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JAN - 9 2001

A. Wes Siegner, Jr., Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005-5929

Dear Mr. Siegner:

This is in response to your letter of December 4, 2000 to the Food and Drug Administration (FDA), on behalf of your client Starlight International, Monterey, California, 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 Starlight International is making the following claims, among others, for the product **LifeGuard™ Cholesterol Control**:

“Maintains healthy cholesterol levels...”

“...maintain healthy cholesterol levels, improve circulation...”

“...helps control the harmful LDL cholesterol...”

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 this product, including the inclusion of the term “cholesterol control” in its name, suggest that it is intended to treat, prevent, cure or mitigate diseases such as hypercholesterolemia and vascular diseases that impair blood circulation. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, 7520 Standish Place, Rockville, Maryland 20855.

The product that is the subject of the above claims contains the ingredient red yeast rice. We wish to advise you of the current status of products that contain red yeast rice. FDA announced its administrative decision on May 20, 1998 that a product named

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"Cholestin¹," manufactured by Pharmanex, Inc., which was promoted as a dietary supplement intended to affect cholesterol levels, is not a dietary supplement, but is instead an unapproved drug under the Act. This decision meant that Cholestin could not legally be sold in the United States.

A February 16, 1999 decision by the United States District Court for the District of Utah that "held unlawful and set aside" the FDA's administrative finding was reversed by the United States Court of Appeals for the Tenth Circuit on July 21, 2000. This reversal reinstated FDA's administrative decision that Cholestin is a drug, not a dietary supplement. Thus, products containing red yeast rice or *Monascus purpureus* that contain lovastatin are unapproved new drugs that are in violation of the Act. Marketing a product that is in violation of the Act may result in enforcement action being initiated by FDA without further notice. The Act provides for the seizure of illegal products and for injunction against manufacturers and/or distributors of illegal products.

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

¹Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson, Goldsmith)

r/d:HFS-811:RMoore:12/21/00

revised:GCF-1:DGoldsmith:1/2/01

f/t:HFS-811:RMoore:1/2/01:docname:73709.adv:disc53

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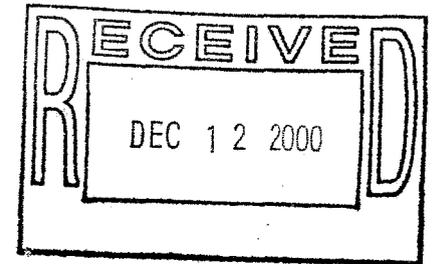
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December 4, 2000



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: LifeGuard™ Cholesterol Control

Dietary ingredients: red rice yeast (*Monascus purpureus*) plant, Fo-Ti (*Polygonum multiflorum*) plant, soy, beta sitosterol, English hawthorn (*Crataegus laevigata*) fruit.

Statements of nutritional support:

- Maintains healthy cholesterol levels as part of a program of healthy reduced-fat eating, exercise, and regular serum cholesterol monitoring

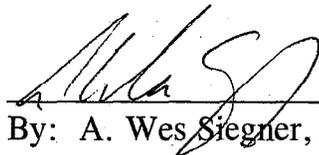
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- Along with a well-balanced diet, red rice yeast is an important element of your overall program to maintain healthy cholesterol levels, improve circulation, strengthen the spleen and help digestion
- Beta sitosterol helps control the harmful LDL cholesterol, without negatively impacting the positive effects of HDL, the "good" cholesterol
- Soy powder: a protein that has been used for many years to help promote a healthy cardiovascular system

Hyman, Phelps & McNamara, P.C.

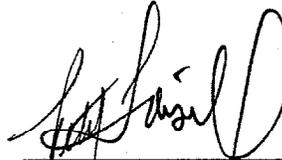

By: A. Wes Siegner, Jr.

AWS/SNR/dng

Attachment - Certification

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

I certify that the information contained in the preceding section 403(r)(6) notice for LifeGuard™ Cholesterol Control 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

December 4, 2000