



MAR 30 2000 3 28 5 '00 APR 25 P 2:39

Ms. Maggie Li  
Vice President  
Tianshi Health Products, Inc.  
728-134th Street, SW  
Suite 222  
Everett, Washington 98204

Dear Ms. Li:

This is in response to your letter of March 10, 2000 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 Tianshi Health Products, Inc. is making the following claims, among others, for the product **Tianshi Energy Balanced Cardio System**:

“...maintaining healthy cholesterol levels...”  
“...helps maintain healthy cholesterol levels...”

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 this product suggests that it is intended to treat, prevent, cure or mitigate disease, namely hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

Please contact us if we may be of further assistance.

Sincerely,

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

975-0163

LET350

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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, Seattle District Office, Office of Compliance, HFR-PA340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

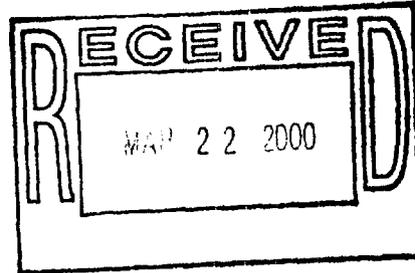
GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-811:rjm:2/28/00:docname:69860.adv:disc45



TIANSHI  
HEALTH PRODUCTS INC.

69810c



March 10, 2000

Dr. Elizabeth Yetley  
Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, D.C. 20204

RE: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as notification of the nutritional support label statements being made by Tianshi Health Products, Inc., located at 728 - 134<sup>th</sup> Street SW, Suite #222, Everett, WA 98204, in connection with the marketing of its line of dietary supplements. A list of the products and their respective nutritional support statements are listed in the attached Exhibit "A".

Tianshi Health Products, Inc. certifies that the information contained in this notice is complete and accurate, and that the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel free to contact the undersigned.

Sincerely,

Maggie Li  
Vice President  
Tianshi Health Products, Inc.

### 3. Product: Tienshi Energy Balanced Immune System

#### A dietary supplement containing:

Vitamin A (as vitamin A acetate And 50% as beta carotene)	Zinc (as zinc amino acid acetate)
Vitamin C (as ascorbic acid)	Selenium (as selenium amino acid chelate)
Vitamin E (dl-alpha Tocopheryl acetate)	Copper (as copper citrate)
Thiamin (as thiamin mononitrate)	Manganese (as manganese citrate)
Riboflavin	Chromium (as chromium polynicotinate)
Niacin (as niacinamide)	Molybdenum (as molybdenum citrate)
Vitamin B6 (as pyridoxine hydrochloride)	Cordyceps Fungus Fruiting Body (cyanocobalamin)
Folic Acid	Boron (as boron citrate)
Vitamin B12	Vanadium (as vanadium citrate)
Biotin	
Pantothenic Acid (as calcium pantothenate)	
Magnesium (as magnesium oxide)	

#### Statements of Nutritional Support:

- Providing maximum herbal support for the healthy functioning of the immune system.
- It assists you in gaining a healthy functioning immune system, enhancing the efficiency of your lungs and giving you more energy.
- It assists in maintaining a healthy immune system and in boosting stamina.

### 4. Product: Tienshi Energy Balanced Cardio System

#### A dietary supplement containing:

Vitamin A (as vitamin A acetate and 50% as beta carotene)	Zinc (as zinc amino acid chelate)
Vitamin C (as ascorbic acid)	Selenium (as selenium amino acid chelate)
Vitamin E (as dl-alpha tocopheryl acetate)	Copper (as copper citrate)
Thiamin (as thiamin mononitrate)	Manganese (as manganese citrate)
Riboflavin	Chromium (as chromium polynicotinate)
Niacin (as niacinamide)	Molybdenum (as molybdenum citrate)
Vitamin B6 (as pyridoxine hydrochloride)	Proprietary Blend
Folic Acid	Carrot Rowder
Vitamin B12 (as cyanocobalamin)	Gynostemma Stem
Biotin	Green Tea Polyphenols
Pantothenic Acid (as calcium pantothenate)	Boron (as boron citrate)
Calcium (as calcium carbonate)	Vanadium (as vanadium citrate)
Magnesium (as magnesium oxide)	

**Statements of Nutritional Support:**

- Providing maximum herbal support for the healthy functioning of the heart and circulation system.
- Providing maximum herbal support for the healthy functioning of the heart and circulation system.
- Tienshi Energy Balanced Cardio System assists the body in maintaining healthy cholesterol levels and promoting the healthy functioning of your heart and immune systems.
- Tienshi Energy Balanced Cardio System especially benefits and maintains your circulatory system, keeping it healthy. From yard work to sports, this supplement allows your body to process oxygen more efficiently.
- Provides maximum herbal support for a healthy heart and circulatory system.
- It also helps maintain healthy cholesterol levels and assists in restful sleep.

**5. Product: Tienshi Energy Balanced Healthy Skin and Anti-Oxidant**

**A dietary supplement containing:**

Vitamin C  
Vitamin E (as d-alpha tocopheryl acetate)  
Calcium (from calcium carbonate and seabuckthorn seed oil)  
Seabuckthorn Seed Oil (hippophae rhamnoides)

**Statements of Nutritional Support:**

- Purifies and helps maintain youthful, healthy and vibrant skin and energy.
- Seabuckthorn Seed Oil has the ability to eliminate free radicals and to support the body's natural immune defense mechanisms.
- The naturally existing calcium in this oil actively maintains healthy bones.
- This Seabuckthorn Seed Oil Tonic is ideal for improving over all body condition.
- Enhancing your complexion and hair by supporting the proper functioning of your digestive system.
- It provides nutritional support internally and externally producing healthy, vibrant, youthful tissue, inside and out.

**6. Product: Tienshi Energy Balanced Internal Cleanser**

**A dietary supplement containing:**

Chinese Goldthread Root  
Baikal Skullcap Root  
Chinese Rhubarb Root  
Bitter Orange Fruit  
Figwort Root