



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 3rd Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

August 8, 2007

WARNING LETTER

VIA FED-EX

Refer to MIN 07-19

Lee Swanson, President
Swanson Health Products, Inc.
4075 40th Ave. SW
Fargo, ND 58104

Dear Mr. Swanson:

This letter concerns your firm's marketing of the products Red Yeast Rice and Red Yeast Rice/Policosanol Complex on your website, www.swansonvitamins.com. You promote Red Yeast Rice and Red Yeast Rice/Policosanol Complex as dietary supplements. A laboratory analysis conducted by the Food and Drug Administration (FDA) determined that your Red Yeast Rice and Red Yeast Rice/Policosanol Complex products contain significant levels of lovastatin. Lovastatin is the active pharmaceutical ingredient in Mevacor and its generic counterparts, which are FDA-approved drugs used to treat patients with primary hypercholesterolemia. If consumed as directed, your products would provide more than 5 mg lovastatin per day, which is approximately half of the lowest recommended daily dose of lovastatin in Mevacor and its generic counterparts.

Traditional red yeast rice does not contain more than trace amounts of lovastatin, if any. Because Red Yeast Rice and Red Yeast Rice/Policosanol Complex contain red yeast rice with enhanced or added lovastatin and bear claims about lipid control and other cardiovascular benefits supplied by this ingredient, they cannot be marketed as dietary supplements. Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(ff)) specifically excludes from the dietary supplement definition articles that are approved as new drugs under section 505 of the Act (21 U.S.C. § 355), unless the article in question was marketed as a dietary supplement or food before its approval as a drug. 21 U.S.C. § 321(ff)(3)(B). FDA approved Mevacor as a new drug on August 31, 1987; neither lovastatin as a single ingredient, nor any red yeast rice product manufactured and promoted for lovastatin content, was marketed as a dietary supplement or as a food before that date. Therefore, lovastatin's approval as a new drug preceded its marketing as a food or dietary supplement, and your lovastatin-enhanced Red Yeast Rice and Red Yeast Rice/Policosanol Complex are excluded from the dietary supplement definition. FDA's interpretation of the exclusion in 21 U.S.C. § 321(ff)(3)(B) and the agency's conclusion that a lovastatin-enhanced red yeast rice product was not a dietary supplement were upheld in litigation involving a product called Cholestin.¹

¹ *Pharmanex, Inc. v. Shalala*, 221 F.3d 1151 (10th Cir. 2000), *on remand at*, 2001 U.S. Dist. LEXIS 4598 (D. Utah Mar. 30, 2001).

Page Two

Lee Swanson
August 8, 2007

According to information on your website, Red Yeast Rice and Red Yeast Rice/Policosanol Complex are intended to prevent, treat, or cure disease conditions or to affect the structure or function of the body. Statements on your website that document these intended uses include, but are not limited to, the following:

Red Yeast Rice

- “An all-natural supplement that helps maintain healthy lipid levels”
- “constituents in red yeast rice help promote a healthy lipid balance in the bloodstream.”

Red Yeast Rice/Policosanol Complex

- “Policosanol decreases cholesterol levels”
- “Policosanol moderately decreased total cholesterol levels and raised levels of apolipoprotein A1 (APO A1), a component of high-density lipoprotein (HDL) cholesterol . . .”
- “Total plasma cholesterol dropped from 7.37 to 6.99 mmol/L . . .”
- “can help keep your blood lipid levels within a healthy range . . .”
- “safe and effective ways to promote healthy serum lipid levels for everyday heart-health maintenance.”
- “[P]olicosanol has earned widespread acclaim in the scientific community for its lipid-balancing capabilities.”

Your Red Yeast Rice and Red Yeast Rice/Policosanol Complex products are drugs, as defined by section 201(g)(1) of the Act, 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. Moreover, these products are new drugs, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for their labeled uses. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of Red Yeast Rice and Red Yeast Rice/Policosanol Complex without approved applications violates these provisions of the Act.

The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that the drug products that you manufacture or distribute meet all of the requirements of the Act and its implementing regulations.

•Page Three

Lee Swanson
August 8, 2007

You must immediately correct the above violations. If you do not immediately correct them, you may be subject to enforcement action without further notice. The Act provides for seizure of illegal products and for injunction against manufacturers and distributors of illegal products. Individuals and businesses that violate the Act may also be subject to criminal prosecution. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

You must notify this office in writing within 15 working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations and to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Furthermore, please advise this office what actions you will take to address product that you have already distributed.

Address your reply to the U.S. Food and Drug Administration, 212 3rd Ave. South, Minneapolis, MN 55401, Attention: Tyra S. Wisecup, Compliance Officer.

A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/cder/regulatory/applications/default.htm>. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, Maryland 20857.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

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