arthritis....

"Both short and long term studies have been performed with a nutrient called Glucosamine Sulfate. Glucosamine works to stimulate joint ... repair. It is most effective in treating osteoarthritis, the most prevalent form of arthritis. A number of studies over the last 20 years have shown this to be true. For example, a 1982 clinical study compared usage of the NSAID ibuprofen with glucosamine sulfate, for osteoarthritis of the knee. The overall results showed that 44% of the glucosamine group had pain relief compared to 15% for ibuprofen.

A long-term effects study was done with glucosamine and arthritis reported in the Lancet. The authors concluded that, 'Glucosamine sulfate prevents the progression of osteoarthritis of the knee, in addition to relieving the symptoms.'

Studies have also been done on discs with Chelated magnesium and new research has shown promising benefits with essential fatty acids.

The Greatest Vitamin in the World not only contains all of these nutrients, it utilizes the exact forms that were shown in the studies to be effective."

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a “new drug” 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 new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are 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 reach FDA electronically (e-mail) at [Kenneth.Taylor@CFSAN.FDA.GOV](mailto:Kenneth.Taylor@CFSAN.FDA.GOV), or you may respond in writing to Kenneth M. P. Taylor, Ph.D., Chemist, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

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If you have any questions concerning this letter, please contact Dr. Taylor at (301) 436-1439.

Sincerely,

/s/

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