



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

August 7, 2007

WARNING LETTER NYK 2007-18

VIA FEDEX

Sunburst Biorganics
2250 Grand Avenue
Baldwin, NY 11510

Dear President/Owner:

This letter concerns your firm's marketing and sale of the product Cholestrix on your website, www.vitasaver.com. You promote Cholestrix as a dietary supplement. Your website states, "Sunburst's Cholestrix is made from a specially concentrated red yeast rice extract which is standardized to contain 1.35% of naturally occurring lovastatin. Just 2 capsules per day provide 10mg. of natural lovastatin." Lovastatin is the active pharmaceutical ingredient in Mevacor and its generic counterparts, which are FDA-approved drugs to treat patients with primary hypercholesterolemia.

Traditional red yeast rice does not contain more than trace amounts of lovastatin, if any. Because Cholestrix contains red yeast rice with enhanced or added lovastatin, and bears a claim about the "powerful cholesterol fighting" benefits supplied by this ingredient, it cannot be marketed as a dietary supplement. 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 product is 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 is 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).

According to information on your website, Cholestrix is 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:

Cholestrix

- “Powerful Cholesterol Fighting Formula . . .”
- “Also included are nutrients which have been shown to help support choelsterol [sic] metabolism.”

Cholestrix is a drug as defined by section 201(g)(1) of the Act, 21 U.S.C. § 321(g)(1), because it is 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, this product is a new drug, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because it is not generally recognized as safe and effective for its 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 Cholestrix without an approved application 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.

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.

Additionally, if your firm does not manufacture the product identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturer.

Address your reply to the U.S. Food and Drug Administration, 158-15 Liberty Ave., Jamaica, NY 11433, Attention: Anna Alexander, Compliance Officer. If you have questions about this letter, please contact Compliance Officer Anna Alexander at 718-662-5683.

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,

Otto D. Vitillo
District Director

Cc: New York State Board of Pharmacy
89 Washington Ave, Second Floor W
Albany, NY 12234-10004