



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

2004 APR 23 11:14

APR - 6 2004

Ms. Cecilia Zhou  
Manager of Marketing & Sales  
LIFEnhance, Inc.  
11155 S. Main  
Houston, Texas 77025

Dear Ms. Zhou:

This is in response to your letter of February 23, 2004 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 LIFEnhance, Inc. is making the following claim, among others, for the product **Relazovac™** :

“...ease conditions related to insomnia...”

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, or mitigate a disease (i.e., insomnia). 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 748

Page 2 - Ms. Cecilia Zhou

**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, Dallas District Office, Office of Compliance, HFR-SW140

*We Care About Your Quality of Life*



MAR 09 2004

Feb 23, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740.

To Whom It May Concern:

LIFEnhance, Inc., pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, hereby submits the original copy of its structure/function claim notification for the statements presented below. LIFEnhance retains scientific documentation supporting the statements.

**1. Supplement Brand Name**

**Leucozepin™**

**Text of Statements of Nutritional Support**

Leucozepin™ bolsters the body's defense system to:

- Naturally fortifies the immune system\*
- Promote activity of various leukocytes or white blood cells \*
- Improve fatigue\*
- Assist in recovery \*

Astragalus, known as an immune stimulator, restores damaged immune cells, activates white blood cells and stimulates the production of interferon. Reishi Mushroom promotes NK cell activity and T-cells.\* Atractylodes stimulates macrophages and lymphocytes (B-cells, T-cells).

87602

**LIFEnhance, Inc.**  
11155 S. Main  
Houston, TX 77025  
tel: 713-777-7090  
fax: 713-777-7091  
www.lifenhance.net

*We Care About Your Quality of Life*



**2. Supplement Brand Name**

**Relazovac™**

**Text of Statements of Nutritional Support**

Relazovac™ facilitates natural internal processes to:

- Ease restless sleep and stress\*
- Increase total sleep time \*
- Support both mind and body \*

MAR 09 2004

Jujube seed, is known to relieve irritability and to aid sleep.\* For centuries past in Asia, Chinese skullcap has been used as traditional remedies for insomnia and headaches. Coptis is also historically known to ease conditions related to insomnia, nervousness, and anxiety.\*

**3. Supplement Brand Name**

**Apazin™**

**Text of Statements of Nutritional Support**

Apazin™ regulates the digestive system to:

- Stimulate appetite\*
- Promote digestion\*

The essential oil in Fennel is known to sensitize the sense of taste, increase gastric and saliva secretion and boost stomach activities, thereby prompting appetite and promoting digestion.\* Several compounds in Ginger are known to stimulate blood circulation in the stomach, hence improving digestion and absorption, resulting in relieving temporary vomiting and diarrhea.\* Both Dendrobium and Job's Tears have been used to regulate the retention of body fluid.

These statements are accompanied by the required disclaimer, which is prominently displayed in bold-faced type.

The undersigned is an authorized representative of LIFEnhance, Inc. and certifies that the information contained in this notice is complete and accurate and the above statement is based on data, which renders these statements substantiated, truthful and non-misleading.

Respectfully submitted,

  
Cecilia Zhou  
Manager of Marketing & Sales

57602

**LIFEnhance, Inc.**  
11155 S. Main  
Houston, TX 77025  
tel: 713-777-7090  
fax: 713-777-7091  
www.lifenhance.net