

Food and Drug Administration  
Washington DC 20204JAN 24 2001  
3 6 1 1

01 MAR 16 17:15

Ms. Sonia Rodriguez  
Mason Vitamins  
5105 Northwest 59th Street  
Miami, Florida 33014-6370

Dear Ms. Rodriguez:

This letter is in response to your FAX letter to the Food and Drug Administration (FDA) dated January 19, 2001, requesting that we comment on a revised label for the product "Heart & Cholesterol" that you intend to market as a dietary supplement.

Dietary supplements are regulated under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Dietary Supplement Health and Education Act of 1994 (the DSHEA), and under the Fair Packaging and Labeling Act. There is generally no requirement that a firm obtain approval of a product or its label or labeling from FDA before marketing dietary supplements in the U.S.

Under the Act, FDA does not "approve" of individual product labels or labeling. Nonetheless, we have reviewed the label you provided us, which was revised based on comments I provided in a telephone call on January 10, 2001. We have no further comment on the claims being made for this product on the label. However, you should not interpret this to be an all-inclusive review of your proposed labeling or a determination that the labeling is in compliance with the requirements of the Act. It is the responsibility of the manufacturer to ensure that a label meets the requirements of the Act.

We also wish to re-emphasize one point made in our previous letter to you and our January 10, 2001 phone conversation about the status of products that contain red yeast rice. The product contains a red yeast rice extract. FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin<sup>1</sup>", 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 be legally sold in the United States.

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<sup>1</sup>Cholestin 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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A February 16, 1999 United States District Court for the District of Utah decision that "held unlawful and set aside" the FDA's administrative finding of date was reversed by a United States Court of Appeals for the 10th Circuit decision on July 21, 2000. This reversal reinstates 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 FD&C Act. If the red yeast rice extract used in your product contains lovastatin, then the product would be in violation of the Act. Marketing of 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 the manufacturer and/or distributor illegal products.

We hope this information is helpful.

Sincerely,

Robert J. Moore, Ph.D.  
Chief, Dietary Supplements Branch  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements

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, Florida District Office, Office of Compliance, HFR-SE240

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 (Nckerson, Warren, Goldsmith)  
r/d:HFS-811:RMoore:12/21/00  
docname:73709.adv:disc53

MEMORANDUM OF TELEPHONE CONVERSATION

January 10, 2001

Between: Sonia Rodriguez  
Mason's Vitamins  
Miami, Florida

and: Robert J. Moore, Ph.D.  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition

Subject: FDA Courtesy letter #353

Ms. Rodriguez contacted FDA to discuss how to remedy the labeling of a product that they had submitted a 30-day structure/function claim notification for and which we advised her had a potentially illegal ingredient and had claims not permitted under section 403(r)(6) of the Act on its label. FDA's letter was sent on March 23, 2000 for the product Proherbs Heart and Cholesterol.

I explained that the cholesterol and blood pressure claims were implied disease claims because they did not explicitly disclaim effects on abnormal blood pressure and cholesterol levels. I explained that we would not object if the claims were to state that the product was intended to maintain cholesterol levels or blood pressure that "were already in the normal range." I also explained that the name of the product, "Heart and cholesterol" would be an unauthorized health claim if there were no other claims on the label that placed that statement in the context of an appropriate structure/function claim. We also discussed that the claim "clean the arteries" was a disease claim and that I didn't believe there was any context capable of remedying that claim.

We also discussed the current legal status of products containing red yeast rice. I explained that in our Administrative Finding for Cholestin, we concluded that red yeast rice that has been historically used as food did not contain lovastatin or contained trivial amounts. Thus, a product that contained measurable amounts, such as their product, would be deemed by FDA to be a drug pursuant to the *Pharmanex v. Shalala* decisions. I explained that if a red yeast rice product did not contain lovastatin or any other statin which would trigger section 201(ff)(3)(B), we have no objection to the use of the ingredient in dietary supplements.

She indicated that they would contact their supplier to ensure that their product complied with the law and that they would revise their label and submit us a revised copy for review.

Robert J. Moore



5105 NORTHWEST 59TH STREET  
MIAMI, FLORIDA 33114-6370  
NATIONAL WATTS: 800/327-6005  
DADE: 305/624-5557  
FAX: 305/623-0795 - 800/328-3944

The Vitamin Marketing Experts

FACSIMILE TRANSMITTAL SHEET

TO: <i>Roger Moore</i>	FROM: <i>Sonia Rodriguez</i>
COMPANY: <i>FDA</i>	DATE: <i>1/19/01</i>
FAX NUMBER: <i>202-205-4594</i>	TOTAL NO. OF PAGES INCLUDING COVER: <i>2</i>
PHONE NUMBER: <i>202-205-4605</i>	SENDER'S REFERENCE NUMBER: _____
	CC: _____

URGENT     FOR REVIEW     PLEASE COMMENT     PLEASE REPLY     PLEASE RECYCLE

NOTES/COMMENTS

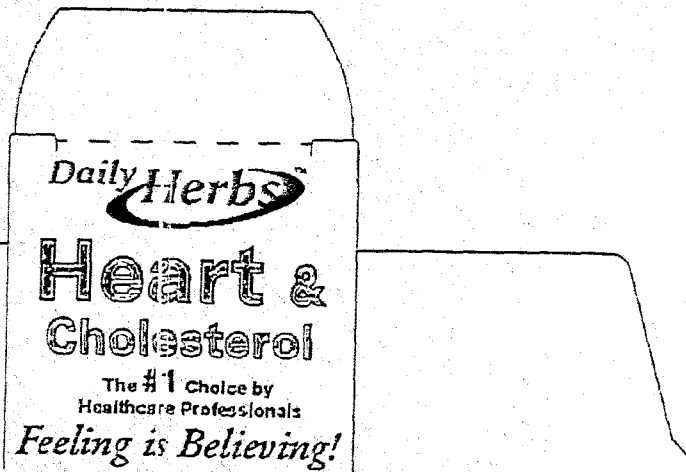
*Rogers:*  
*Here is our updated label. I will  
call you on Monday to review.*

*Thanks!*

*Sonia*



*ndm/req-2,html*



**Supplement Facts**  
Serving Size 2 Tablets  
Servings Per Container 15

	Amount Per Serving	%DV
Niacin (as niacinamide)	20 mg	100%
Vitamin B6 (as pyridoxine HCl)	60 mg	2500%
Folate (as folic acid)	400 mcg	100%
Vitamin B12 (as cyanocobalamin)	200 mcg	3333%
Magnesium (as magnesium oxide)	200 mg	50%
Red Yeast Rice Extract (Monascus purpureus)	1200 mg	--
Isoflavones (soy)	30 mg	--

Cholesterol Support Blend containing:  
Oder controlled garlic extract (ajoene calcium) (standardized to 10,000 ppm ajoene) and Green Tea Extract (catechins) (standardized to 99% polyphenols).

\*Daily Value not established.

**DailyHerbs™ Heart & Cholesterol** is a potent formula that contains Red Yeast Rice, a Chinese herb used for centuries that has been clinically shown to be highly effective in the maintenance of the cardiovascular system. It contains Garlic and Green Tea, two herbs known to protect the heart and help maintain strong arteries. Diets that include Soy Isoflavones are associated with enhancing cardiovascular health. A combination of B Vitamins and Folic Acid further enhance heart health by helping to lower homocysteine levels in the blood. **DailyHerbs™ Heart & Cholesterol** formula contains the right selection of herbs and vitamins to fortify the cardiovascular system.\*

**Daily Herbs™**  
STANDARDIZED  
herbal formula with  
**Clinically Tested Ingredients.**  
**Heart & Cholesterol**  
Use to maintain  
cholesterol and  
blood pressure  
levels that are  
already within  
normal ranges.\*  
Dietary Supplement

**DailyHerbs™** brings the professionals' recommendations to you in one product...  
With so many herbs to choose from, it is hard to determine which one is right for you. **DailyHerbs™** helps you make the choice with the optimum selection of herbs and vitamins for your specific health needs. **DailyHerbs™** are professionally formulated by a brand picked team of leading pharmacist and scientific specialists. They chose the very best herbs for you - clinically tested standardized herbal extracts. Unlike other products, every **DailyHerbs™** formula contains ONE or MORE standardized herbal extracts along with complementary vitamins and minerals to provide you with maximum effectiveness.

**Mason Natural Guarantee:**  
We guarantee that all standardized herbal extracts in this formula have been laboratory tested to verify the active ingredients.

**Other Ingredients:** Menthocrylamine Cellulose, Stearic Acid, Silica, Magnesium Stearate, FD&C Red #40 Lake, FD&C Yellow #6 Lake, Titanium Dioxide, Hydroxypropylmethylcellulose, Triethyl and Mineral Oil.

**FREE OF:** Sugar, Starch, Sodium, Casein, Wheat, Dairy, Gluten, Egg, Fragrance, Artificial Flavors and Preservatives.

**Directions:** Adults take two (2) tablets daily, as a dietary supplement, preferably with meals.

**Keep Out of the Reach of Children.**  
Store in a dry, controlled room environment.

**CAUTION:** If you are taking any medication or medicine, consult your physician or pharmacist before taking this product.

\*The information here has not been reviewed by the Food and Drug Administration. This product has not been approved, tested, or certified by the FDA.

Actual  
tablet size



30 Tablets

**Questions? Comments?**  
Please call 1-888-860-5376  
Monday thru Friday 9:00 AM - 5:00 PM  
Visit us on [www.masonnatural.com](http://www.masonnatural.com)

**MASON** Manufactured for Mason Vitamins Inc.  
Miami Lakes, FL 33014 USA

Order No. 1354-30



Lot:  
Exp. Date: