DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 27 2001

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William E. Wheeler, Ph.D., RD
Director of Science and Technology
Vita Cube Systems, Inc.
480 South Holly Street, Suite 5
Denver, Colorado 80246

Dear Dr. Wheeler:

This is in response to your letter of December 5, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Vita Cube Systems, Inc. is making the following claims, among others, for the following products:

Visual Eyes - Vision Health

"...help stop the progression of macular degeneration"
"...help stop the progression of Macular Degeneration, the leading cause of blindness..."
"...treat a wide array of eye disorders such as cataracts and retinopathy"

Pure Heat - Soft Tissue Support

"...sport injuries and chronic joint pain..."
"...alleviate pain and enhance healing"
"...contains natural COX-2 inhibitor like actions, which may have pain-relieving characteristics"
"...why millions of individuals suffer from joint pain and arthritis"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0168

LET 563

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

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V3S
VITACUBE · SYSTEMS™
Life To The Third Power™

RECEIVED
DEC 1 0 2001
BY:

December 5, 2001

Via Overnight Delivery
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

RE: Notification Of Statements Concerning Dietary Supplements

Dear Sir or Madam:

Vita Cube Systems, Inc., 480 South Holly Street, Denver, CO 80246 ("V3S"), a packager and distributor of dietary supplements, hereby notifies the FDA that it has made certain structure/function statements concerning its products, some which were first marketed pursuant to the statements in the last 30 days and others of which will be marketed pursuant to the statements in the near future.

V3S is a start-up company which has just begun to market many of its dietary supplement products using a novel "Cube" system (Patent Pending). The enclosed materials describe the Cubes, which contain a number of complementary supplements. The supplements contained in the Cubes are V3S' primary line of supplements. Other supplement products are stand alone products, sold separately in bottles placed in boxes. These supplements are V3S' specialty products. V3S also sells a protein shake product, and an electrolyte drink powder.

I have enclosed copies of labels for the Cubes marketed by V3S. The structure/function claims for the primary supplements are contained in the very brief descriptions included on the labels. (At some point these primary supplements will also be marketed in bottles and boxes; I will send along the labeling claims as soon as they are prepared.) I also enclose verbatim copies of the language on the bottles and boxes in the specialty line and copies of the labels for the protein shakes and electrolyte powder. The labels on the specialty line boxes and bottles are currently under study and review and may be revised. (The revisions will be forwarded when made.) Further, a V3S Product Guide, which may be given to consumers at the time they receive their Cubes or specialty products and also contains structure/function claims, is enclosed. Lastly, I include Cube and supplement descriptions on our website which recently went online and allows consumers to purchase products from the company through the use of email.

This notice is hereby certified as accurate and complete. Vita Cube Systems, Inc. has substantiation that all statements made in the attached pages are truthful and not misleading.

Please call me at 303-316-8577 if you have questions or comments.

Sincerely,

Dr. William E. Wheeler, PhD, RD
Director of Science and Technology
Vita Cube Systems, Inc.

Encl.

JOINT HEALTH CARE VITACUBE

30-day supply

GOAL SPECIFIC

Improper care of cartilage, tendons, and ligaments are the major reason why millions of individuals suffer from joint pain and arthritis. When the body is provided with the proper nutrients to strengthen and rebuild these elements, individuals may be able to continue with their active schedule. The Joint Health Care VitaCube is designed to focus on the special needs that are associated with high activity.

The Joint Health Care VitaCube contains 7 dietary supplements.

Providing the proper nutrients for any part of the body starts with a solid foundation, therefore, M32+, a multivitamin, begins the Joint Health Care VitaCube. Essential for strong bones and muscles, Cal/Mag+ is added to support development in those areas. For repair and recovery at a cellular level, GC Elite supports cellular metabolism, and fat utilization. Directly assisting in cartilage, ligament and tendon health is our unique formulation, JSH containing Glucosamine, Chondroitin, and MSM. Ultra EFA+E is added to support the body's ability to build lean muscle mass. AlphaNac and CP Complex serve as antioxidants to help the body to release and neutralize free radicals.

The Joint Health Care VitaCube contains the perfect elements needed to support proper joint health care.

V3S 42

These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent disease.

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Supplen

Serving Size 11 tablets 4 capsules 3 soft g
Servings Per Container 30

Vitamin A (as retinyl acetate and 50% as	
Vitamin C (as ascorbic acid, calcium ascor	
ascorbate, magnesium ascorbate, C-P Cor	
Vitamin D (as cholecalciferol)	
Vitamin E (as d-alpha tocopheryl acetate,	
Thiamin (as mononitrate)	
Riboflavin	
Niacin (as niacinamide)	
Vitamin B6 (as pyridoxine hydrochloride)	
Folate (as folic acid)	
Vitamin B12 (as cyanocobalamin)	
Biotin	
Pantothenic Acid (as d-calcium pantothen	
Calcium (as carbonate, citrate, gluconate, ascorbate, succinate, aspartate, Cal/Mag+	
Vitamin K	
Iodine (as kelp)	
Magnesium (as oxide, amino acid chelate	
Zinc (as oxide, amino acid chelate)	
Selenium (as selenomethionine)	
Copper (as amino acid chelate, gluconate	
Manganese (as amino acid chelate)	
Chromium (as polynicotinate, picolinate, s	
Molybdenum (as amino acid chelate)	
Potassium (as chloride, gluconate, amino	
GC Elite	
L-Glutamine (2,000 mg), L-Carnitine L	
JSH	
Glucosamine HCl (1,500 mg), Chondr	
Methyl Sulfonylmethane (750 mg), Ca serrata Gum Extract (85%), Turmeric R	
Ultra EFA+E	
Flaxseed Oil, Marine Lipid Concentrate	
Sunflower Oil, Sesame Seed Oil, d-Al	
Tocopherols (1,350 mg Omega-3, 525	
60 mg Medium Chain Triglycerides)	
AlphaNAC	
N-Acetyl-L-Cysteine (1,000 mg), Alpha	
L-Cysteine, Conjugated Linoleic Acid	
VitaCube Activating System	
Orange Bioflavonoid Complex, Grapef	
Bioflavonoid Complex, Alfalfa Leaf, Gi	
Leaf, Spirulina Algae, Cayenne, Apple	
Odorless Garlic, 7-Isopropoxy Flavoni	
L-Glutathione, Lemon Bioflavonoid Co	
Lycopene 1%, Dimethylglycine, Potas	
Glycerophosphate, Rutin, Bromelain,	
Inositol	
Para Aminobenzoic Acid	
Vanadium (as sulfate)	
Boron (as citrate;Cal/Mag+)	

*Daily Value not established.
**

SPECIALTY LINE

Bottle Statements:

1. Gingko Clear – Mental Clarity

   - Ginkgo Clear was developed to aid in mental clarity and acuity which can increase one's ability to focus on competition, training and specific tasks
   - Ginkgo Biloba has been used in Chinese medicine for over 5000 years and is believed to improve the flow of blood and oxygen to the brain, increasing alertness and mental responsiveness while maintaining healthy blood vessel tone.

   FDA Disclaimer

2. Visual Eyes- Vision Health

   - Visual Eyes is a total vision health formulation for all ages
   - Visual Eyes provides 6 mg per day of Lutein which is reported to help stop the progression of Macular Degeneration
   - Visual Eyes is enhanced by a balanced formulation of vitamins and minerals that support better eye health

   FDA Disclaimer

3. Muscle MR3 – Repair, Recover, Restore

   - MR3's compounds have been known to help the body's ability to recover and repair soft tissue more quickly
   - MR3's proprietary blend helps support the body's ability to restore the natural balance of nutrients in the muscles
   - MR3 helps to neutralize the lactic acid build-up in the muscle

   FDA Disclaimer

4. Enduro Max – Stamina and Endurance

   - Enduro Max contains a proprietary combination of six hot and cold Ginsengs that improve stamina and enhance endurance
   - Enduro Max is natural and safe to use as it does not affect the central nervous system, and has no dangerous stimulants as Ephedrine)Ma Huang).
   - Natural cell energizers, Thiamin, and Riboflavin are added in significant quantities

SPECIALTY LINE

Box Statements

1. Ginkgo Clear – Mental Clarity

Regain your edge by sharpening your mind's ability to focus.
For over 5000 years, Chinese medicine has used Ginkgo biloba for brain and respiratory track health. Improving the flow of blood and oxygen to the brain is how the herb is thought to be a success for mental clarity and acuity. V3S further balanced the formula with essential vitamins and minerals to aid in neurological function which can increase one's ability to focus on competition, training and specific tasks. These additions include Vitamin A, Vitamin E, Thiamine, Riboflavin, Niacin, Pantothenic Acid, Calcium, Zinc, Selenium, and Chromium.

FDA DISCLAIMER ALSO ON BOX

2. Visual Eyes-Vision Health

Our eyes are the windows to the world and the mirrors of our souls. Too often, we take vision for granted, and assume that visual deterioration with age is unavoidable. Perhaps we can improve those odds by taking a carotinoid called Lutein. As little as 6 mg a day, Lutein has been shown in significant research to stop the progression of Macular Degeneration, the leading cause of blindness, for those over the age of 45. The unique formulation of Visual Eyes includes a complete balance of vitamins and minerals, plus an herb called Eyebright which is used in Chinese medicine to maintain healthy vision and treat a wide array of eye disorders such as cataracts and retinopathy.

FDA DISCLAIMER ALSO ON BOX

2. Muscle MR 3 – Repair, Recover, Restore

Workout pain has a gratifying feeling unlike other types of pain. But nevertheless it is still pain. We exercise hard, and our reward is all-to-often sore muscles aching for relief. Muscle MR3 goes straight to the point of pain and helps to recover, restore and repair the soft tissue and muscle soreness caused by exercise and daily activities. In order to neutralize the lactic acid build-up in the muscle, and help the body's ability to restore and repair soft tissue more quickly, V3S has developed a proprietary combination of Calcium Citrate Malate, Vitamin C, Pueraria Root and other natural ingredients such as Bromelain. This powerful blend will help the body restore the natural balance of nutrients in the muscle which in turn, helps to reduce soreness. Get back in high gear.

FDA DISCLAIMER ALSO ON BOX

adults and children. Made of a fruit and vegetable base, (no sugar or aspartame), these wafers also include Chromium which help the body use insulin, a hormone that transfers blood sugar (glucose) to the cells, where it is burned as fuel. With enough Chromium, the body uses insulin efficiently and is able to maintain normal blood sugar levels.

FDA DISCLAIMER ALSO ON BOX

8. Balanced Mood – Mood Support

Achieve balance naturally. Balanced Mood is formulated with a standardized extract of St. John's wort, a gentle alternative to conventional medications that has been shown to naturally relieve symptoms of mental and physical fatigue related to stress or over training. This proprietary blend is rounded out with L-Tyrosine, an amino acid directly involved in brain function that may reduce the effects of stress and enhance cognitive performance. This formulation was designed to help support the formation of neurotransmitters in the brain that naturally elevate mood.

FDA DISCLAIMER ALSO ON BOX

9. Pure Heat – Soft Tissue Support

Healing, HEAT! It is not uncommon for sport injuries and chronic joint pain to occur in individuals who train hard and lead a highly active lifestyle. Boswellic Acid, Cayenne and Turmeric are used in this high-performance, natural formulation of Pure Heat. These key ingredients may help to increase blood flow to the area of need and encourage the body's natural ability to alleviate pain and enhance healing. Pure Heat is the result of extensive research at V3S to provide natural COX-2 inhibitor actions, which have been

FDA DISCLAIMER ALSO ON BOX