



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

0203 '00 DEC -7 P3:08

NOV 27 2000

A. Wes Siegner, Jr.  
Hyman, Phelps & McNamara, P.C.  
700 Thirteenth Street, N. W.  
Suite 200  
Washington, D.C. 20005-5929

Dear Mr. Siegner:

This is in response to your letters of October 31, 2000 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 submissions of the behalf of Starlight International of Monterey, California 93940, is making the following claims, among others, for the products below:

**Ideas™**

“Spirulina helps the body maintain proper blood sugar levels...”

**Fat Free!™**

“Help maintain healthy cholesterol levels.”

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 treat, prevent, cure, or mitigate diseases. 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.

975-0163

LET 429

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Please contact us if we may be of further assistance.

Sincerely,

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, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:afp:11/20/00:docname:73161:disc1

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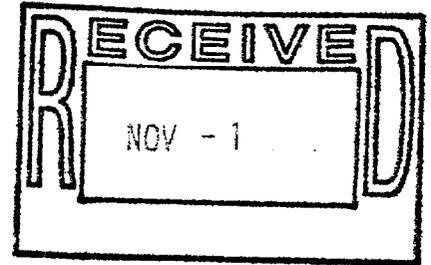
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October 31, 2000



Office of Nutritional Products, Labeling,  
 and Dietary Supplements (HFS-800)  
 Center for Food Safety and Applied Nutrition  
 Food and Drug Administration  
 200 C Street, S.W.  
 Washington, D.C. 20204

## NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

On behalf of Starlight International, Monterey, California 93940, the undersigned files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 343(r)(6). The certification required by 21 C.F.R. § 101.93(a)(3) is attached.

Brand name: FatFree!™

Dietary ingredients: Maitake mushroom (*Grifola frondosa*) extract, *Platycodon grandiflorum* root extract, glucomannan (*Amorphophallus konjac*) root, *Gymnema sylvestre* leaf.

Statements of nutritional support:

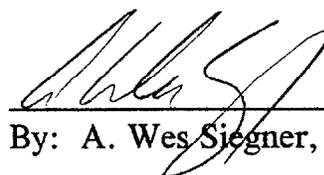
- Helps to control fat and curb your appetite
- Aids digestion and elimination
- Keeps you slim because you will have a feeling of fullness before you eat
- Helps to prevent the absorption of fat and then expels it from your body

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HYMAN, PHELPS & MCNAMARA, P.C.

- ✓ Help maintain healthy cholesterol levels
- Feel energetic
- Glucomannan also works in combination with Gymnema sylvestre and other herbs to diminish your appetite

Hyman, Phelps & McNamara, P.C.

  
By: A. Wes Siegner, Jr.

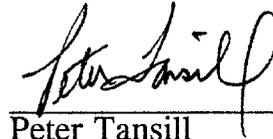
AWS/SNR/dng

Attachment - Certification

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21 C.F.R. § 101.93(a)(3) Certification

I certify that the information contained in the preceding section 403(r)(6) notice for the FatFree!™ Dietary Supplement is complete and accurate, and that Starlight International has substantiation that the statements are truthful and not misleading.



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Peter Tansill  
Director of Manufacturing  
Starlight International

October 30, 2000

October 31, 2000

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To sharpen mental focus and improve memory

St. John's wort helps reduce stress and tension

Gingko biloba helps increase circulation and blood flow to the brain

Basil/tulsi has been used as a tonic for the nerves, relieves restlessness, soothes muscles and aids digestion

Lemon balm leaf is an herb used for its ability to reduce anxiety

Siberian ginseng increases physical resiliency, combats fatigue, and aids in healthy immune function

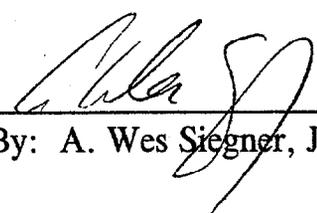
Gotu kola used to increase concentration, focus and clarity

Spirulina helps the body maintain proper blood sugar levels, which can affect mood

Rosemary aids the body in digestion

Lavender is known for its exceptional calming properties, relieving tension and nervousness

Hyman, Phelps & McNamara, P.C.



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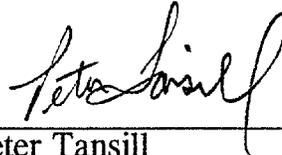
AWS/SNR/dng

Attachment - Certification

73161

21 C.F.R. § 101.93(a)(3) Certification

I certify that the information contained in the preceding section 403(r)(6) notice for the Ideas™ Dietary Supplement is complete and accurate, and that Starlight International has substantiation that the statements are truthful and not misleading.



---

Peter Tansill  
Director of Manufacturing  
Starlight International

October 30, 2000

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