

# CELL TECH INTERNATIONAL IN CORPORATED P3:15

565 Century Court, Klamath Falls, Oregon 97601

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May 5, 2003

# 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

Chief Operating Officer

Cell Tech International Incorporated

Encl.

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#### **ATTACHMENT "A"**

#### 1. Product: Contain<sup>TM</sup>

A dietary supplement containing a proprietary blend of: alginate, sodium bicarbonate, calcium carbonate, enzyme blend (protease, protease BC, Lipase, and amylase) and freeze-dried blue-green algae (*Aphanizomenon flos aquae*).

#### **Statements of Nutritional Support:**

- Helps keep stomach acid where it belongs\*
- Meanwhile, the enzymes in the formulation work in the stomach to aid in the
  efficient breakdown of food helping to minimize occasional in digestion at the
  outset. \*
- Helps keep stomach acid where it belongs and occasional heartburn under control. \*
- Helps control occasional acid indigestion with all-natural ingredients\*
- Provides wholesome relief for occasional heartburn\*
- Supplies enzymes to aid digestion\*
- Besides being formulated with enzymes to help reduce occasional indigestion,
   Contain also includes Omega Sun algae for added nutritional value. \*
- Contain does not act to neutralize stomach acid—rather, it relieves symptoms of occasional heartburn naturally, by forming a protective buffer to keep stomach acid where it belongs. \*
- All in all, Contain offers an ideal combination of beneficial ingredients that can help alleviate the stressful effects of occasional heartburn. \*

#### 2. Product: OsteoSun<sup>TM</sup>

A dietary supplement containing freeze-dried blue-green algae (Aphanizomenon flos-aquae) and red yeast rice (Monascus purpureus Went).

# **Statements of Nutritional Support:**

- Support your bone health with OsteoSun<sup>TM\*</sup>
- Taken daily, OsteoSun is a safe and all-natural way to help maintain your bone health and strength. \*
- OsteoSun, Cell Tech's all-natural and unique non-calcium supplement, has been scientifically proven to promote bone health. \*
- Give your bones the extra support they need to stay healthy with Cell Tech's OsteoSun. \*
- Take OsteoSun and other dietary supplements to maximize bone health. \*
- Cell Tech is proud to introduce OsteoSun<sup>™</sup>, a new, natural, and unique noncalcium dietary supplement, which is scientifically proven to promote bone health. \*
- Take OsteoSun<sup>™</sup> daily as a safe and all-natural way to help maintain your bone health and strength. \*

- OsteoSun strengthens existing bone and is scientifically proven to form new bone, as well. \*
- Unlike other products on the market, OsteoSun enhances the body's natural ability to restore bone mass and is scientifically proven to build new bone.
- Only OsteoSun is scientifically proven to build bone and increase bone mineral density. \*

#### 3. Product: ImmuSun<sup>TM</sup>

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

#### **Statements of Nutritional Support:**

- ImmuSun<sup>TM</sup> powerfully combines with our other great products—to provide the best possible support for our immune systems.\*
- ImmuSun<sup>TM</sup>, which contains the active ingredient WGP beta glucan, supports the production and activity of beneficial white blood cells. \*
- WGP beta glucan stimulates certain receptors on macrophages, a type of white blood cell. \*
- Now Cell Tech offers another way to help keep your immune system healthy.
- Containing the active ingredient WGP<sup>TM</sup> beta glucan, a patented form of the complex carbohydrate beta 1,3 glucan, ImmuSun<sup>TM</sup> is an all-natural dietary supplement that fortifies the body's own immune system. \*
- Since then, it has been shown to produce multiple broad-scale effects that have the potential to strengthen the vitality of the immune system. \*

#### 4. Product: Spectrabiotic®

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

### **Statements of Nutritional Support:**

- The most powerful probiotic support available, Cell Tech's Spectrabiotic, is designed to build and maintain healthy intestinal flora. \*
- These bacteria help promote the healthy balance of intestinal flora, stimulate the function of the entire digestive system, and produce essential vitamins. \*
- Help from special herbs that enhance blood circulation in the GI tract\*

#### 5. 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-management formula is designed to work in conjunction with our body's inherent waste elimination systems to help you reduce fat and control your weight the way nature intended. \*
- NaturaLight contains elements that activate your body's fat elimination process and reduce your cravings while increasing your metabolism. \*
- Combining NaturaLight with a balanced diet and exercise will help increase energy, reduce cravings, and improve mental clarity and attitude. \*
- You can keep lean muscle mass while helping your body to reduce fat and maintain a healthy weight. \*