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APR 16 2004

Ms. Lisa Ni  
V.P. Product Development  
Tianshi Health Products, Inc.  
917 134<sup>th</sup> Street SW  
Suite A-8  
Everett, Washington 98204

Dear Ms. Ni:

This is in response to your letter of March 14, 2004 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 letter states that the product **Tiens Quick Cal II** will use the claim "Formulated to help maintain a healthy blood sugar level...."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood sugar levels; that is, a claim that does not establish that the claims are about blood sugar levels that are already within normal limits implies that the product is intended to treat elevated blood sugar levels (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood sugar but does not also include a statement about it being intended to affect blood sugar that is already in the normal ranges, it is an implied disease claim.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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

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nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SIL', with a long horizontal stroke extending to the right.

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

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

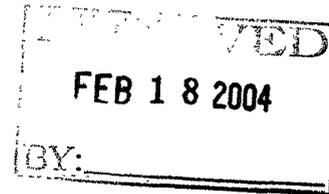
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

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



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March 14, 2004

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 a notification of the nutritional support label statements being made by Tianshi Health Products, Inc., located at 917 – 134<sup>th</sup> Street SW, Suite #A7-8, 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,

Lisa Ni  
V.P. Product Development  
Tianshi Health Products, Inc.

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## Exhibit "A"

### Product A : Tiens Quick Cal I

#### A dietary supplement containing:

Vitamin A (as palmitate)
Vitamin C (as ascorbic acid)
Vitamin D3 (as cholecalciferol)
Calcium (from milk calcium concentrate)
Phosphorus (from milk calcium concentrate)
Magnesium (from milk calcium concentrate)
Sodium (from sodium bicarbonate)
Beet root

#### Statements of Nutritional Support:

1. Calcium plays an important role in the development and maintenance of strong bones and healthy teeth.
2. Natural and Highly Bio-Available Calcium: Natural calcium extracted from milk, preserves the naturally occurring 2:1 calcium and phosphorus ratio, resulting in highly bio-available natural calcium.
3. Effervescence Provides Quicker Absorption: A new scientifically proven technology enables quick, complete, and uniform absorption, allowing nutrients to transfer into the blood stream much more efficiently than tablets.

### Product B : Tiens Quick Cal II

#### A dietary supplement containing:

Vitamin A (as palmitate)
Vitamin C (as ascorbic acid)
Vitamin D3 (as cholecalciferol)
Thiamine (as mononitrate)
Riboflavin
Calcium (from milk calcium concentrate)
Phosphorus (from milk calcium concentrate)
Magnesium (from milk calcium concentrate)
Sodium (from sodium bicarbonate)

**Pumpkin Seed (4:1 extract)**

**Statements of Nutritional Support:**

1. Formulated to help maintain a healthy blood sugar level while providing maximum support for a healthy skeletal system.
2. . Natural and Highly Bio-Available Calcium: Natural calcium extracted from milk, preserves the naturally occurring 2:1 calcium and phosphorus ratio, resulting in highly bio-available natural calcium.
3. Effervescence Provides Quicker Absorption: A new scientifically proven technology enables quick, complete, and uniform absorption, allowing nutrients to transfer into the blood stream much more efficiently than tablets.
4. Additional Health Benefits: Tiens Quick Cal II is formulated to help maintain a normal blood sugar level.\* Vitamin fortified to aid the body in overall health. This product is especially beneficial for the elderly because it is easy on the stomach and will not lead to constipation, a symptom, which can occur when consuming calcium supplements

**Product C : Tiens Mobility Enhancer**

**A dietary supplement containing:**

Vitamin D3 (as cholecalciferol)

Riboflavin

Calcium (from calcium lactate & calcium carbonate)

Magnesium (from magnesium sulfate)

Sodium (from sodium bicarbonate & sodium carbonate)

Glucosamine HCl

Chondroitin Sulfate

Beet Root

Boron (as boron amino acid chelate)

**Statements of Nutritional Support:**

1. Assists in maintaining healthy joints and enhancing flexibility
2. Providing maximum support for a healthy skeletal system
3. Tiens Enhanced Mobility features an excellent combination of Glucosamine, Chondroitin, Calcium, and Magnesium. These ingredients offer the following benefits:  
-- Glucosamine: Aids in nourishing cartilage, maintaining normal cartilage production and helping to promote joint health.

-- Chondroitin: Acts as a flexible connecting material in the cartilage. It helps attract fluid into the cartilage, and gives cartilage its shock absorber properties.

**Product D : Tiens Weight Loss II**

**A dietary supplement containing:**

Chromium (as chromium amino acid chelate)
Proprietary blend containing: Processed Chinese rhubarb root & rhizome (Da Huang), Chinese motherwort fruit (Chong Wei Zi), Astragalus root (Huang Qi), Rugose rose flower (Mei Gui Hua) Chinese licorice root (Gan Cao).

**Statements of Nutritional Support:**

1. Providing maximum herbal support for healthy weight management
2. Tiens Weight Loss II is a milder formula designed to assist you in continuing weight management upon completion of the 30- day program of tiens Weight Loss Plus.