

565 Century Court, Klamath Falls, Oregon 97601

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

APR 0 8 2002

April 1, 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,

Vice President, Cell Tech

975 0162 LET 9886

Encl.

#### ATTACHMENT "A"

## 1. General Product Statements

- Support physical stamina, natural immune defenses, and mental clarity.\*
- Establish a balanced ecosystem to keep digestion and elimination on track with "friendly bacteria" (acidophilus, bifidus, etc.).\*
- Cell Tech's probiotics are designed to work synergistically to help build and maintain healthy intestinal flora.\*
- When used simultaneously, these products combine to provide an unparalleled, comprehensive system to promote good digestion and optimum health for you.\*
- Our cleansing and antioxidant support products are designed to give your body the boost it needs to perform its complex functions effectively.\*

## 2. Product: Alpha Sun®

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

# **Statements of Nutritional Support:**

• Support all the normal functions of the human body, particularly digestion and elimination.\*

## 3. Product: Acidophilus

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

# Statements of Nutritional Support:

- Friendly bacteria have many important roles, helping maintain proper acid/alkaline intestinal balance.\*
- Friendly bacteria have many important roles, promoting healthy peristalsis and elimination.\*
- Regular use helps keep the immune system and digestion strong and healthy.\*
- Acidophilus also benefits peristalsis, the normal movement of food through the small intestine.\*
- Promotes regular bowel movements.\*
- Supports pH levels in the small intestine.\*

## 4. Product: Bifidus

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

- Cell Tech's Bifidus helps repopulate the large intestine with friendly bacteria, supporting the healthful environment it needs to function efficiently.\*
- Support proper pH levels in the large intestine.\*
- Maintain a health-promoting environment for your colon.\*

#### 5. Product: Spectrabiotic®

A dietary supplement containing a proprietary blend of Lactobacillus Acidophilus, Bifidobacterium fifidus, Streptococcus faecium, Lactobacillus bulgaricus, Lactobacillus caseii, 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:**

- Spectrabiotic contains eight key "good bacteria", 50 mg of Super Blue Green Omega Sun, rose hips, Jerusalem artichoke, and acerola, providing the entire digestive tract with superb nutritional and probiotic support, especially when combined in a regular program with Acidophilus and Bifidus.\*
- Powerful support for a strong, resilient digestive tract.\*
- Additional support from a broader spectrum of friendly bacteria.\*
- Benefit from special herbs that enhance blood circulation in the GI tract.\*

#### 6. Product: Super Sprouts & Algae

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

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

 Super Sprouts and Algae provides: Powerful antioxidant protection, Good physical energy from a rich source of nutrients, and Nutritional support for joints and connective tissues.\*

#### 7. 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 (*Aphanizomenon flos-aquae*), fennel, ginger, and cayenne.

- E-12 Super Enzymes allows the body to digest and utilize a broader spectrum of nutrients.\*
- E-12 offers you: More energy after eating large meals\*, A full spectrum of digestion-enhancing ingredients\*, Help in breaking down meals with different types of proteins, fats, and carbohydrates.\*

• Cell Tech's E-12 Super Enzymes help break down fats, carbohydrates, and fiber, and support many other vital functions.\*

## 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:**

- Co-enzyme Q<sub>10</sub> assists the body with energy production and cellular repair, and appears to improve the metabolism of the heart, brain, gums, and muscles.\*
- Excellent support for heart and cardiovascular health.\*

## 9. Product: New Seasons

A dietary supplement containing blue-green algae (Aphanizomenon flos-aquae),

- The Herbal Formula contains enzymes, and all-natural ingredients that gently support the release of toxins.\*
- The Fiber Formula helps bind the toxins and remove them from the digestive tract.\*
- Provides herbs that assist the lymph in the removal of toxins.\*
- Contains natural sources of fiber that root out toxins and clean and tone the bowels.\*
- Helps your system rebuild and re-establish healthy digestive function after your body has been cleansed and refreshed.\*
- The New Seasons Cleansing System is a complete two-product cleansing program that helps your body naturally flush out toxins from your tissues and eliminate them.\*
- The Herbal Formula supports your body while it gently releases toxins locked in your tissues, cleanses the lymph, the liver and the blood in the liver, and releases bile into the digestive system for safe evacuation.\*
- The Fiber Formula helps the body capture toxins in the digestive system, promotes the growth of helpful bacteria, and protects and supports the intestinal wall while supporting your body's proper bowel function.\*
- Provides herbs that promote removal of toxins through the lymphatic system\*
- The New Seasons<sup>™</sup> Cleansing System is a two-product program that is designed to assist your body's natural elimination systems in removing toxins.\*
- The Herbal Formula supports the processes that remove toxins from the tissues of the body; then the Fiber Formula helps the body safely eliminate those toxins.\*

- Our Herbal Formula contains a selection of herbs, enzymes, and other natural ingredients that support these important body functions: Releasing toxins from the tissues\*, Cleansing the lymph\*, Cleansing the blood through the liver\*, Cleansing the liver\*, Releasing bile into the digestive system\*.
- Our Fiber Formula contains dietary fiber and a selection of herbs, enzymes, and other natural ingredients that support these important body functions: Capturing toxins in the digestive system\*, Promoting the growth of beneficial intestinal bacteria\*, Protecting and supporting the intestinal wall\*, Releasing intestinal plaque\*, Supporting proper bowel function\*.
- The New Seasons Cleansing System is a great way to help your body's systems do their job of eliminating toxins.\*
- Formulated with Super Blue Green Algae, herbs specially selected for their properties, and other natural ingredients, New Seasons is a gentle program that nourishes your body's natural detoxification systems and helps them work at peat efficiency.\*
- Fiber Formula dietary supplements help bind toxins in the digestive tract and gently remove them.\*

## 10. Product: NaturaLight

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

- Superfood sources, plant based enzymes and botanicals are combined to create an environment conducive to fat-burning and weight loss, while maintaining lean muscle mass.\*
- Cell Tech International has applied the natural laws of human metabolic physiology in creating this unique formulation, which is designed to provide the cells of the body with optimal nutrition and aid the body in the utilization of enzymes to digest fat and turn it into energy.\*
- This product has been specifically formulated with an appropriate blend of
  enzymes, botanicals, and other select dietary ingredients that help provide an
  environment that is conducive to fat burning and weight loss while
  maintaining lean muscle mass.\*