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NOV 14 2001

Amha Belay, Ph.D.  
Scientific Director  
Earthwise Nutritionals, Inc.  
424 Payran Street  
Petaluma, California 94954

Dear Dr. Belay:

This is in response to your letter of October 15, 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 Earthwise Nutritionals, Inc. is making the following claims, among others, for the following products:

**Earthrise® Spirulina**

**Organic Earthrise® Spirulina**

“Supports normal cholesterol levels”

“For...normal cholesterol”

**Spirulina Heart Blend**

“...maintain normal cholesterol levels”

“Supports normal blood pressure”

“Supports normal 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 these products suggest that it is intended to treat, prevent, cure, or mitigate diseases, namely, hypercholesterolemia and hypertension. 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.

975-0163

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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

**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, Los Angeles District Office, Office of Compliance, HFR-PA240



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October 15, 2001

Office of Nutritional Products (HFS-800)  
Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW,  
Washington, DC  
20204

RECEIVED  
OCT 29 2001  
BY: \_\_\_\_\_

**Re: Notification of Structure/Function Statements**

Dear Administrator,

As per 21 CFR section 101.93, this letter is a notification of new structure/function claims made on the labeling of various Earthrise Nutritionals dietary supplements.

The structure-function statements are listed on the enclosed attachment. The products include: Earthrise® Spirulina, Spirulina Certified Organic, Chlorella, Spirulina Greens Blend, Spirulina Multi Blend, Spirulina Light Appetite® Blend, Spirulina Digestion Blend, Spirulina Energy Blend, Spirulina Heart Blend, Spirulina Joint Blend, Spirulina Wellness Blend, SpiruStruct C-30, and SpiruStruct P-50.

Manufacturer/Packer/Distributor: Earthrise Nutritionals Inc.	
424 Payran Street	113 East Hooper Road
Petaluma, CA 94954	Calipatria, CA 92233
Tel: 707-778-9078	Tel: 760-348-5027
Fax: 707-778-9028	Fax: 760-348-2895

The firm believes it has substantiation that the structure-function claims are appropriate, truthful and not misleading. If you have any questions or concerns, please do not hesitate to contact me.

Kind regards,

Amha Belay, Ph.D.  
Scientific Director

**Earthrise Nutritionals Inc.**  
113 East Hooper Rd, Calipatria, California 92233 USA  
Telephone: (760) 348-5027 Fax: (760) 348-2895



Oct. 15, 2001

**Earthrise Nutritionals Dietary Supplements:**  
**List of Ingredients & New Structure-Function Statements**

**1. Earthrise® Spirulina (Tablet, Powder)**

*Ingredient:* Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*].

- Earthrise Spirulina for enhanced nutritional support, vitality, and good health\*
- Earthrise Spirulina contains a rainbow spectrum of mixed carotenoids, antioxidants and phytonutrients that promote health at multiple sites in the body\*
- Supports healthy immune system\*
- Supports normal cholesterol levels\*
- Boosts energy and cellular health\*
- For immune health, normal cholesterol\*
- Nutrient-rich green superfood for cellular health & energy\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

**2. Organic Earthrise® Spirulina (Tablet, Powder)**

*Ingredient:* Organic Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*].

- Certified Organic Earthrise Spirulina for enhanced nutritional support, vitality, and good health\*

-Certified Organic Earthrise Spirulina contains a rainbow spectrum of mixed carotenoids, antioxidants and phytonutrients that promote health at multiple sites in the body\*

-Supports healthy immune system\*

-Supports normal cholesterol levels\*

-Boosts energy and cellular health\*

-For immune health, normal cholesterol\*

-Nutrient-rich green superfood for cellular health & energy\*

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### 3. Chlorella (Tablet)

*Ingredient:* Chlorella (*Chlorella pyrenoidosa*).

-For immune system support, cleansing & overall wellness\*

-Take Earthrise-Yaeyama Chlorella for enhanced nutritional support, vitality, good health & well-being\*

-Supports the immune system\*

-Enhances cleansing\*

-Supports cleansing\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

#### **4. Spirulina Greens Blend (Caplet, powder)**

**Ingredients:** Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], Chlorella (*Chlorella pyrenoidosa*), Barley Grass (*Hordeum vulgare*), Wheat Grass (*Triticum Aestivum*), Alfalfa (*Medicago sativa*), Broccoli (*Brassia oleracea*), Apple Powder (*Malus sylvestris* or *Pyrus malus*), and Lecithin (from *Glycine soja*).

-Earthrise Greens Blend refreshes & nourishes your body with nature's best green foods\*

-Earthrise Greens Blend contains nature's most powerful plant foods designed to promote health & wellness\*

-Supports immune system\*

-Increases energy & fat metabolism\*

-Aids cleansing/digestion & reduces effects of stress\*

-Revitalizing greens blend\*

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(The disclaimer appears in the appropriate places on labels and brochures).

#### **5. Spirulina Multi-Blend (Caplets)**

**Ingredients:** Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], natural Beta Carotene, Vitamin A Acetate, Ascorbic Acid, Citrus Extract (from *orange* fruit), Calcium Aspartate, Potassium Iodide, Folic Acid, Vitamin B-12 (Cyanocobalamin), Vitamin D (Cholecalciferol), Copper amino acid chelate, Manganese amino acid chelate, Boron citrate, Boron Aspartate, Boron Glycinate, Vanadium amino acid chelate, Iron amino acid chelate, Potassium aspartate, Potassium ascorbate, Vitamin B-1 (Thiamine HCl), Vitamin B-2 (Riboflavin), Vitamin B-3 (Niacinamide), Vitamin B-6 (Pyridoxine HCl), Magnesium Ascorbate, Calcium Pantothenate, Biotin, Zinc amino acid chelate, Selenium

aspartate, Vitamin E (d- $\alpha$ -tocopherol succinate), Chromium yeast, and Molybdenum amino acid chelate.

-Earthrise Spirulina Multi Blend protects against the effects of stress\*

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(The disclaimer appears in the appropriate places on labels and brochures).

## 6. Spirulina Light Appetite® (Caplet)

Ingredients: Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], Alfalfa leaf powder (*Medicago sativa*), Soy Lecithin (from *Glycine soja*), Calcium Phosphate, Kelp (*Nereocystis luetkeana*), Apple Cider Vinegar Powder (from *Malus sylvestris* or *Pyrus malus*), Bladderwrack (*Fucus vesiculosus*), Plantain leaf powder (*Plantago*), L-Phenylalanine, Bromelain (from *Ananas comosus*), Vitamin B-6 (Pyridoxine HCl), Vitamin C, Gymnema powder (*Gymnema Sylvestre*), Niacin, Vitamin B-2 (Riboflavin), Vitamin B-1 (Thiamin Mononitrate), Chromium Picolinate, and Cyanocobalamin (Vitamin B-12).

-Earthrise Spirulina Light Appetite Blend uses energizing nutrients to curb appetite\*

-Provides essential vitamins and minerals\*

-Helps maintain energy\*

-Supports long-term weight maintenance\*

-Stimulant-free weight control\*

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(The disclaimer appears in the appropriate places on labels and brochures).

## 7. Spirulina Digestion Blend (Caplet)

Ingredients: Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], Enzyme Complex\*, and Peppermint Leaf Powder (*Mentha x piperita*).

\*Enzyme Complex-almost all enzymes are derived from fungus fermentation (the only exception is Malt Diastatse). The sources are as follows: Amylase (*Aspergillus Oryzae*), Glucoamylase or Amyloglucosidase (*Aspergillus niger*), Invertase (*Saccharomyces cerevisiae*), Lactase (*Aspergillus oryzae*), Malt Diastatse (Barley malt: *Hordeum vulgare*), Lipase (*Aspergillus niger*), Protease 4.5 (*Aspergillus oryzae*), Peptidase (*Aspergillus oryzae*), Protease 6.0 (*Aspergillus oryzae*), Acid-Stable Protease (*Aspergillus niger*), and Cellulase (*Trichoderma long brachiatum*).

-Earthrise® Spirulina Digestion Blend enhances digestion & utilization of nutrients\*

-Helps break down fats, fibers, starches, dairy & proteins\*

-Soothes the stomach\*

-Supports cellular health in the digestive tract\*

-Supports liver and colon health\*

-Promotes healthy digestion\*

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## 8. Spirulina Energy Blend (Caplets)

Ingredients: Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], Siberian Ginseng Extract (*Eleutherococcus senticosus*), Potassium-Magnesium Aspartate, and Guarana Extract (*Paullinia cupana*).

-Earthrise Spirulina Energy Blend prevents fatigue & increases stamina & endurance\*

-Improves mental acuity & physical endurance\*

-Increases metabolic rate\*

-Maintains energy & combats fatigue\*

-Increases energy levels\*

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(The disclaimer appears in the appropriate places on labels and brochures).

## 9. Spirulina Heart Blend (Caplet)

Ingredients: Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], Vitamin E Succinate (from *Glycine soja*), Folic Acid, Coenzyme Q-10, Garlic (*Allium sativum*), and Hawthorn Extract (*Crataegys species*).

-Take Earthrise Heart Blend to maintain normal cholesterol levels & cardiovascular health\*

-Supports the body's oxygen & energy cycles\*

-Supports normal blood pressure, healthy circulation & cardiovascular functions\*

-Supports normal cholesterol levels & healthy heart cells\*

-Supports cardiovascular health\*

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(The disclaimer appears in the appropriate places on labels and brochures).

## 10. Spirulina Joint Blend (Caplets)

Ingredients: Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], Glucosamine Hydrochloride, and Chondroitin Sulfate.

- Earthrise Spirulina Joint Blend maintains joint mobility for an active lifestyle\*
- Stimulates new cartilage production\*
- Promotes connective tissue health\*
- Prevents premature breakdown of cartilage\*
- Supports joint health\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

## 11. Spirulina Wellness Blend (Caplets)

Ingredients: Earthrise® Spirulina [*Spirulina (Arthrospira) platensis*], Echinacea Extract (*Echinacea Angustifolia* and *E. purpurea*), Garlic (*Allium sativum*), Astragalus Extract (*Astragalus* species), Citrus Extract (from orangette fruit), and Zinc Chelate.

- Take Earthrise Spirulina wellness Blend to stimulate the immune system\*
- Provides Wellness-boosting phytonutrients\*
- Stimulates, supports & strengthens the immune system\*
- Improves cellular health\*
- Strengthens the immune system\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

## 12. SpiruStract™ P-50 (Powder)

Ingredients: Spirulina [Spirulina (Arthrospira) platensis] polysaccharide extract and dextrin.

-Supports immune function\*

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(The disclaimer appears in the appropriate places on labels and brochures).

## 13. SpiruStract™ C-30 (Powder)

Ingredients: Phycocyanin extract of Spirulina [*Spirulina (Arthrospira) platensis*], lactose, trisodium citrate, and sodium dihydrogen phosphate.

-Antioxidant protection\*

-Supports cell-mediated immunity\*

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(The disclaimer appears in the appropriate places on labels and brochures).

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