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Justin Straus
Vice President
Cell Tech
1300 Main Street
Klamath Falls, Oregon 97601-5914

Dear Mr. Straus:

This is in response to your letter of October 13, 1999 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 Cell Tech is making the following claims, among others, for the product Spectrabiotic®:

“Helps guard the body against harmful bacteria and yeast...”

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, cure, or mitigate disease, namely, infections resulting from pathogenic microorganisms. 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 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,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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

975-0163

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (file, r/f)

HFD-3 10 (B Williams)

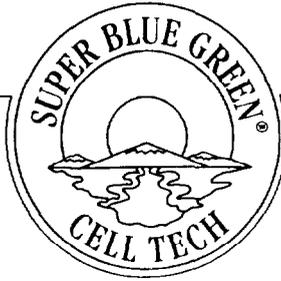
HFD-3 14 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Barnett, Nickerson, Dorsey)

f/t:HFS-456:rjm: 10/20/99:docname:67734.adv:disc42



October 13, 1999

07734

**CERTIFIED MAIL, RETURN
RECEIPT REQUESTED**

Dr. Elizabeth Yetley
Office of Special Nutritionals
Food and Drug Administration
200 C Street, S.W.
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 Cell Tech located at 1300 Main Street, Klamath Falls, Oregon 97601, in connection with products being marketed by Cell Tech. A list of the products and their respective nutritional support statements are listed in the enclosed Attachment "A".

The company hereby certifies that the information contained in this notice is complete and accurate, and that the company can substantiate the statements of nutritional support that are the subject of this notification letter.

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

Sincerely,

Justin Straus
Vice President, Cell Tech

Encl.

ATTACHMENT “A”

1. **Product: Alpha Sun@**

A dietary supplement containing freeze-dried blue-green algae (*Aphanizomenon flos-aquae*).

Statements of Nutritional Support:

- Promotes physical health and immune system function*
- Promotes normal cholesterol levels through its natural source of omega-3 and omega-6 fatty acids*
- Because its cell walls contain a high percentage of floridian starch, it provides natural complex carbohydrates critical for the health and vitality of tissues and cells.*
- Promotes biomodulation within the entire body to enhance overall performance*
- Contains a vast array of micronutrients that your body utilizes for physical well-being*

2. **Product: Omega Sun'**

A dietary supplement containing freeze-dried blue-green algae (*Aphanizomenon flos-aquae*).

Statements of Nutritional Support:

- Promotes normal cholesterol levels through its natural source of omega-3 and omega-6 fatty acids*
- Omega Sun@ is an abundant source of raw materials for feeding and enhancing brain activity.*
- Hence, Omega Sun@ exerts a positive impact on mood, attention, concentration, and the nervous system in general.*
- A nutritional source of the raw materials the brain needs to function optimally. *
- Promotes mental health and immune system function*
- This super-concentrated product contains a high overall amino acid content making Omega Sun@ an abundant source of raw materials for building the neuropeptides which feed and enhance brain activity.*
- Omega Sun@ is Super Blue Green@ Algae with the cell wall removed and is intended for the natural promotion of mental health and immune system support.*
- Promotes biomodulation within the entire body to enhance overall performance*

3. Product: **Alpha Gold**

A dietary supplement containing a propriety blend of wheat grass juice, blue-green algae (*Aphanizomenon flos-aquae*), bee pollen, turmeric, noni, and green tea.

Statements of Nutritional Support:

- Green tea may be the Oriental secret to greater health and vitality. *
- Noni (Indian Mulberry) helps support the body's defense system. *
- The catechin-rich green tea powder provides immune system support. *
- Contains gluten-free Wheat Grass Juice with active enzymes to aid digestion. *
- Noni (Indian Mulberry) may help support proper natural defense system function.*
- The catechin-rich green tea powder, considered decaffeinated, provides immune system support, *
- These ingredients work synergistically for a natural means of increased physical energy and vitality*
- Vitamin-rich bee pollen may help enhance stamina and vitality. *
- Noni (Indian mulberry) provides beneficial support for effective natural defense system function. *
- The polyphenols (catechins) found in green tea possess unique properties to help the body protect cellular health.*
- In fact, green tea may be the Oriental secret to greater health and vitality.*
- Works synergistically to help promote overall physical well-being through an enzymatically-active blend of natural ingredients*
- Supports the body's natural defenses with Hawaiian noni and Alpha Sun@*
- Increases assimilation with enzyme-rich wheat grass juice*
- Protects the health of your cells by utilizing green tea's unique properties*
- The polyphenols (catechins) found in green tea possess unique properties to help the body protect cellular health.*

4. Product: **Omega Gold**

A dietary supplement containing a proprietary blend of wheat grass juice, blue-green algae (*Aphanizomenon flos-aquae*), turmeric, noni, bee pollen, Siberian ginseng, and *Ginkgo biloba*.

Statements of Nutritional Support:

- Contains *Ginkgo biloba*, which has demonstrated positive effects on memory and mental clarity. *
- Siberian ginseng's adaptogenic properties help to enhance stamina and endurance.*
- Siberian ginseng (the only ginseng recommended for both men and women) is added to enhance mental and physical performance. *
- Contains Siberian ginseng for supporting healthy brain function and mental alertness. *
- These ingredients work synergistically for a natural means of increased mental energy. *

- Hundreds of scientific studies have shown the benefits of *Ginkgo biloba* in helping to nutritionally support memory, mental clarity, and proper circulation throughout the entire vascular system. *
- Promotes memory function and mental clarity through ginkgo and Omega Sun@*
- The added Siberian ginseng (the only ginseng recommended for both sexes) enhances mental and physical performance.*
- Vitamin-rich bee pollen may help enhance stamina and vitality.*
- Noni (Indian mulberry) provides beneficial support for effective natural defense system function.*
- In addition, by aiding circulation this remarkable herb helps support healthy brain function and mental alertness.*
- Works synergistically to help promote overall mental well-being.*

5. Product: **Acidophilus**

A dietary supplement containing *Lactobacillus acidophilus* and blue-green algae (*Aphanizomenon flos-aquae*).

Statements of Nutritional Support:

- Provides a simple, natural, and effective way to promote digestive health. This beneficial bacteria promotes normal digestion, assists absorption of nutrients, and promotes immune function and overall health.*
- Provides a simple, natural, and effective way to promote digestive health*
- Helps enhance the body's ability to utilize nutrients*
- Acidophilus also promotes normal peristalsis (movement of food) through the small intestine, and creates a favorable environment for the growth of beneficial flora, which dramatically influence metabolism and physical well-being.*
- An unparalleled probiotic product, providing a simple, natural, and effective way to promote digestive health*
- Cell Tech's Acidophilus helps to create a favorable environment for the growth of beneficial flora, which dramatically influences metabolism and physical well-being.*

6. Product: **Bifidus**

A dietary supplement containing *Bifidobacterium bifidum* and blue-green algae (*Aphanizomenon flos-aquae*).

Statements of Nutritional Support:

- Helps promote digestive health.*
- Promotes efficient digestion.*
- Helps inhibit gas and bloating.*
- Provides support for overall digestive system health.*
- This beneficial bacteria lowers the pH of the intestine (which helps it establish residency in the intestine), manufactures specific B-vitamins, and promotes immune function and overall health.*

- Creates a favorable environment for good bacteria growth to keep your large intestine healthy*
- Contains the beneficial bifidobacteria, which lowers the pH of the intestine, manufactures specific B-vitamins, and promotes immune function and overall health*
- Each Bifidus capsule is microblended with 85 mg of Super Blue Green@ Omega Sun® to help promote digestive health, especially when used in conjunction with Acidophilus and Spectrabiotic®.*
- A good intestinal flora in the large intestine can help inhibit gas and bloating.
- Contains *Bifidobacterium bifidum* to help promote digestive health*
- The all-important presence, then, of good intestinal flora not only promotes efficient digestion, it can help inhibit gas and bloating.*
- Bifidus, when used in conjunction with Cell Tech's Acidophilus and Spectrabiotic®, provides crucial probiotic support for overall digestive system health.*
- Each capsule is micro-blended with 85mg of Super Blue Green@ Omega Sun® to help promote digestive health*
- Each Bifidus capsule is microblended with 85 mg of Super Blue Green@ Omega Sun® to help promote digestive health, especially when used in conjunction with Acidophilus and Spectrabiotic®.*

7. **Product: Spectrabiotic®**

A dietary supplement containing a proprietary blend of *Lactobacillus acidophilus*, *Bifidobacterium bifidus*, *Streptococcus faecium*, *Lactobacillus bulgaricus*, *Lactobacillus caseii*, *Lactobacillus plantarum*, *Lactobacillus salivarius*, *Streptococcus thermophilus*, lipase, amylase, protease, cellulase, blue-green algae (*Aphanizomenon flos-aquae*), Jerusalem artichoke, acerola and rosehips.

Statements of Nutritional Support:

- Formulated specifically to help promote overall digestive health. *
- Helps guard the body against harmful bacteria and yeast, stimulate the function of the entire digestive system, and produce essential vitamins. *
- Super Blue Green@ Spectrabiotic® supplies a wide spectrum of beneficial bacteria to support overall intestinal health. *
- Complements Acidophilus and Bifidus to promote overall digestive health*
- Eight key good bacteria are microblended with 50 mg of Super Blue Green® Omega Sun®, providing the entire digestive tract with superb probiotic support, especially when combined in a regular program with Acidophilus and Bifidus.*

8. **Product: Super Sprouts & Algae**

A dietary supplement containing a proprietary blend of wheat sprouts, Betatene® (carotenoid extracts), and blue-green algae (*Aphanizomenon flus-aquae*).

Statements of Nutritional Support:

- Helps combat free radicals.*

- Provides 62% of the RDA of Vitamin A via beta-carotene*
- Helps promote cellular health.*
- Nourishes your central nervous system*
- Beta-carotene, also known as provitamin A because the body converts it to vitamin A, is widely recognized as one of the most valuable nutrients for establishing and maintaining good health.*
- The Super Blue Green@ Algae Alpha Sun® and Red Beta Algae in Cell Tech's Super Sprouts & Algae are remarkably rich sources of beta-carotene. Beta-carotene, also known as provitamin A because the liver converts it to vitamin A, is widely recognized as one of the most valuable nutrients for establishing and maintaining good health.*

9. Product: Original Enzymes

A dietary supplement containing a proprietary blend of amylase, protease, lipase, lactase, cellulase, and blue-green algae (*Aphanizomenon flos-aquae*).

Statements of Nutritional Support:

- Promotes optimum digestion and assimilation of nutrients. *
- Helps the body break down foods, including fats, carbohydrates, protein, and fiber. *
- Helps enhance the digestive process. *
- In addition to taking enzymes just before meals and significant snacks, taking enzymes on an empty stomach will help to break down and eliminate undigested food particles from previous meals. *
- Supplementation of food enzymes can positively affect the entire digestive process and, in turn, promote overall health.*
- Cell Tech's Super Blue Green@ Enzymes contain a full range of food enzymes to help you break down all types of foods, including fats, carbohydrates, protein, and fiber, to help enhance the digestive process.*

10. Product: E-12 Super Enzymes

A dietary supplement containing a proprietary blend of amylase, glucoamylase, invertase, lactase, pectinase (w/phytase), cellulase, lipase, protease, bromelain, papain, blue-green algae (*Aphanizomenonflos-aquae*), fennel, ginger, and cayenne.

Statements of Nutritional Support:

- Provide fennel, ginger, and cayenne to further aid digestion *
- E- 12 Super Enzymes contain a superior blend of plant-based enzymes combined with Super Blue Green@ Alpha Sun@ Algae, fennel, ginger, and cayenne for additional digestive support. *
- Working with the special ingredients fennel, ginger, and cayenne, all known for their beneficial effects on the digestive system, E-12 Super Enzymes allow the body to digest and utilize a broader spectrum of nutrients.*

11. Product Name: Super Sun Smoothie

A dietary supplement containing soy protein isolate, blue-green algae (*Aphanizomenon flos-aquae*), natural flavors, soy lecithin, sesame meal, ascorbic acid, and niacinamide.

Statements of Nutritional Support:

- Helps to promote proper cholesterol levels and cardiovascular health.*
- The daidzein contained in soy may be beneficial in maintaining bone density.*
- Soy protein provides a natural source of isoflavones (including genistein and daidzein) which promotes overall health, particularly for women.*
- Soy protein, the primary ingredient in Super Sun Smoothie powder, is a source of vegetarian protein which, unlike animal protein, helps to promote proper cholesterol levels and cardiovascular health.*
- Contains genistein, which support women's health*

12. Product Name: Mazama Mix

A dietary supplement containing a proprietary blend of Basmati rice Trin®, pea fiber, apple pectin, barley sprouts, flax seed, green oat grass, Jerusalem artichoke tubers, lecithin, oat sprouts, quinoa sprouts, soy sprouts, wheat grass, wheat sprouts, sprouted millet, sprouted spelt, date fiber, barley grass, blue-green algae (*Aphanizomenon flos-aquae*), dulse, kelp, Siberian ginseng root, lipase, stevia leaf, amylase, cellulase, and protease.

Statements of Nutritional Support: NONE

13. Product Name: Super

A dietary supplement containing a proprietary blend of coenzyme Q₁₀, Betatene® (carotenoid extract), essential oils (fennel, ginger, and cinnamon), and blue-green algae (*Aphanizomenon flos-aquae*).

Statements of Nutritional Support:

- Nutritionally supports heart health and the body's natural defense system. *
- Numerous scientific investigations and clinical studies have shown that replenishing levels of CoQ₁₀ by supplementation has had remarkable results on cardiovascular health, natural defense system function, and rejuvenation of energy systems. *
- Hundred of clinical studies conducted worldwide have shown that CoQ₁₀ is essential for energy production, helps strengthen the entire body at the cellular level to help support cardiovascular health, and nourishes the body's natural defense system. *
- Supports your heart's health and your body's natural defense system*
- Boosts your cardiovascular health with this rich source of omega-3 and omega-6 essential fatty acids*
- It is the ideal supplement to assist the miracle of the body's cells in converting nutrients into energy.*

14. Product Name: New Seasons Cleansing System

A dietary supplement system consisting of two formulas as listed below.

Herbal Formula

A dietary supplement containing rice bran, Jerusalem artichoke tubers, milk thistle seed, pumpkin seed, turmeric root, wheat grass, aloe vera gel, amylase, burdock root, dandelion root, *Echinacea purpurea* root, fennel seed, plantain leaf, cabbage juice powder, cinnamon bark, clove flowerbuds, garlic bulb, ginger rhizome, thyme leaves, blue-green algae (*Aphanizomenon flos-aquae*) cayenne pepper, protease, black walnut leaf, cat's claw bark, cellulase, centaury herb, elecampane root, fenugreek seed, gentian root, grapefruit seed extract, licorice root, yellow dock root, and lipase.

Fiber Formula

A dietary supplement containing oat fiber, apple fiber, beet root fiber, pea fiber, acacia gum, aloe vera gel, apple pectin, barberry root bark, cascara sagrada bark, turmeric root, Irish moss algae, konjac root glucomannan, slippery elm bark, wheat grass, cabbage juice powder, protease, blue-green algae (*Aphanizomenon flos-aquae*), amylase, cellulase, and lipase.

Statements of Nutritional Support:

- Enables the organs to perform their vital functions at an optimal level*
- Promotes circulation through the liver and intestinal tract*
- Promotes cleansing in five systems-digestive tract, urinary tract, skin, the respiratory system, and the lymphatic*
- Supports proper bowel elimination*
- This internal cleansing program helps cleanse internally, promotes circulation through the liver and intestinal tract, and aids in the assimilation of nutrients.*
- This is a gentle, natural, and complete program to cleanse and nourish. *
- Contains a blend of herbs, fiber, and other natural ingredients to enhance the body's natural cleansing processes*
- Helps re-establish healthy digestive system function*
- The herbs and green foods in Cell Tech's Herbal formula support these systems and function of organs like the liver and kidneys. *
- The Fiber formula provides specific herbs and fiber which work to remove fecal matter along the intestinal walls and gently support good bowel function. *