



MAR 23 2000

3 2 8 8 '00 APR 25 P2:39

Ms. Sonia C. Rodriguez
President
Mason Vitamins, Inc.
5105 N.W. 159th Street
Miami Lakes, Florida 33014-6370

Dear Ms. Rodriguez:

This is in response to your letter of March 8, 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 submission states that Mason Vitamins, Inc. is making the following claims, among others, for the products:

Proherbs Migra-Ease

“Get the head relief you want with a complete Migra-Ease formula...”
“...ease the constriction of blood vessels in the heat, it has been shown to help relieve the inflammatory responses associated with sudden head pressure changes.”
“...protect the integrity of blood vessels in the head from sudden pressure changes.”

Proherbs Heart and Cholesterol

“For healthy blood circulation, cholesterol, and blood pressure”
“..maintain healthy cholesterol levels”
“...clean the arteries and support normal levels of blood cholesterol and healthy blood pressure”
“...health 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, including the names of them, suggest that they are intended to treat, prevent, cure or mitigate diseases, namely hypercholesterolemia, hypertension, and migraines. 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

975-0163

LET 353

Page 2 - Ms. Sonia C. Rodriguez

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.

We also note that the product **Proherbs Heart and Cholesterol** contains the ingredient red rice yeast. We would also like to advise you of the current status of products that contain red yeast rice (*Monascus purpureus*). FDA announced its administrative decision on May 20, 1998 that a product named "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 FD&C Act. This decision meant that Cholestin could not be legally sold in the United States.

On February 16, 1999, the United States District Court for the District of Utah "held unlawful and set aside" the FDA's administrative finding of May 20, 1998. FDA has appealed the District Court's decision to the United States Court of Appeals for the 10th Circuit. The future regulatory status of all red yeast rice products will depend, in part, on the decision of the courts on the merits of the Cholestin matter. At this time, FDA believes that products containing red yeast rice or *Monascus purpureus* that contain lovastatin are unapproved new drugs that are in violation of the FD&C Act.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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.

Page 3 - Ms. Sonia C. Rodriguez

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-811 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

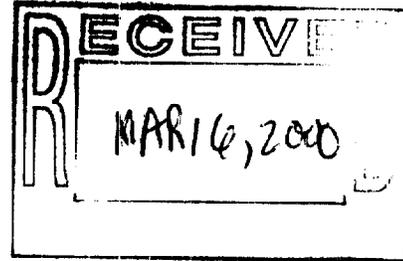
f/t:HFS-456:rjm:2/6/00:docname:69789.adv:disc45



The Vitamin Marketing Experts

March 8, 2000

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204



Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement PROHERBS HEART AND CHOLESTEROL. PROHERBS HEART AND CHOLESTEROL will be first marketed with these statements of nutritional support on Monday, April 3, 2000. The statements of nutritional support are as follows:

“For healthy blood circulation, cholesterol and blood pressure”

“Fortify your heart and maintain healthy cholesterol levels with a complete formula that combines clinically tested ingredients. Recent clinical studies show that **Red Rice Yeast** effectively maintains healthy cholesterol levels. **Garlic** and **Green Tea** further help clean the arteries and support normal levels of blood cholesterol and healthy blood pressure. Diets that include **Soy** are associated with healthy cholesterol levels. A combination of **B Vitamins**, **Folic Acid**, and **Niacin** are included because of their positive effect in reducing toxins in the blood. Include Heart and Cholesterol in your daily nutrition for a healthier you”

Very truly yours,

MASON VITAMINS, INC.

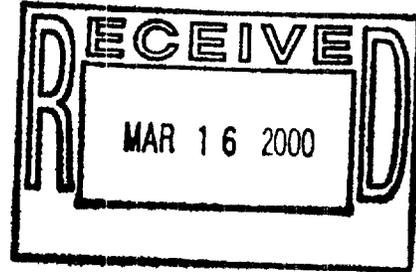
Sonia C. Rodriguez
President

69789



30-day notification
69789

March 8, 2000



Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

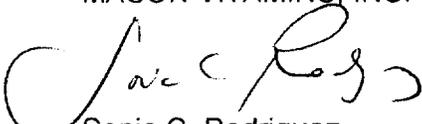
Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement PROHERBS MIGRA-EASE. PROHERBS MIGRA-EASE will be first marketed with these statements of nutritional support on Monday, April 3, 2000. The statements of nutritional support are as follows:

"Helps ease constriction of blood vessels in the head"

"Get the head relief you want with a complete Migra-Ease formula that combines clinically tested ingredients. Because **Feverfew** is an herb specifically studied to help ease the constriction of blood vessels in the head, it has been shown to help relieve the inflammatory responses associated with sudden head pressure changes. **Ginkgo Biloba** adds to this effect by improving blood circulation to the brain. **Kava Kava** is needed to promote relaxation during moments of head tension. **Magnesium** helps protect the integrity of blood vessels in the head from sudden pressure changes. Include Migra-Ease in your daily nutrition for a healthier you"

Very truly yours,

MASON VITAMINS, INC.


Sonia C. Rodriguez
President