



OCT 11 2002

Mr. Justin Straus  
Vice President  
Cell Tech International, Inc.  
565 Century Court  
Klamath Falls, Oregon 97601

Dear Mr. Straus:

This is in response to your letter of September 17, 2002 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 International, Inc. is making the following claims, among others, for its product **ImmuSun™**:

“Based on extensive published research, it is widely accepted that the beta 1,3-glucan derived from baker’s yeast is the most potent anti-infective beta glucan immunomodulator;”

“ImmunSun™ [sic] contains the active ingredient WGP beta glucan, which binds with macrophages, a type of white blood cell whose job it is to detect intruders and coordinate the body’s defenses against them;”

“WGP beta glucan stimulates certain receptors on the macrophages, convincing them that the body is being attacked;”

“Phagocytic activity, the ability of the white blood cell to engulf foreign cells;”

“The antibodies, working with the immune system, bind the invaders into clusters which are then engulfed by macrophages. In this way, the immune system rids the body of harmful invaders.”

Your submission states that Cell Tech International, Inc. is making the following claims, among others, for its products **Aspha Gold** and **Omega Gold**:

“Bee pollen also helps support and the immune system and protects both red and white blood cells against their usual depletion from radiation.”

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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 prevent disease (i.e., infectious diseases and disorders associated with acute high-dose radiation exposure, such as that associated with radiation therapy). 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.

Please contact us if we may be of further assistance.

Sincerely yours,



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



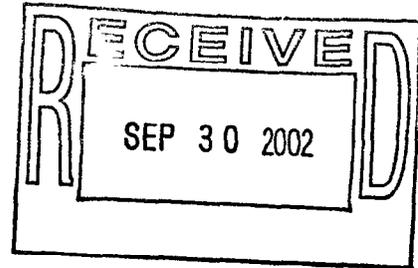
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**CELL TECH INTERNATIONAL INCORPORATED**

565 Century Court, Klamath Falls, Oregon 97601

Phone 541 882 5406 Fax 541 884 1869 www.celltech.com

— September 17, 2002



**CERTIFIED MAIL, RETURN  
RECEIPT REQUESTED**

Office of Nutritional Product, Labeling and  
Dietary Supplement (HFS 810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Notification of Product claims

Dear Sir or Madam:

This letter serves as notification of the nutritional support label statements being made by Cell Tech located at 565 Century Court, Klamath Falls, OR 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:**

- Provides energy, immune support, vitamins, well-rounded natural minerals and amino acids for whole-body health.\*

2. **Product: Omega Sun®**

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

**Statements of Nutritional Support:**

- This is the interior part of the cell and provides a stronger concentration of nutrients that feed the central nervous system, to help us deal with stress, improved memory, concentration, focus and clarity.\*

3. **Product: Acidophilus**

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

**Statements of Nutritional Support:**

- Beneficial organisms to replenish the intestinal flora in the stomach and small intestine, boost the immune system and assist elimination.\*

4. **Product: Original Formula Enzymes**

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

**Statements of Nutritional Support:**

- Natural food enzymes, to use with and between meals to predigest food, help with assimilation and elimination and to cleanse cells and organs of unwanted debris.\*

5. **Product: SBGAnytime™**

A dietary supplement containing blue-green algae (*Aphanizomenon flos-aquae*), orange juice, honey, soy lecithin, and natural vanilla flavoring in a chewable form.

**Statements of Nutritional Support:**

- Strong immune system\*
- Good digestion and absorption\*

6. **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:**

- Bee pollen also helps support the immune system and protects both red and white blood cells against their usual depletion from radiation.\*
- Hawaiian Noni, used traditionally by Polynesians, contains natural phytochemicals that support immune function as well as cardiovascular and joint health.\*
- Turmeric, from India, is noted for its significant antioxidant activity and its ability to help maintain normal cell reproduction.\*
- Turmeric: It is good for digestion, and may improve and balance metabolism in the body.\*
- Green Tea: The active constituents in green tea possess unique properties to help the body protect cellular health and are effective in the important antioxidant action of scavenging destructive free radicals.\*

7. **Product: Omega Gold**

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

**Statements of Nutritional Support:**

- Bee pollen also helps support the immune system and protects both red and white blood cells against their usual depletion from radiation.\*
- Hawaiian Noni, used traditionally by Polynesians, contains natural phytochemicals that support immune function as well as cardiovascular and joint health.\*
- Turmeric, from India, is noted for its significant antioxidant activity and its ability to help maintain normal cell reproduction.\*
- Turmeric : It is good for digestion, and may improve and balance metabolism in the body.\*
- Siberian Ginseng: It is referred to as an adaptogen because it produces a generalized rebalancing effect on the body.\*
- *Ginkgo biloba*: By aiding circulation, this remarkable herb helps support an alert and active brain.\*

8. **Product: Super Q10**

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 defense system with this remarkable formula\*
- Promotes health and vitality through a powerful combination of antioxidants, Coenzyme Q<sub>10</sub> and Super Blue Green® Alpha Sun® Algae\*
- Extensive research confirms that this amazing nutrient boosts energy at the cellular level, counteracts free radical damage, supports strenuous physical activity, supports the health of teeth and gums, is vital to the health of the cardiovascular system and immune system, and assists in proper weight maintenance.\*

**9. Product: NaturaLight**

A dietary supplement containing a proprietary blend of enzymes, botanicals, and blue-green algae (*Aphanizomenon flos-aquae*).

**Statements of Nutritional Support:**

- This natural weight-loss formula is designed to work with your body to help you reduce fat and lose weight the way nature intended\*.
- Combined with proper diet and exercise, NaturaLight will help you to reduce your cravings, increase your energy, and improve your mental clarity and attitude\*.

**10. Product: ImmuSun™**

A dietary supplement containing WGP™ beta 1,3 / 1,6 glucan.

**Statements of Nutritional Support:**

- Provides enhanced support for the body's immune system\*
- Supports the production and activity of beneficial white blood cells\*
- The result is a stronger immune system.\*
- This all-natural health supplement fortifies the body's immune system, Supports the production and activity of beneficial white blood cells, and Helps maintain overall health.\*
- Combines with Cell Tech's other superior products to provide the best possible support for our immune systems\*
- Supports the production and activity of beneficial white blood cells\*.
- ImmuSun™ is an all natural dietary supplement that fortifies the body's immune system.\*
- ImmuSun™ is an exciting dietary supplement from natural sources that fortifies the body's immune to protect us from these stresses.\*
- These studies have proven the ability of WGP beta glucan to activate macrophages and thus contribute to the health of the immune system.\*
- Based on extensive published research, it is widely accepted that the beta 1,3 glucan derived from baker's yeast is the most potent anti-infective beta glucan immunomodulator.\*

- ImmunSun™ contains the active ingredient WGP beta glucan, which binds with macrophages, a type of white blood cell whose job it is to detect intruders and coordinate the body's defenses against them.\*
- WGP beta glucan stimulates certain receptors on the macrophages, convincing them that the body is being attacked.\*
- Production of white blood cells in the bone marrow, including macrophages, neutrophils, and monocytes\*
- Phagocytic activity, the ability of the white blood cell to engulf foreign Cells\*
- Production of anti-microbial agents that enhance the effectiveness of the immune system\*
- The activated macrophages communicate the activation signal to other members of the immune system – other macrophages, neutrophils and natural killer (NK) cells.\*
- The antibodies, working with the immune system, bind the invaders into clusters which are then engulfed by macrophages. In this way, the immune system rids the body of harmful invaders.\*
- ImmunSun is a scientifically proven immune system enhancer.\*
- Taken daily, one capsule of WGP beta glucan has been show to stimulate the development of new white blood cells, helping the immune system maintain peak performance.\*
- Combines with Cell Tech's other superior products – especially Alpha Sun® and Omega Sun® - to provide the best possible support for the body's immune system.\*