DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY - 5 2001

4355 '01 MAY 15 P2:30

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

Dear Ms. Rodriguez:

This letter is in response to your letter to the Food and Drug Administration (FDA) dated April 20, 2001 informing the agency that you have decided to discontinue the use of red yeast rice as an ingredient in your product "Heart & Cholesterol." You stated that this decision was based on the recent court decision affirming the agency's conclusion that red yeast rice products containing lovastatin are drugs and not dietary supplements. You also expressed concern about other firms marketing products as dietary supplements that are similar to your discontinued product, that is, products containing red yeast rice that contain lovastatin.

As you are aware, FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin[1]", 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.

A February 16, 1999 United States District Court for the District of Utah decision that "held unlawful and set aside" the FDA's May 20, 1998 decision 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. The reversal also remanded the case back to the District Court for consideration of record-based issues not previously reached by the lower court in its original decision. On March 30, 2001, the United States District Court for the District of Utah issued a Memorandum Decision and Order on the remaining record-based issues.

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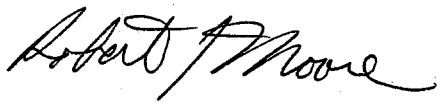
[1]Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

The District Court affirmed the FDA's administrative decision that Cholestin is a drug, not a dietary supplement. Taken together, the courts' decisions in the Pharmanex litigation mean that red yeast rice or similar products containing lovastatin are unapproved new drugs 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. Among other remedies, the Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

The agency appreciates the fact that Mason Vitamins has taken steps to ensure that its products comply fully with the requirements of the Act that apply to the marketing of products as dietary supplements, including the requirements recently affirmed by the courts in the Pharmanex litigation. We are aware that many firms have marketed dietary supplements containing red yeast rice and lovastatin that are now unlawful as a result of the recent courts' decisions. While the agency does not, as a rule, discuss enforcement actions it may be contemplating against specific products, we wish to assure you that FDA intends to take appropriate steps to ensure that products containing red yeast rice or similar products containing lovastatin are removed from the market. The agency is committed to enforcement of the Act to ensure that products that are subject to regulation as drugs are not marketed as dietary supplements.

We hope this information satisfactorily addresses your concerns. If we can be of further assistance, please contact us.

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

c:
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-607 (Bayne-Lisby)
HFV-228 (Benz)
GCF-1 (Nickerson, Parker, Fain)
r/d:HFS-811:RMoore:5/3/00
Revised:GCF-1:NParker:5/4/01
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15707

April 20, 2001

Robert J. Moore, Ph.D.
Chief, Dietary Supplements Branch
Division of Compliance and Enforcement
Office of Nutritional Products,
Labeling and Dietary Supplements
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Moore:

I thank you for your recent input and attention to my company's efforts in complying with the law on our "Heart & Cholesterol" product. Since our conversations, we choose to eliminate the red yeast rice ingredient, especially in light of the recent news that a federal court had affirmed FDA's determination that the red yeast rice product, Cholestin, is a drug, not a dietary supplement.

As you know, our local FDA office in Miami, FL visited us in December of 2000 and we were forced to destroy all of our "Heart & Cholesterol" product which contained the red yeast rice ingredient (see letter attached). Our product labeling had previously stated that this red yeast rice ingredient was standardized to .4% lovastatin. When I specifically asked the local FDA agent if we could continue to sell red yeast rice, she commented that we could as long as it had not been tampered with to raise the natural level of lovastatin found in the red yeast rice. According to your previous letter dated January 24, 2001 products containing red yeast rice or *Monascus purpureus* that contain lovastatin are unapproved new drugs that are in violation of the FD&C Act.

The destruction of our Heart & Cholesterol formula represented a substantial financial loss to our company as well as lost market share as our customers had to wait for 5 months before a new formula and product could be reintroduced to the market. At the same time, competitors in our industry, who have plentiful supply of this item, were able to gain this market share. In light of the news that Pharmanex recently decided to suspend U.S. sales of its Cholestin product containing red yeast rice and the recent Tan Sheet (April 9) article that states, according to an FDA statement, "Other red yeast rice containing products on the market ..can expect to face quick regulatory action.." we feel that it is an unfair market advantage that our competitors can continue to sell an item which is obviously non-compliant with the law.

Mason Vitamins, Inc.*5105 N.W. 159th Street • Miami Lakes, FL 33014-6370 • Phone: **1-800-327-6005** ● (305) 624-5557 • Fax: I-800-3283944

In addition, whether or not our competitors' items state that the red yeast rice in their product does or does not contain a certain amount of lovastatin should not be the determining issue to pull these products off the market. At this time it is difficult to gage just how much lovastatin is in the red yeast rice raw material that is being sold to them. It is our opinion that if the FDA is going to pull some red yeast rice containing products off the market, it should take ALL red yeast rice containing products off the market at once.

The Tan sheet article (April 9) mentions a few brands still available in the marketplace containing red yeast rice. Attached is a website that features another such competitive item.

Mason Vitamins has always prided itself in being an ethical company that complies with the law and takes its position as a dietary supplement supplier very seriously. I would like to know FDA's course of action with respect to these other suppliers that are still selling products containing red yeast rice illegally.

Sincerely,

Sonia C. Rodriguez
President

Cc: Carlos J. Rodriguez, CEO, Mason Vitamins
Ofelia Perez, COO, Mason Vitamins

MASON® VITAMINS

The Vitamin Marketing Experts

1/4/01

I am Sonia C. Rodriguez, President of Meson Distributors Inc. I am voluntarily destroying 485 bottles of Daily Herbs Heart & Cholesterol (Lot #1139), Pro Herbs Heart & Cholesterol 1079 bottles (Lot #1139), 168,430 tablets of Heart & Cholesterol (Lot # 3192), and all labels/boxes associated with these products. Each bottle will be opened, dumped into a bulk container and destroyed by water. Each bulk bag will be covered with a black garbage bag and put into the trash. All containers will also be put in the trash. Heart & Cholesterol Contains Red Yeast Rice Extract standardized to 4% Lovastatin. which I was advised by Investigator Jennifer Menendez that Lovastatin is a prescription drug used for the treatment of hypercholesterolemia. This is being destroyed at a value of $18,600.

X Sonia C. Rodriguez

witnessed by: Jennifer M Menendez, Investigator

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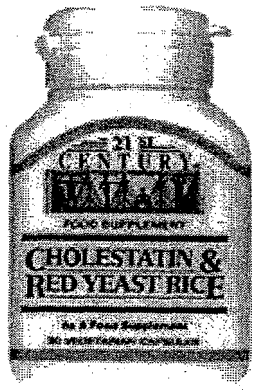
CHOLESTATIN & RED YEAST RICE



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Red Yeast Rice is one traditional Chinese material that has been shown in animal and pilot human studies to effectively lower serum lipid levels. Red Yeast Rice, also known as Monascus purpureus rice, is derived from the strain of M purpureus Went yeast and is prepared by a traditional rice fermentation method. It has been shown that Red Yeast Rice contains compounds with HMG-CoA reductase inhibitor activity, which is responsible for the inhibition of cholesterol synthesis in the liver. In addition, Red Yeast Rice also contains unsaturated fatty acids that may also help reduce serum lipids.

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